Prime THERAPEUTICS™

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Prime Therapeutics

Provider Manual for participating network providers

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Introduction to Prime Therapeutics

Introduction

Prime Therapeutics and Prime Therapeutics Management (collectively, "Prime") provide pharmacy benefit management (PBM) services to benefit sponsors and their members, including access to contracted Pharmacy Networks. Prime is not a health insurer, nor does Prime provide health insurance policies, plans or employee benefit plans.

Prime's services include:

- Pharmacy network management
- Specialty network services
- Claims adjudication
- Drug formulary management
- Pharmacy communication
- Drug utilization review (DUR)
- Clinical programs
- Knowledge, data and analytic services
- Product development
- Prescribing provider outreach
- Member communications and support

Prime supports prescription drug services for our benefit sponsors through our online claims processing system. This system gives Pharmacies real-time access to:

- Covered person eligibility
- Drug coverage information
- Drugs requiring prior authorization
- DUR information

Prime is committed to doing business with integrity and in accordance with all applicable federal, state and local laws. Prime has adopted a compliance program and a Code of Conduct, which include policies and procedures to avoid potential conflicts of interest and fraud, waste or abuse (FWA). Click **here** to access Prime's Code of Conduct.

Provider Manual

This Provider Manual ("Manual"), as revised, explains Prime's administrative and compliance policies and procedures for participation in networks that Prime manages. This Manual is incorporated into the Prime Therapeutics Pharmacy Participation Agreement ("Agreement"). All network Pharmacies (and when contracted through Prime or a designee, all contracted providers) must comply with the terms and conditions of this Manual, as revised, in providing prescription drug services pursuant to such an agreement.

Prime will update this Manual as necessary at its sole discretion. This version of the Manual supersedes all previous versions of the Manual. Prime posts the most current version of the Manual at **PrimeTherapeutics.com**.

Prime posts relevant instructions, notices, information, supplements and changes to this Manual on the **Prime website**. Visit **PrimeTherapeutics.com** for up-to-date information and processing instructions.

Important: This Manual applies to all lines of business (Commercial, Medicare, Medicaid and Health Insurance Marketplace).

Failure to comply with terms and conditions, including, but not limited to, those described in this Manual, as revised, may result in placement on a corrective action plan, payment suspension, full or partial financial recoupment, termination of participation in one or more networks, termination of the Agreement and other remediation actions, as determined by Prime and permitted by applicable law.

Section 1: Prime contact information

Prime's mailing address

If you would like additional information, contact Prime at:

Prime Therapeutics
P.O. Box 64812
St. Paul, MN 55164-0812

Prime's contact center

Please refer to the covered person's identification (ID) card or to **Prime's website** for plan-specific contact center phone numbers.

Prime's contact center has dedicated staff to assist Pharmacies. They can help with contract requests, processing questions and any comments/concerns you may have. Prime's representatives are available 24/7.

Prime's website

Visit **Prime's website** (**PrimeTherapeutics.com**) for the following information:

- **Payer sheets (incorporated into and made part of this Provider Manual by reference)**
- **Medicare prescription drug coverage and your rights form**
- **Formularies – Commercial**
- **Formularies – Medicare Part D**
- **Prime Perspective newsletters**
- **Compliance/fraud, waste and abuse**
- **Plan announcements**
- **Network request form**
- **Common billing errors**
- **Minimum performance and service criteria for Medicare Part D**
- **Prime audit advisor/fax series**
- **Minimum performance and service criteria for long-term care**
- **Maximum allowable cost lists and appeals process**
- **Audit guidelines**
- **Home infusion and long-term care general dispensing processing requirements**
- **Pharmacy audit appeal form**
- **FAQ: Claim adjustments**
- **Home infusion validation**
- **Long-term care validation**
- **Medicaid processing requirements**
- **Vaccine program**
- **Check inquiry form**
- **Network Reimbursement IDs for adjudicated claims**
- **Network participation dispensing thresholds**
- **Provider Manual**

Section 2: Compliance

Report compliance, privacy, or fraud, waste and abuse concerns

Compliance
Report suspected compliance concerns:
Phone: **612.777.5523**
Email: **Compliance@PrimeTherapeutics.com**

Privacy
Report privacy concerns or potential protected health information disclosures:
Privacy Hotline: **888.849.7840**
Email: **Privacy@PrimeTherapeutics.com**

Fraud, waste and abuse
If you suspect fraud, waste or abuse (FWA) by a covered person, prescribing provider, Pharmacy or anyone else, notify Prime:

Phone: **800.731.3269**
Email: **FraudTipHotline@PrimeTherapeutics.com**

Anonymous reporting
Report a compliance concern or suspected FWA anonymously by contacting Prime's 24-hour anonymous compliance hotline:

- Phone: **800.474.8651**
- Email: **Reports@Lighthouse-Services.com**
- Third-party vendor's website: **Lighthouse-Services.com/Prime**

Please contact Prime's compliance department with any concerns including, but not limited to:
Violation of a state, federal, local law, regulation or any governmental guidance

- Conflict of interest
- Acceptance or offers of gifts or entertainment
- FWA
- Improper disclosure of Prime's confidential or proprietary information
- Retaliation for reporting a compliance issue
- Falsification of reports, records or files
- Theft

Compliance program

Prime requires all Pharmacies to adopt appropriate compliance programs, including, but not limited to:

- A Code of Conduct
- An FWA program
- Conflict of interest policies and procedures

Pharmacies must develop policies and procedures in compliance with all applicable rules and regulations, including, but not limited to, Medicare programs.

Pharmacies should have someone who is responsible for establishing and documenting a plan to meet Medicare, Medicaid and other applicable state and federal requirements. Pharmacies should communicate the plan and any means of enforcing the plan to all employees.

Refer to the **Compliance Program Policy and Guidance page** on the Centers for Medicare & Medicaid Services (CMS) website, **CMS.gov**, for a complete list of Medicare Compliance Program requirements.

Fraud, waste and abuse

FWA is the inappropriate use of health care benefits or a benefit plan in connection with the Pharmacy's delivery of or billing, claims or payment for prescription drug services, items or supplies. Fraud may be perpetrated by a Pharmacy, covered person, prescribing provider and/or other individual or entity involved in the production, distribution, prescribing, ordering, dispensing or receiving of prescription drug services, items or supplies. Fraudulent acts committed by other parties do not absolve the Pharmacy's responsibility for the integrity of delivery, billing, claims or payment for prescription drug services, items or supplies.

Fraud is the intentional deception or misrepresentation that an individual or organization knows to be false or does not believe to be true and that the individual or organization makes knowing that the deception or misrepresentation could result in some unauthorized benefit to a person or organization. It also includes any act that constitutes fraud under the applicable federal or state law. Waste means the inappropriate or inefficient use of resources. Abuse means the occurrence, or pattern, of an individual or organization unintentionally providing information to another individual or organization that results in higher payments than an individual or organization is entitled to receive. Abuse can be distinguished from fraud only by the specific facts and circumstances of the situation.

Annual attestation requirement

The annual FWA attestation form is now part of your Pharmacy National Council for Prescription Drug Programs (NCPDP) profile. Please complete the form via the NCPDP website. For your convenience, instructions for completing the NCPDP form are available under Compliance & FWA training and certification requirements on **Prime's website**. Failure to attest to the annual general compliance and FWA training may result in termination of participation in one or more networks or termination of the Agreement.

Medicare Part D FWA and general compliance pharmacy training and offshore services attestation

On behalf of the Part D benefit sponsors that Prime serves, Prime requires any staff providing Medicare Part D services to receive qualified FWA and general compliance training upon hire and annually thereafter. Prime also tracks completion of this training by all Participating Pharmacies. Pharmacies can submit a single attestation to NCPDP (as part of their pharmacy profile), which will be submitted to Prime. When a Pharmacy indicates that offshore services are provided in their FWA and general compliance training attestations, the Pharmacy must complete an additional offshore questionnaire regarding the offshore services vendor.

Reporting of suspicious activity

Pharmacies and Prime have an obligation to help protect and maintain the integrity of the health care system by promptly reporting suspicious activity.

Pharmacies have a corresponding responsibility to ensure prescriptions are valid. For example, if a Pharmacy receives a prescription order that appears potentially altered or forged, the Pharmacy must contact the prescribing provider to:

- Validate the prescription
- Document the prescription order with date and time
- Include the representative's name from the prescribing provider's office

At all times, Pharmacies must remain mindful of FWA and report suspicious activity to Prime promptly.

Please contact Prime's FWA department as set forth in the compliance section of this Manual with any FWA concerns. Examples of potential FWA include, but are not limited to:

- **Misrepresentation of status** — A covered person or other individual misrepresents personal information, such as identity, eligibility or medical condition, in order to illegally receive a drug benefit; or an individual who no longer has prescription drug coverage attempts to use their identity card to obtain prescriptions.
- **Identity theft** — An individual uses another person's Medicare or health insurance card to obtain prescriptions.
- **Illegal resale of drugs** — A covered person falsely reports loss or theft of drugs or fakes illness to obtain drugs for illegal resale.
- **Prescribing provider shopping** — A covered person consults more than one prescribing provider to inappropriately obtain multiple prescriptions. A pharmacist must make every reasonable effort to ensure that any prescription drug order, regardless of the means of transmission, has been issued for a legitimate medical purpose by a prescribing provider within the valid and lawful practice of medicine.

A pharmacist must not dispense a prescription drug if the pharmacist knows or should have known that the order for such drug was issued without a valid preexisting patient-prescribing provider relationship or without a valid prescription drug order.

- Patient-prescribing provider relationship definition: There are three ways a patient-prescribing provider relationship can be established:
- There is a preexisting patient-prescribing provider relationship.
- The prescribing provider communicated with the patient as part of a Call Coverage Agreement with the patient's established prescribing provider.
- The prescribing provider communicates with the patient using:
  - Real-time audiovisual interaction, such as video calls
  - Real-time audio (telephone), along with having access to clinically relevant information, such as videos/images, medical records and test results
  - Any other communication technology that allows the prescribing provider to meet the applicable standard of care and state prescriber requirements

- **Script mills** — A prescribing provider writes prescriptions for drugs that are not medically necessary, often in mass quantities, and often for covered persons who are not the prescribing provider's patients. These prescriptions are sometimes written for drugs found on a schedule of controlled substances for illegal sale. These prescriptions may also result in improper payments to the prescribing provider.
- **Theft of a prescribing provider's Drug Enforcement Administration number or prescription pad** — Prescription pads may have been stolen from a prescribing provider and used to write prescriptions, including for controlled substances or medications, that can be abused or illegally sold.
- **Inappropriate billing practices** — Inappropriate billing practices occur when Pharmacies engage in billing practices that include, but are not limited to:
  - Incorrect billing to secondary payers to receive increased reimbursement
  - Billing for nonexistent prescriptions
  - Billing multiple payers for the same prescriptions, except as required for coordination of benefits transactions
  - Billing for brand-name drugs when generic drugs are dispensed
  - Billing for noncovered prescriptions as covered items
  - Billing for prescriptions that are never picked up (including not reversing claims that are processed when prescriptions are filled but never picked up)
  - Billing for numerous prescriptions without providing prescriptions to covered persons
  - Billing the same prescription/product multiple times a month to obtain additional dispensing fees
  - Inappropriate use of Product Selection Codes (also known as Dispense as Written codes), Submission Clarification Codes and dynamic prior authorizations (PAs)
  - Billing a National Drug Code (NDC) not used to dispense the prescription
  - Billing an NDC or drug that was never ordered
  - Billing an incorrect dosage form (e.g., billing for a tablet when a powder is used to dispense the prescription)
  - Drug diversion
  - Claims phishing to identify a drug that is covered (e.g., a Pharmacy submits a claim for one drug, receives a reject or reverses the claim, and resubmits for a new drug within a short period of time)
  - Prescription splitting to bypass point-of-sale (POS) messaging requiring a PA
  - Billing for a greater vial size than what is necessary to supply the ordered dose
  - Waiving copays, wherein the Pharmacy does not collect the copay due from a covered person when required by the Agreement
  - Misrepresenting or falsifying information to obtain a paid claim
- **Prescription drug shorting** — The Pharmacy provides less than the prescribed quantity and intentionally does not inform the covered person or makes arrangements to provide the balance but bills for the full amount ordered on the prescription.
- **Bait and switch pricing** — The Pharmacy leads a covered person to believe that a drug will cost one price, but at POS, the covered person is charged a higher amount.
- **Prescription forging or altering** — Existing prescriptions are altered to increase the quantity or number of refills without the prescribing provider's permission.
- **Dispensing of expired or adulterated prescription drugs** — The Pharmacy dispenses drugs that are expired or have not been stored or handled according to the manufacturer or Food and Drug Administration requirements.

- **Prescription refill errors** — The Pharmacy provides a higher number of refills than what was prescribed.
- **Illegal remuneration schemes (kickbacks)** — The Pharmacy is offered, solicits or receives unlawful payment that results in an incentive or reward for switching covered persons to different drugs, influencing prescribing providers to prescribe different drugs or steering covered persons to plans.
- **Cost share manipulation** — The Pharmacy manipulates true adjudicated cost share to impact the benefit administration.
- **Failure to offer negotiated prices** — The Pharmacy fails to offer a covered person the negotiated price of a drug available to the covered person through the benefit plan.
- **Inappropriate application of therapeutic interchange protocols** — The Pharmacy dispenses a different covered medication than the prescribed medication without obtaining and documenting the prescribing provider's consent prior to dispensing or without informing the covered person of the substitution per applicable state laws.

Notice to California Pharmacies

This serves as notice to Pharmacies in California about rights under the California Health and Safety Code.

Pharmacy reporting

Pharmacies may report to the department, through the toll-free pharmacy line, email address or other method designated by the California Department of Managed Health Care, instances in which the Pharmacy believes a benefit sponsor is engaging in an unfair payment pattern (Cal. Health and Safety Code §1371.39).

Pharmacy Bill of Rights

Pharmacies have certain rights as a Pharmacy under California Health and Safety Code §1375.7.

Section 3: Claims processing

General information

Online claims submission

The Pharmacy must electronically submit all claims. This may include situations when the covered person has an applicable cost share when no Pharmacy Payment from a benefit sponsor is due.

The Pharmacy must provide a covered person adequate information as to where the prescription service can be electronically submitted in situations in which pharmacist judgment or applicable law permits the denial of prescription drug service.

Online availability

Point of sale (POS) means the method of submitting claims electronically through an automated claims adjudication process. POS messaging and the POS system include interactive POS communications. The POS is not a separate contract and does not create any contractual rights for a submitting Pharmacy.

The online system is generally available for claims processing 24/7.

Claim formats

- POS claims must be submitted in the current National Council for Prescription Drug Programs (NCPDP) format or current industry version.
- POS claims systems must be updated annually with the new NCPDP External Code List values.
- Batch claims must be submitted in the NCPDP batch format or current industry version.
- The Universal Claim Form (UCF) must be submitted for paper claim submissions. UCFs are available on the **NCPDP website**. For a complete list of required and situational processing requirements, refer to the payer sheets located on **Prime's website**.

The Pharmacy must follow the requirements of the payer sheets located on Prime's website to ensure accurate software setup and must also review all incoming POS messages to ensure accurate claim submission.

Pharmacies should follow all POS messaging and obtain a paid claim prior to dispensing medication, to the extent not inconsistent with applicable law. For Prime to assist your Pharmacy with claims adjudication, please email your unique processing codes, condor codes and/or input codes to **ProviderRelations@PrimeTherapeutics.com.**

Medicare reference materials

These documents are available on **Prime's website**:

- **Medicare prescription drug coverage and your rights standardized pharmacy notice instructions**
- **Medicare prescription drug coverage and your rights form (English and Spanish)**
- **Minimum performance and service criteria for Medicare Part D**
- **Minimum performance and service criteria for Medicare Specialty Network participation**
- **Minimum performance and service criteria for Medicare Part D LTC**
- **High-risk medications for elderly members**

Collection of copay/cost share

The Pharmacy must accept and collect from the covered person and/or covered person's designee payer's adjudicated copay(s), cost shares or other charges for services not covered under the covered person's benefit plan, provided the covered person has agreed up front to pay for such noncovered services, unless otherwise prohibited by applicable law.

The Pharmacy cannot waive, discount, reduce, increase or fail to collect the copay communicated to the Pharmacy at POS unless otherwise authorized in writing by Prime or the benefit sponsor or unless otherwise required by applicable law. In no event, including, but not limited to, nonpayment by a benefit sponsor payer for prescription drug services rendered to covered persons by Pharmacy, insolvency of a benefit sponsor payer or breach by Prime of any term or condition of the Agreement, will the Pharmacy bill, charge, collect a deposit from, seek compensation, remuneration or reimbursement from or have any recourse against any covered person or persons acting on behalf of the covered person for prescription drug services eligible for reimbursement under the Agreement. If a discrepancy is found as a result of an audit or investigation and there is an impact to the covered person's copay or cost share, the Pharmacy is responsible to reimburse the covered person as directed in the findings report, consistent with applicable law.

Eligibility

Covered person identification card

Prime is not obligated to remit payment to the Pharmacy for services provided to an individual who was not eligible to receive benefits at the time services were provided. The Pharmacy must verify a covered person's eligibility and must require a covered person to present a covered person identification (ID) card prior to providing a prescription drug service.

The covered person ID card does not ensure a covered person's eligibility. If a covered person does not have a covered person ID card, and the Pharmacy is unsure of eligibility, the Pharmacy must take reasonable steps to confirm the identity of the covered person through validation of a government-issued ID card or call **Prime's contact center** to obtain accurate information, when appropriate, about a covered person prior to dispensing a product or processing a claim.

Covered person eligibility

A covered person's eligibility can be verified through the POS system during claim adjudication or by calling **Prime's contact center**. Unless expressly allowed in this Manual, a covered person whose eligibility has been verified must never:

- Be denied a covered prescription drug service (subject to a pharmacist's professional judgment or as allowed by applicable law). If drug service is denied based on professional judgment or applicable law, the Pharmacy or pharmacist must provide the covered person adequate information as to where the prescription service can be provided
- Be asked to pay more than is due under the terms of the Agreement
- Be asked to pay cash and submit a paper claim, unless otherwise allowed by applicable law

If a covered person's eligibility is obtained using an eligibility lookup system, this information must be confirmed with the covered person prior to dispensing the prescription drug service.

In the event a claim is processed using incorrect eligibility, upon notice, Prime may adjust the claim to reflect correct eligibility and corresponding benefit plan coverage.

Prime may direct the Pharmacy to reverse claims for prescription drug services and any other related actions. If the Pharmacy is unwilling or unable to reverse requested claims, Prime will reverse claims on behalf of the Pharmacy by providing written notice to the Pharmacy.

Covered person protection

Other than the required cost share or copay, the Pharmacy may not bill, charge or collect payment for prescription drug services from a covered person and/or covered person's designee. The Pharmacy may not seek compensation from, condition the provision of services on payment from or have any recourse against any covered person or other person acting on behalf of the covered person, other than Prime, including in instances where Prime has denied or reversed payment to the Pharmacy for failing to comply with terms and conditions of the Agreement or this Manual. In the event a discrepancy is found as a result of an audit or investigation and there is an impact to the covered person's copay or cost share, the Pharmacy is responsible to reimburse the covered person as directed in the findings report.

Controlled substance prescription dispensing considerations

Pharmacies may not use or accept prefilled prescriptions to dispense controlled substances. Pharmacies may only dispense controlled substances based on a written or electronic prescription that complies with all applicable laws and regulations for prescribing and dispensing controlled substances.

The quantity prescribed must be submitted on each claim for Schedule II controlled substances. The total quantity prescribed may be dispensed in incremental fills to the extent permitted by law. The sum of quantities dispensed in incremental fills cannot exceed the quantity prescribed.

A prescription for a Schedule II controlled substance may not be refilled. A separate prescription is required if a prescribing provider wishes to authorize continuation of a patient's use of a Schedule II prescription drug beyond the amount specified on the first prescription.

Claims process for multiples

When processing claims for multiples with the same birth date and same medication, use the following procedure:

- Process the first claim as usual.
- Attempt to process the second claim as usual.
- If the second claim rejects, call **Prime's contact center** to verify the multiple-birth eligibility flag has been set.

Medicare E1 Eligibility Query

The E1 Eligibility Query is a real-time transaction that the Pharmacy submits to RelayHealth, the transaction facilitator. It helps determine a covered person's Medicare Part D coverage and payer order if the covered person has insurance through more than one insurer. Pharmacies generally submit E1 Queries when covered persons do not have their Medicare Part D ID card.

Additional information on E1 transactions can be found at **RelayHealth**.

Pharmacies should not submit an E1 for pharmaceutical manufacturer copay assistance coupon programs.

Medicare and Medicaid dual-eligible covered persons

According to 42 CFR 422.504(g)(1)(iii), if a Pharmacy provides prescription drug services to a covered person who is eligible for both Medicare and Medicaid, the covered person will not be held liable for payment and the Pharmacy must accept the Medicare plan payment as payment in full or bill the Medicaid benefit plan. The Pharmacy may not seek payment from a covered person for any fees that are the legal obligation of the Medicare plan.

According to 42 CFR 423.505(g)(1), beneficiary financial protections, each Medicare Part D benefit sponsor must adopt and maintain arrangements satisfactory to the Centers for Medicare & Medicaid Services (CMS) to protect its enrollees from incurring liability for payment of any fees that are the legal obligation of the Medicare Part D sponsor. To meet this requirement, the Medicare Part D benefit sponsor must ensure that all contractual or other written arrangements prohibit the sponsor's contracting agents from holding any beneficiary enrollee liable for payment of any such fees.

Qualified Medicare Beneficiary Program

The Qualified Medicare Beneficiary (QMB) Program is a state Medicaid benefit that assists low-income dual-eligible beneficiaries with Medicare Part A and Part B premiums and cost sharing, including deductibles, coinsurance and copays.

Section 1902(n)(3)(B) of the Social Security Act, as modified by Section 4714 of the Balanced Budget Act of 1997, prohibits Medicare and Medicare Advantage providers from balance billing QMB individuals for Medicare cost sharing under any circumstances.

A value of 51 may be sent in the benefit stage qualifier field (NCPDP field 393-MV) to notify the Pharmacy that a claim is submitted under the Part D Bank Identification Number (BIN)/Processor Control Number (PCN) but is NOT paid for by the Part D benefit plan. It is paid for by the Part B benefit plan.

The Pharmacy should not attempt to collect cost share for Medicare Part B–covered drugs but instead should attempt to bill coordination of benefits (COB), the beneficiary's Medicaid benefit plan. Pharmacies that inappropriately balance bill individuals enrolled in the QMB Program are subject to sanctions and possible termination of participation in one or more networks or termination of the Agreement.

Best Available Evidence

Covered persons eligible for the low-income subsidy (LIS) under the Medicare Part D Prescription Drug Program are enrolled in the claims system with the correct LIS copay level based on the latest information. If the claims system does not show the correct LIS status for the covered person, Medicare requires the Pharmacy to accept Best Available Evidence (BAE) when the covered person or their representative presents it at the POS.

Medicare also requires Pharmacies to assist covered persons who think they are eligible for LIS but do not have BAE documentation.

For covered persons with supporting BAE documentation:

- The Pharmacy must call **Prime's contact center** to ask for an immediate LIS status update in the claims system.
- The Pharmacy may submit the claim once the claims system is updated with the LIS status.
- The Pharmacy must fax a copy of the covered person's supporting BAE documentation to
- **Prime's contact center**.
- Prime forwards the supporting BAE documentation to the Medicare Part D sponsor, who works with CMS to update the covered person's LIS status in the CMS system.

For covered persons without supporting BAE documentation:

- The Pharmacy asks the covered person if they have less than three days of medication (an "immediate need").
- The Pharmacy calls **Prime's contact center** to begin the process of updating the covered person's LIS status; the request must say if the need is immediate or not immediate.
- Prime calls the Medicare Part D sponsor, who completes the BAE assistance worksheet and submits it to CMS to validate or update the covered person's LIS status in the CMS system.
- CMS updates the covered person's LIS status within one business day for an immediate need.

Hospice BAE

A covered person's hospice provider pays for medications used for palliative symptom management of a terminal illness and related conditions. Some medications submitted under Medicare Part D will reject at POS for covered persons in hospice care. If the claims system does not show the correct hospice status for the covered person, CMS requires the Pharmacy to accept BAE when presented at the POS, and the Pharmacy must forward any copies of the BAE to the contact center.

If the covered person has never previously been in hospice:

- The Pharmacy must call **Prime's contact center** to ask for a hospice prior authorization (PA).
- If Prime does not have dual system authentication of hospice admission, Prime asks the hospice provider to fax a signed hospice determination form to clinical review so the contact center can notify the plan.

If the covered person was in hospice but has since been released and Prime does not have dual system authentication of hospice revocation:

- Prime asks the hospice to fax both the signed hospice determination form and the covered person's letter of revocation to Prime's clinical review at **800.693.6703**, with the date the revocation is to be effective, as well as one of the following documents:
  - The Notice of Medicare Coverage from the hospice
  - The Notice of Medicare Non-Coverage
  - The discharge notice from the hospice saying the covered person has left hospice

Submitting the claim

Pharmacies must submit all claims according to the processing rules and guidelines outlined in the Agreement, this Manual, as revised, and in compliance with regulations, Prime's payer sheets, which are incorporated into and made part of this Provider Manual, the Pharmacy Participation Agreement and POS messaging.

Bank Identification Number and Processor Control Number

A Bank Identification Number (BIN) and Processor Control Number (PCN) are required when adjudicating claims through the POS system. A list of the BINs and PCNs used to adjudicate claims through Prime's POS system can be found in the payer sheets on **Prime's website**.

National Provider Identifier

- **Pharmacy National Provider Identifier (NPI)** — The Pharmacy must have a Pharmacy NPI, and all online claims must be submitted with the Pharmacy NPI. Online claims submitted with the Pharmacy NCPDP number will reject.
- **Prescribing provider identifiers** — Prime will only accept a valid, active individual (Type 1) NPI. The Pharmacy must submit the correct prescribing provider identifier at POS. Claims submitted without a valid prescribing provider NPI number will reject at POS. Reject Code 619 may be displayed with message "PrescrTyp1NPI required." In some instances, a Submission Clarification Code (SCC) may be used to attest that the prescribing provider NPI number supplied at POS is, or will soon be, a valid NPI. For further assistance on when an SCC can be used, the Pharmacy can reach out to Prime's Pharmacy Help Desk. The Pharmacy must submit the prescribing provider's NPI number for all Medicare Part D claims.

For controlled substance prescriptions, the Pharmacy is responsible for ensuring the prescribing provider is appropriately licensed and has the necessary prescriptive authority associated with their Drug Enforcement Administration (DEA) number for the drug being dispensed. Prime will communicate with the Pharmacy via a claim rejection if the submitted NPI is associated with an inactive or invalid DEA number or a prescribing provider without the correct prescriptive authority, the Pharmacy can enter an SCC in field 420-DK to attest that they have verified that the prescribing provider has appropriate prescriptive authority.

- The Pharmacy is responsible for validating the legitimacy of every prescription, especially controlled substance prescriptions. Self-prescribing controlled substances (Schedules II-IV) is prohibited or heavily restricted by most state laws, professional ethical guidelines and federal DEA regulations. Prescriptions filled for self-prescribed controls should be closely evaluated.

Prime will contact the Pharmacy to request that it correct any claims submitted with an invalid prescribing provider identifier and update its system for future claims. Failure to resubmit the claim(s) or update the Pharmacy's system for future claims with the correct identifier may result in termination of participation in one or more networks or termination of the Agreement.

Usual and customary

The Pharmacy must submit the lowest price the Pharmacy would charge a customer who was paying cash for the identical prescription drug service on the date dispensed. This includes any applicable discounts, including, but not limited to, senior discounts, frequent shopper discounts, coupons, discount card programs and other special discounts used to attract customers. The Pharmacy must report an accurate usual and customary (U&C) and must not underreport or conceal U&C or other pricing for prescription drug services. Membership programs are subject to U&C pricing if the membership fee charged to the customer is deemed nominal.

Documentation

Approved or confirmed verbal changes and clarifications to the prescribing provider's prescription order must be documented on the original hard copy or electronically noted in the Pharmacy's online system prior to dispensing. The Pharmacy should not request changes to a prescription for the sole purpose of avoiding POS messaging. For example, if a Pharmacy receives a POS message indicating a PA is required or that it must call **Prime's contact center**, the Pharmacy is expected to follow the POS messaging and **Prime's contact center** instructions. Electronic documentation must be noted prior to dispensing and must have a system-assigned user, date and time stamp in order to take the place of hard copy documentation. When additional refills are ordered, a new prescription number must also be assigned and appropriately documented on a hard copy.

Days' supply for non-Medicare Part D claims

The Pharmacy must submit the number of consecutive days' supply for which the prescription product is dispensed within the covered person's benefit. Future refills may be rejected if the days' supply is inaccurately submitted.

For prescription products that cannot be broken (such as inhalers), where the smallest unit exceeds the benefit days' supply, the Pharmacy must submit the maximum days' supply allowed under the covered person's benefit plan.

Example: A covered person's benefit allows up to a 30-day supply. One inhaler will last 40 days. The Pharmacy must bill the inhaler as a 30-day supply.

In situations where one unit does not maximize the benefit days' supply (such as inhalers), the Pharmacy must submit only the quantity that is dispensed within the covered person's benefit.

Example: A covered person's benefit allows up to a 30-day supply. One inhaler will last 28 days. The covered person receives one inhaler as a 28-day supply. This will vary by benefit plan.

Days' supply for Medicare Part D claims

The Pharmacy must submit the number of consecutive days' supply for which the prescription product is dispensed within the covered person's benefit. Future refills may be rejected if the days' supply is inaccurately submitted. There are some prescription products that cannot be broken in which the calculated days' supply may exceed common values (e.g., more than 30 days or more than 90 days). In these instances, the Pharmacy should submit the accurately calculated days' supply.

Example: Prolia for a 180-day administration should be submitted with a 180-day supply.

A small subset of prescription products cannot be broken (such as topical products). For this subset, the smallest unit exceeds the maximum benefit days' supply, and there is subjectivity in calculating the days' supply. In this case, the Pharmacy must submit the maximum days' supply allowed under the covered person's benefit plan.

Example: A covered person's benefit allows up to a 30-day supply. One unbreakable unit may last 40 days; however, the Pharmacy must bill the bottle as a 30-day supply.

In situations where one unit does not maximize the benefit days' supply (such as inhalers), the Pharmacy must submit only the quantity that is dispensed within the covered person's benefit.

Example: The benefit allows up to a 30-day supply. One inhaler lasts 28 days. The covered person receives one inhaler as a 28-day supply. This will vary by benefit plan.

Accurate quantity

The quantity dispensed must be equal to or less than the quantity prescribed and accurately reflect the exact quantity dispensed to the covered person. Submit the exact quantity, including decimal points, on claims and do not round up or down.

Dispensed package size/National Drug Code

When the Pharmacy submits a claim for a prescription drug service, the Pharmacy must submit the National Drug Code (NDC) for the original package size dispensed at the prescription drug service. The quantity of the prescription drug service dispensed must comply with the dispensing limitations indicated in the online POS response.

Prescriptions may not be separated, dispensed or billed by dose. If separate packaging is required, the Pharmacy must use a duplicate label. For example, a dose required in a school or adult care center should not be dispensed as a separate prescription.

Pharmacies must submit claims with the lowest cost package size available and the lowest ingredient cost dosage route of administration. If the lowest ingredient cost route is not commercially available and/or the prescribing provider requires a higher ingredient cost route be used, the Pharmacy may submit claims with a higher ingredient cost route of administration.

National Drug Codes

Pharmacies are required to use standard NDCs.

Timely filing

The Pharmacy must submit all claims online within 90 days of the date of dispensing the prescription drug service, unless otherwise required by law.

For Commercial/Health Insurance Marketplace benefit plans, if a pharmacy claim is not adjudicated online within 90 days of the prescription fill date, the claim will reject as too old to process.

For Medicare Part D benefit plans, if a pharmacy claim is not adjudicated online within 180 days or within the time frame allotted per the applicable benefit plan, the claim will reject as too old to process.

To open a window for resubmission, the Pharmacy must submit the request in writing to **ProviderRelations@PrimeTherapeutics.com**.

ePrescribing

The Pharmacy agrees to comply with applicable laws for ePrescribing.

Prescription origin code

The Pharmacy must submit all claims with the corresponding prescription origin code as outlined in the applicable payer sheets:

1 Written

2 Telephone

3 Electronic

4 Facsimile (fax)

5 Pharmacy

All claim submissions must indicate the prescription origin code to facilitate CMS reporting and tracking of ePrescriber participation. The documentation retained by the Pharmacy must support the prescription origin code submitted on the claim.

Requirements for Pharmacies contracted with 340B covered entities

The 340B Drug Pricing Program requires participating drug manufacturers to offer covered outpatient drugs to eligible health care organizations at reduced prices. Federal law prohibits duplicate discounts, meaning a manufacturer cannot provide both a 340B discount and a Medicaid drug rebate for the same claim.

To ensure accurate identification and prevent duplicate discounts, Pharmacies contracted with 340B covered entities must:

- Submit a value of "20" in the Submission Clarification Code (NCPDP field 420 DK) for any claim that uses 340B purchased drug inventory
- Submit a value of "08" in the Basis of Cost Determination field (NCPDP field 423 DN) when the submitted cost reflects the 340B acquisition cost, unless otherwise prohibited by applicable law

These requirements support accurate claim processing and compliance with federal 340B program standards.

Prime may, when necessary, contact Pharmacies to clarify 340B claim information in accordance with applicable program requirements.

To view the specific claim processing requirements, please visit **Prime's website**.

Compound prescription billing guidelines

Pharmacies must submit compound prescription claims through the POS system using the following directions:

- Submit compound prescription with a code of "2" in the compound code field.
- Submit a zero in the product/service ID field in the claim segment and submit the information for each ingredient in the compound segment.
- Enter the product ID qualifier the NDC used to prepare the compound prescription, quantity, cost and cost basis for each ingredient in the compound prescription.
- Submit the final product quantity (the quantity of the finished compound prescription product) in the quantity dispensed field:
  - For a liquid, submit the number of milliliters of the finished compound product.

  - For solid oral dosage forms, submit the total number of units being dispensed.
  - For creams or ointments, submit the total number of grams being dispensed.
  - Submit the total ingredient cost. (For total ingredient cost, multiply the quantity used for the individual ingredient and the average wholesale price for the individual ingredient according to the pricing source at the time of dispensing for each eligible ingredient used. Then, calculate the total sum of the individual ingredient costs.)
  - Plan-excluded drugs and invalid NDCs are not eligible for reimbursement.
  - Eligible ingredient costs do not include costs for labor, equipment, professional fees or flavoring.
- Maintain a compound prescription log with documentation for each compound prescription dispensed. The log must document quantities and NDCs of the ingredients used to prepare the compound prescription. NDCs submitted for the compound prescription must be the exact formulation of what is dispensed.
- Prime will accept a multiple-ingredient compound prescription submission using NCPDP's Compound segment for up to 25 ingredients.
- Dynamic PAs for processing compound prescriptions that contain situational Medicare Part B versus Medicare Part D drugs will not apply, even if the compound meets the criteria for inclusion as a Medicare Part D–covered drug. A one-time PA will be issued if the compound prescription claim meets the criteria for coverage under Medicare Part D.
- If a compound prescription claim rejects, the Pharmacy must follow POS messaging to determine if the ingredients submitted require a PA.
- If a PA is required, the Pharmacy must follow the POS messaging to obtain a PA. If a PA is not required and one or more ingredients are not covered by the covered person's benefit plan, the Pharmacy may use SCC 08 to receive payment for all covered ingredients. Not all benefit plans support the use of SCC 08.
- Each benefit setup determines claim coverage and may vary by covered person. As the compound prescription claim is processed, the Pharmacy receives system messaging on the status of the submission. Pharmacies are required to follow all system messaging.
- Compound prescriptions containing a Medicare Part B ingredient must be processed under Medicare Part B.

Pharmacies are expected to observe applicable state and federal laws, relevant U.S. Pharmacopeia (USP) Chapter Guidelines, professional standards and Food and Drug Administration (FDA) communications when preparing and dispensing compound prescriptions. Evidence of unprofessional or unsafe compounding found during the Pharmacy's audit process or otherwise may be reported to the applicable State Board of Pharmacy or the FDA and may result in termination of the Pharmacy Participation Agreement.

Prime administers pharmacy benefits on behalf of many different benefit sponsors. Each individual benefit sponsor determines benefit plan design, such as the specific drugs/ingredients covered, cost sharing, days' supply limitations and other benefit design attributes.

The following are examples of compound prescription drugs where benefit designs may vary:

- Modified-release compounds (based on covered person benefit design)
- Any compound that contains active ingredients not approved by the FDA
- A compound for which the stability is unknown at the time of dispensing or cannot be determined by referencing a USP-approved reference material
- For Medicare business:
  - Compound components
  - Methods of administration

  - Other criteria that do not satisfy the definition of a Medicare drug
- Experimental/investigational items, products or services
- Any finished product intended to address medical diagnosis (such as sugar-free products) where the covered person's medical diagnosis does not support the need for the finished product
- Any compound that differs from the equivalent commercial form only by the addition of cosmetic agents or agents intended to produce a cosmetic effect

The following drugs cannot be submitted to Prime as a compound prescription:

- Reconstituted nonsterile products to which only water, alcohol or sodium chloride solution are added to the active ingredient (e.g., children's antibiotic suspensions)
- Any prescription that is subdivided into unit dose(s)
- Medications that come with the manufacturer's base solution (e.g., IVIG)
- Injectable drugs that require reconstitution but do not require the medication to be tailored to the needs of an individual patient
- Any finished product that does not include a federal legend drug as an ingredient
- Any compound that has an equivalent commercial form, except in situations where a compound prescription is preferred according to the benefit plan (this exception may vary by state)

Prime also considers the following to be unacceptable billing practices for compound prescription claims:

- Billing for a different NDC than what was used in the compound prescription
- Billing for the full package size when only a partial amount was dispensed to the covered person
- Billing for a different dosage form than what was used in the compound prescription
- Billing for a quantity other than what was used to prepare the compound prescription
- Any compound prescription to which active ingredients are added that were not part of the prescription order
- Not following POS messaging, including, but not limited to, messaging for rejected claims
- Obtaining changes to compound prescription orders to avoid POS messaging
- Claims phishing for a drug that is covered (e.g., Pharmacy submits a claim for one drug, receives a reject or reverses the claim and resubmits for a new drug within a short period of time)
- Billing each compound ingredient as a separate prescription drug service claim
- Billing claims in a manner that bypasses system messaging that requires further review

Example: Billing claims multiple times in a month to avoid obtaining a PA or reaching plan dollar thresholds

- Billing claims for a new order prior to verifying the patient-prescribing provider relationship
- Billing compound prescription claims for a covered person:
  - Where there is no literature supporting clinical use
  - Where the Pharmacy is not registered as a 503B entity with the FDA
  - From a central fill Pharmacy that is not contracted with Prime
  - In a manner that violates any federal, state or local law regarding compounding, marketing or dispensing compound medications
  - That results in the Pharmacy giving or receiving payment to or from any prescribing provider for referrals
- Balance billing for any products that are not eligible for payment determined by the benefit sponsor or CMS

- Billing for compounds where the final product is not prepared in compliance with USP guidelines.

If you have questions regarding compound drugs, please call **Prime's contact center**.

Insulin and diabetic supply benefits

- A valid prescription must be on file for insulin dispensed to a covered person.
- An emergency fill can be dispensed by the pharmacist as allowed by applicable law.
- Insulin should be dispensed within the days' supply limits set by the covered person's benefit plan.
- Specific dosing directions must be documented at the time of dispensing. If a sliding scale is used, the Pharmacy must obtain and document maximum and minimum quantities at the time of dispensing.
- Directions limited to "Use as Directed" are not accepted.

Insulin supplies

- Unless otherwise indicated at POS, insulin syringes and needles are a covered benefit.
- For Medicare business:
  - Supplies, including insulin syringes and needles, are covered only when used to administer insulin.
  - Refer to **Medicare Part A and Part B vs. Part D claims adjudication** for additional information.
- A valid prescription is required for insulin supplies to be dispensed to a covered person.
- Some benefit sponsors will waive the copay for insulin supplies dispensed at the same time as insulin. In this situation, the insulin must be processed first.
- Diabetes management supplies submitted to insurance are considered prescriptions and must follow all terms and conditions outlined in this Manual, as revised.

Long-term care and home infusion processing requirements

Prime requires long-term care (LTC) and home infusion (HI) Pharmacies to submit NCPDP Telecommunication Standard Implementation Guide version D.0 fields as outlined on the payer sheets.

Processing guidelines for submitting LTC and HI claims are located on **Prime's website**.

Hemophilia billing guidelines

Pharmacies are expected to maintain accurate records of a hemophilia patient's available on-hand supply in order to support appropriate future dispensing. Patient bleed records must be collected and maintained by the Pharmacy.

Pharmacies are expected to ensure that patients have an emergency bleed supply on hand for major and minor bleeds. If a bleed occurs, the Pharmacy may replenish the on-hand bleed supply. If there is a need for additional prophylactic doses before a surgical or dental procedure, the Pharmacy must document, at the time of dispensing, the reason the additional supply was dispensed.

Single-use vials should be dispensed in a manner that most closely aligns with the prescribed dose to minimize waste. For example, Pharmacies are expected to process two separate size vials to most closely align with the prescribed dose. If a Pharmacy dispenses clotting factor with an assay of greater than 5% variance of the prescribed dose, the Pharmacy must document the reason the assay was not met at the time of dispensing. Factor products must have expiration dates of no less than one year from the date of dispensing unless there is specific documentation of discussing expiration with the patient or caregiver. Doses dispensed for as-needed use for bleeds should not be dispensed with an expiration of less than one year. Pharmacies must not dispense more units per dose than what is necessary and must not dispense short-dated products.

Medicare Part D Program coordination of benefits

Coordination of benefits (COB) claims for Medicare Part D programs should be processed in Prime's claims processing system.

Pharmacies must submit the primary claim to Prime electronically. After Prime adjudicates the claim, Prime will provide POS messaging that contains the claim transaction information and the covered person's supplemental coverage record if Prime is aware of other supplemental coverage. This POS messaging generally accommodates supplemental plans and includes information to process the supplemental claim(s).

Supplemental claims must be processed through a switch to capture these transactions for accurate TrOOP calculations. This process is designed to function in real time and to process all levels of payer submissions for a claim at the POS. When the primary payer or payer order information is not known or is in doubt, the pharmacist can send an E1 Eligibility Query to RelayHealth to determine proper payer order. Medicare Part D supplemental payer sheets are available on **Prime's website**.

Additional information on Medicare COB can be found at **CMS.gov**.

Time limits for COB

There are time limits for coordinating benefits with state pharmaceutical assistance programs, other entities providing prescription drug services or other payers.

The time limits cannot exceed three years from the date the prescription for the Medicare drug was filled. This does not affect time frames for Medicare Secondary Payer prescription drug claims and the ability to recover amounts.

Medicare Prescription Payment Plan

As part of your respective Participation Agreement and Prime's Provider Manual, Pharmacies are required to abide by all applicable federal and state laws, including those requirements associated with the Medicare Prescription Payment Plan (M3P). This includes, but is not limited to:

- Ensuring that eligible Medicare Part D members receive the appropriate Likely to Benefit Notice provided by the Pharmacy based on CMS requirements.
- Providing proper training to pharmacy staff surrounding M3P, such as continuing education credits, webinars and educational materials.
- Documentation or oversight measures are in place to ensure proper adherence to the M3P provider requirements on **Prime's website**.

Pharmacies are expected to comply with all CMS-defined requirements for the M3P Program.

Prime will return Approved Message Code 056 "Beneficiary likely to benefit from Medicare Prescription Payment Plan" on all Medicare Part D claims where the member's out-of-pocket cost meets or exceeds the CMS-defined threshold. When Approved Message Code 056 is returned, Pharmacies are responsible for providing the M3P Likely to Benefit Notice to the member at the POS. LTC Pharmacies are to provide the notice to the Part D enrollee at the time of its typical enrollee cost sharing billing process. If a member would like to participate in the program, they should contact the number on the back of their ID card.

In instances where the enrollee chooses to take time to consider opting into the program and leaves the Pharmacy without the prescription that triggered the notification, when the enrollee returns to the Pharmacy to pick up their prescription after opting into the program, the prescription claim that triggered the notification must be reversed and reprocessed. Then the COB claim should be submitted for M3P processing.

Subsequent to enrollment in the M3P Program, should a Part D enrollee have other unpaid claims at the same Pharmacy for covered Part D drugs from dates of service prior to M3P eligibility, in addition to the prescription that may have triggered the Likely to Benefit Notice, the covered person may request that those claims be reversed and reprocessed with the current date, so as to be included in the M3P Program.

When a Medicare Part D member is participating in the M3P Program and a Medicare Part D claim is processed where the member has an out-of-pocket cost, Prime will return Approved Message Code 057 "Beneficiary participating in Medicare Prescription Payment Plan," indicating that the M3P plan should be billed. The claims processing information for the member's M3P plan will be returned in the other payer information section of the claim response. The Pharmacy is responsible for using that information to bill a COB claim to the M3P plan. M3P claims must be billed using the Other Payer Patient Responsibility Amount method of COB processing. An Other Coverage Code of 8 should be used on all M3P claims. The final patient pay prior to the M3P claim should be submitted as a single amount with Other Payer – Patient Responsibility Amount Qualifier 06 – Patient Pay Amount. For additional claims processing information, please see the M3P payer sheet.

In situations where a supplemental payer is billed after the Part D claim and before the M3P claim, if the supplemental claim returns a higher out-of-pocket cost than the Part D claim, the M3P plan will pay up to the Medicare Part D out-of-pocket cost and the remainder will be a patient pay amount on the M3P claim that must be collected from the member unless they choose not to use their supplemental coverage.

Prime will return Reject Code DO3 "This claim is not eligible for Medicare Prescription Payment Plan" on M3P claims in situations where the product was covered as an enhanced benefit and not a product defined as covered by the Medicare Part D core benefit. These claims cannot be billed to M3P.

Nothing in this guidance precludes a Pharmacy from educating a Part D member about this program, regardless of whether the Part D member's cost sharing reaches the POS threshold for required notification.

Pharmacies' responsibility to provide eligible M3P enrollees Likely to Benefit Notice

In pharmacy settings in which there is direct contact with enrollees (e.g., community Pharmacies where enrollees present in person to pick up prescriptions), the M3P Likely to Benefit Notice must be provided to enrollees identified as likely to benefit (or the person acting on their behalf) at the time the prescription is picked up. This includes Pharmacies with a drive-through or curbside pickup option. If the Pharmacy is in contact with a Part D enrollee identified as likely to benefit and the enrollee declines to complete the prescription purchase, the Pharmacy must provide the M3P Likely to Benefit Notice to the Part D enrollee.

For example, if a Part D enrollee visits a retail Pharmacy to pick up their prescription but then declines to complete the transaction because of the cost, the Pharmacy must still provide the standardized M3P Likely to Benefit Notice to that Part D enrollee.

In the case of LTC Pharmacies, when the POS notification is received by a LTC Pharmacy, the Pharmacy is required to provide the M3P Likely to Benefit Notice to the Part D enrollee (or their authorized representative) at the time of its typical enrollee cost sharing billing process.

For other pharmacy types without in-person encounters (such as mail order Pharmacies), the Pharmacy must notify the Part D enrollee via a telephone call or their preferred contact method. This requirement should not, however, be interpreted as a requirement to delay dispensing the medication. Pharmacies are encouraged to utilize existing touchpoints with Part D enrollees, such as outreach to review medication instructions or collect a method of payment, to convey the content of the M3P Likely to Benefit Notice prior to processing payment for the prescription that triggered the notice.

Pharmacy obligation to offer negotiated prices

The Pharmacy shall provide Medicare programs' benefit plan subscribers access to negotiated prices for all drugs on the drug formulary, even when subscribers are not entitled to any benefit under the terms of the Medicare programs' benefit plan because of the application of any Part D cost share. The total negotiated price of the drug must include any dispensing fees outlined in the Pharmacy Participation Agreement. Negotiated prices must be uniform and available to Medicare programs' benefit plan subscribers for a particular covered drug when purchased from the same Pharmacy.

Medicare Part A and Part B vs. Part D claims adjudication

Medicare Part D excludes any drugs covered under Medicare Part A or Part B, such as drugs that are administered via durable medical equipment (DME; e.g., a nebulizer or nondisposable infusion pump) for members residing in their homes and drugs that are covered under hospice benefits, end-stage renal disease (ESRD) benefits or Medicare transplant benefits. Pharmacies are responsible for ensuring that claims eligible for coverage under Medicare Part A or Part B are not adjudicated under Medicare Part D.

Diabetic supplies (insulin syringes, swabs, needles, gauze) are only covered when used to administer insulin. All other uses are not covered.

Medicare Part B covers insulin for a member who resides in their home and receives insulin through a DME pump. Medicare Part D covers insulin for members who do not use a DME pump. This information may be available from the prescription, member and/or prescriber.

If the member is in their home and enrolled in a Medicare Part D Prescription Drug Plan and insulin is being administered via a DME pump, the Pharmacy should submit the claim to the member's Part B insurance directly.

When evidence exists that the member is in their home and enrolled in a Medicare Part D Medicare Advantage Prescription Drug Plan and that insulin is being administered via a DME pump, advise the member or prescriber to seek a coverage determination. Upon review, the correct billing entity will be determined, and claims will automatically process to the correct payer when resubmitted.

Pharmacies that serve LTC facilities are required to determine potential Medicare Part A eligibility by reviewing Medicare Part A eligibility information with their contracted LTC facilities. Pharmacies should seek payment from the LTC facility for prescription drug services for covered persons under a qualifying and covered Medicare Part A stay.

Drugs and biological products that are related to ESRD for members receiving dialysis must be furnished by ESRD facilities or dispensed by Pharmacies that are part of or contracted with ESRD facilities. Medicare already pays for these drugs via a bundled Part B payment to the ESRD facility. Separate Medicare payment, via Part B or Part D, is not available to the Pharmacy for these products.

Prime provides POS messaging on certain claims that may be eligible for coverage under Medicare Part A or Part B, depending on the covered person's circumstances. For example, Pharmacies may receive NCPDP Reject Code A3 – Product May Be Covered Under Hospice – Medicare Part A, in conjunction with NCPDP Reject Code 569 — Provide notice: Medicare prescription drug coverage and your rights — requiring the Pharmacy to distribute the Prescription Drug Coverage and Your Rights form. This written notice informs covered persons of their right to request and receive a coverage determination. The Pharmacy must take appropriate steps, as necessary, to ensure Medicare Part A– and Part B–eligible claims are not adjudicated under Medicare Part D.

The Pharmacy must promptly reverse any Medicare Part D claims after determining they were eligible for coverage under Medicare Part A or Part B and refund any Medicare Part D cost sharing collected from the covered person.

Aside from the Pharmacy's obligation to reverse ineligible claims, Prime may, at its discretion, reverse ineligible Medicare Part D claims. Prime conducts outreach to Pharmacies to reverse previously adjudicated claims that include, but are not limited to, those that have been identified with a retroactive ESRD date of service or claims where insulin is used in a nondisposable pump. The Pharmacy must reverse the identified claim(s) and resubmit to the covered person's correct Medicare Part A or Part B coverage. If the Pharmacy fails to reverse the claim as directed, Prime will reverse the claim on its behalf.

If a Pharmacy mistakenly bills Medicare Part D for a drug that is covered under Medicare Part A or Part B, Prime will recoup any money incorrectly paid through the pharmacy audit process and notify the Pharmacy of the error. Retroactive recoupment for hospice drugs may be coordinated directly with the hospice or covered person.

If a claim is submitted to the incorrect BIN/PCN, Prime may reject the claim with the following message:

- NCPDP Reject Code 85: Claim not processed (Please use the BIN/PCN on the member's ID card.) For more information, refer to the Medicare Part B vs. Part D Coverage Issues document on the **CMS website**.

For additional processing requirements, refer to the payer sheets on **Prime's website**.

Utilization management program

Drug formularies

Prime administers many drug formularies for benefit sponsors and administers formularies through the POS system. Drug formularies can be accessed on **Prime's website**.

During the benefit year, a benefit sponsor may remove a brand-name drug from a drug formulary and replace it with a new generic version of that drug on the same or a lower cost sharing tier and with the same or fewer restrictions (utilization management, for instance). The brand-name drug may remain on the formulary but may be subject to a higher cost sharing tier or additional restrictions.

Medicare Part D drug formularies

Medicare Part D drug formularies are published on **Prime's website** beginning in October, prior to the year they become effective, and are updated monthly to reflect additions, deletions, tier changes and utilization management changes.

If a benefit sponsor makes other types of drug formulary changes during the year, Prime will notify affected covered persons and prescribing providers at least 30 days before the change takes effect. Changes will also be posted on Prime's website. These changes may include:

- Drugs that are removed from the drug formulary, with or without the addition of a generic version of that drug
- Changes to PAs, quantity limits (QLs) or step therapy (ST) programs
- Drugs that have moved to a different or higher cost sharing tier, with or without the addition of a generic version of that drug

If the FDA declares a drug to be unsafe or the drug's manufacturer removes the drug from the market, the drug will be removed from the drug formulary, and covered persons who have received the drug will be notified.

Covered persons may be notified of drug formulary changes by United States Postal Service via email, or when they check their benefit sponsor's website. Prescribing provider and pharmacy drug formulary notifications are available on **Prime's website**. To view the comprehensive list of Medicare Part D drug formularies, visit **Prime's website**.

Prior authorization

Benefit sponsors use several types of PAs:

- **One-time override** — Benefit sponsors may direct Prime to use the one-time override to:
  - Process dosage changes
  - Request a vacation supply
  - Replace lost, stolen, damaged or spilled medications
  - Fix an incorrect days' supply
  - Request to dispense through mail rather than retail (or through retail if mail service is disrupted)
  - Process emergency fills where provided by the benefit sponsor and consistent with applicable law

  At the time of the fill, the Pharmacy must document the reason with support (e.g., dates and location of vacation, emergency that occurred) for the override on the hard copy or within an electronic system. Electronic notes are only considered acceptable documentation when the Pharmacy's system automatically dates and time-stamps the entry. The Pharmacy may call **Prime's contact center** to inform Prime of the member's need for medication. The contact center agent will assess and determine if Prime has been delegated to authorize an override on behalf of the plan.

  Dynamic PA — Some benefit sponsors use an automatic override process referred to as dynamic PA. The Pharmacy must enter a predetermined PA number for certain conditions, such as a vacation request, adverse weather, insulin syringes being used for insulin administration or dosage change.

  At the time of the fill, the Pharmacy must document the reason for the override on the hard copy or within an electronic system. Electronic notes are only considered acceptable documentation when the Pharmacy's system automatically dates and time-stamps the entry. The Pharmacy may need to request a PA for a dosage change or vacation override.

The following PAs must be completed by the prescribing provider or staff, covered person or covered person's appointed representative, as documented by a valid appointment:

- **Drug formulary exception** — Used when a prescribing provider requests a medication for a covered person that is not in the drug formulary, such as, for example, when the covered person is sensitive or unresponsive to a therapeutic alternative in the drug formulary. If the benefit sponsor has elected to use this PA, Prime will provide POS messaging for additional instructions on requesting a drug formulary exception. The Pharmacy must follow POS messaging and notify the covered person and/or prescribing provider of the need for a PA. There are three ways to obtain a Request for a Drug Formulary Exception form:

  The prescribing provider can contact the benefit sponsor by phone or in writing based on the information provided on the covered person's ID card.

  The covered person can call the toll-free number on the back of their ID card.

  The covered person can visit their benefit sponsor.
- **Clinical PA** — This PA is used for a medication that requires clinical review of specific criteria before the medication is covered by the benefit sponsor. If the benefit sponsor has delegated this function to Prime, Prime will review the PA request to determine if the covered person is eligible for coverage. In these cases, Prime requires clinical documentation from the prescribing provider. The Pharmacy must follow POS messaging and notify the covered person and/or prescribing provider of the need for a PA. In no event may the Pharmacy complete a clinical PA. POS messaging may vary based on the drug or program and may include QLs, ST or other clinically necessary requirements in addition to the PA.

- Covered persons should always contact their benefit sponsor if they have any questions. Examples of medications included in the clinical PA program are growth hormones, medications used to treat hepatitis C and compound prescriptions. Please refer to POS messaging as these claims will reject. For the most current information on medications that require a PA, visit the website of the covered person's benefit sponsor.
- **Medicare Part D eligibility verification** — This PA is used specifically for certain drugs [such as tadalafil (2.5 mg and 5 mg tablets) or Ozempic] in Medicare Part D. Claims for these drugs should reject at POS and require a PA to determine that:
  - The covered person's use of that drug is eligible for coverage under Medicare Part D
  - The covered person's use of that drug satisfies any of the benefit sponsor's CMS-approved utilization management criteria

NOTE: Medicare Part D transition — If a covered person is within the transition period, the covered person will not immediately receive a temporary supply of these drugs as a covered person would for other drugs that are covered under Medicare Part D. Following review of a PA request for one of these drugs, it may be determined that the covered person's use of that drug is covered under Medicare Part D but is not covered under the benefit sponsor's CMS-approved utilization management criteria. In these cases, Prime or the benefit sponsor may reach out to the Pharmacy where the initial claim rejected and inform the Pharmacy that the covered person is eligible to receive a temporary supply of these drugs during the remainder of the covered person's transition period.

- **Hospice PA** — CMS generally pays for the following categories of drugs under Medicare Part A when prescribed to covered persons in hospice:
  - Laxatives
  - Antiemetics
  - Antianxiety agents
  - Analgesics (non-narcotic, opioid and anti-inflammatory) Claims will reject with the following NCPDP reject codes:

Claims will reject with the following NCPDP reject codes:

- A3 "Product may be covered under hospice — Medicare A"
- 75 "Prior authorization required"
- 569 (Notice of Med D coverage and rights)

The Pharmacy should work with the hospice care provider to get paid for drugs within the four categories listed above. However, if the hospice care provider (or the prescribing provider not on the hospice staff) determines that a drug in one of these four categories is unrelated to the covered person's terminal illness or related condition, Medicare Part D may cover the drug.

In this case, a hospice PA is required. The drug may still need to satisfy any other existing utilization management criteria for Medicare Part D to pay.

The covered person's prescribing provider can follow the standard coverage determination process to request a hospice PA. The hospice care provider may also submit a hospice PA form on the covered person's behalf to request the hospice PA.

- If the covered person's eligibility indicates they are actively enrolled in hospice when they are not and their claim for a drug in these four categories rejects at the Pharmacy, the Pharmacy may need hospice PA to override the incorrect eligibility to adjudicate the covered person's claim. As mentioned above, the covered person's prescribing provider can submit a coverage determination, or the hospice care provider must also fax a signed hospice determination form and notice of termination/revocation to Prime's clinical review team. The Pharmacy may call **Prime's contact center** to request the fax number and initiate this process.

Electronic submission of PA requests

If the Pharmacy has received POS clinical PA messaging, the Pharmacy may initiate an electronic PA (ePA) request through **CoverMyMeds.com**, **Surescripts.com** or another ePA provider/vendor as directed by Prime. The Pharmacy must notify the covered person and/or prescribing provider to indicate that a PA is required for the prescription drug service.

In no event may the Pharmacy submit a PA on behalf of a prescribing provider or covered person through another ePA provider/vendor. See **CoverMyMeds.com** or **Surescripts.com** for more information.

Step therapy/Contingent therapy programs

Some benefit sponsors require the covered person to try one or more preferred medications before a nonpreferred medication is considered for payment. This is called step therapy (ST). Refer to the benefit sponsor's drug formulary to determine if a drug is subject to ST. For the most current information on ST, visit the covered person's benefit sponsor's website. Drugs subject to ST may reject based on whether there is history of prerequisite drugs on file. Sponsors may have special POS messages, which may vary based on the drug or program.

Quantity limit

Many benefit sponsors restrict the quantity that may be dispensed on certain drugs. These limits follow clinical dosing guidelines and restrict the dispensing of the drug to a maximum quantity. A claim that exceeds the QL will result in a NCPDP Reject Code 76 "Plan limits exceeded." The Pharmacy's software system must be able to capture the reject code and its associated POS message. This section of the Manual does not apply to prescription drug services where a Pharmacy receives a rejection message at the POS indicating "Prior Authorization Required," "Call Pharmacy Help Desk" and/or "Plan dollar limit exceeded."

If the quantity prescribed exceeds the QL allowed by the covered person's benefit, the Pharmacy must reduce the quantity dispensed and adjust refills according to the quantity dispensed. If the covered person requests a smaller amount, the Pharmacy may reduce the quantity dispensed. The pharmacist must document this on the hard copy at the time of the fill or on the electronic documentation prior to dispensing to reflect the covered person's request. Electronic documentation must have a system-assigned user, date and time stamp to take the place of hard copy documentation.

Drug utilization review

Prime will alert Pharmacies through the POS system in situations that include, but are not limited to:

- Drug compliance screening
- Drug — drug interaction screening
- Drug — disease screening
- Dosing/duration screening
- Drug — age screening
- Drug — sex screening
- Duplicate prescription screening

- Duplicate therapy screening
- Acetaminophen toxicity screening
- Opioid misuse
- Opioid naïve days' supply limit
- Opioid benzodiazepine concurrent use
- Opioid buprenorphine concurrent use
- Opioid antipsychotic concurrent use
- Polypharmacy use of multiple anticholinergic medications

The Pharmacy is responsible for reviewing any claim with a drug utilization review (DUR) alert from the POS system. The Pharmacy is responsible for ensuring that its systems accept DUR messaging. Pharmacists should use professional judgment to follow up with covered persons and/or prescribing providers to provide professionally appropriate counseling regarding the DUR messages. Following a clinical decision, the pharmacist should provide appropriate documentation on the hard copy.

CMS regulations and Prime require Pharmacies in Prime's Medicare Network to review, update and implement quality assurance systems and procedures at the POS. Pharmacies must obtain and refer to the covered person's allergy information before dispensing. In addition, Pharmacies must ensure that all employees or other agents who dispense medications are aware of and use these DUR procedures, and that they follow currently accepted standards for contemporary pharmacy practice as established by the applicable jurisdiction.

Maximum allowable cost

Prime's maximum allowable cost (MAC) list provides pricing for drugs that are reimbursed at an upper limit per unit price, based on current market sources. All products are reviewed on a regular basis and will be adjusted as needed based on market conditions. Prime's MAC lists are updated, at a minimum, every seven days or in accordance with applicable law. If the availability of a drug becomes limited, the MAC will be suspended or the drug may be permanently removed from the MAC lists. The drug may be added back when market sources confirm adequate supply and distribution.

Pharmacies can appeal Prime's MAC pricing by submitting an appeal through **Prime's website** or by sending a MAC appeal to Prime at **MACAppeals@PrimeTherapeutics.com** or by fax to **877.823.6373**. If a fax is sent, an email address is required so a response may be provided.

Please contact **PharmacyPricingAppeals@PrimeTherapeutics.com** with any questions or issues with the appeals process. Prime will adhere to each state's applicable timeline to accept an appeal. If an appeal is sent outside of the established timeline, the appeal may be denied. If a state does not specify a timeline to accept an appeal, Prime will allow 30 business days after the date of the claim to accept an appeal.

Please refer to **Prime's website** where Pharmacies can register to access and search Prime's MAC lists, weekly MAC changes, MAC pricing appeals process and the sources used to determine MAC pricing. After Pharmacy Network participation is verified, the Pharmacy will receive a secure username and password via email to access Prime's MAC lists.

The sources currently used to determine MAC pricing are regional and national wholesalers, which include AmerisourceBergen, Cardinal Health, McKesson, Anda Pharmaceuticals, the National Average Drug Acquisition Cost published by CMS, Predictive Acquisition Cost and Medi-Span. Prime may change pricing sources at any time and provide notice to the Pharmacy (including through updates posted to Prime's Provider Resources online or this Provider Manual).

Section 4: Benefit plan

Post claim adjudication

Return to stock — Unclaimed prescriptions

Pharmacies are required to reverse any claim for a prescription drug service that is not delivered to or received by the covered person within 14 days of submission, unless a shorter time period is required by law. Claims not reversed within 14 days for prescription drug services that are not received by the covered person are subject to audit and may be collected through the retrospective pharmacy audit process.

Notice of payment error

Pharmacies must report any alleged error in payment to Prime within 14 days, or, based on the Pharmacy Participation Agreement or any other Pharmacy contractual agreement between Prime and the Pharmacy, of the date of the remittance advice for each submitted claim. Failure to report alleged errors in payment constitutes a waiver for any claims adjustment or correction.

In cases where Prime has previously paid for a claim and the Pharmacy reverses the claim, the Pharmacy is responsible for any outstanding balance of a prior payment on the claim later reversed. Payments for a paid claim will be paid first to any outstanding balance owed, consistent with applicable law.

When Prime alters the adjudication of a claim based on audit or investigation findings, the Pharmacy shall not further manipulate the claim after this action.

Benefit plan design

Benefit plans may change without prior notice to the Pharmacy. New benefit plans may be added at the request of a benefit sponsor.

Brief explanations of common benefit designs are listed in the following sections. Keep in mind that these conditions may or may not apply to a particular benefit sponsor or benefit plan.

Pharmacy Networks

Benefit sponsors may elect to include or exclude a Pharmacy from any or all benefit plan(s). This applies to Pharmacies in any or all Pharmacy Networks through which the benefit sponsor provides prescription drug services.

Pharmacy contracting and claim adjudication

Network participation and system setup cannot be backdated. Please review point-of-sale (POS) messaging for further details regarding network participation prior to dispensing medication, to the extent consistent with applicable law.

Long-term care guidelines

For Pharmacies providing prescription drug services to covered persons residing in another form of congregate residential setting, the covered person must meet the same institutionalized level of care as a covered person residing in a long-term care (LTC) facility in order to be eligible for LTC reimbursement.

Services provided to family members and self

In accordance with a covered person's benefit plan and applicable law, prescription drug services prescribed by or provided to self or a family member may not be covered, and such prescription drug services may be identified after claim adjudication and subject to additional review.

Product Selection Code

For purposes of this Manual, as revised, Dispense as Written (DAW) and Product Selection Code (PSC) are used interchangeably. The Pharmacy must submit an accurate PSC, in accordance with the National Council for Prescription Drug Programs (NCPDP) specifications when processing claims electronically. PSC submissions may change the calculation of the claims adjudication, depending on the benefit plan. The covered person's copay for PSC 1 or 2 may vary based on the benefit plan. Some benefit sponsors may require the covered person to pay the difference between the brand-name product and the generic equivalent. If appropriate, and consistent with applicable law, NCPDP PSC may be restricted by the benefit design; please contact the Help Desk for assistance and note that justification will be required. Prime may audit claims to ensure appropriate documentation to support PSC selection for each claim submission. Findings of inappropriate use may result in up to full recoupment.

Value	NCPDP description	Processing requirements
0	No product selection indicated This is the field default value used for prescriptions for single source brand, single biologic, co-branded/ co-licensed, generic or interchangeable biosimilar products. DAW 0 is not appropriate for a multisource branded product with available generic(s) or for a reference product with interchangeable biosimilar(s).	
1	Substitution not allowed by prescriber This value is used when the prescriber indicates, in a manner specified by prevailing law, that the product is medically necessary to be dispensed as written. DAW 1 is based on prescriber instruction and not product classification.	The prescription order at the time of the fill must contain documentation of the DAW order from the prescribing provider. If the prescription is telephoned in, the pharmacist must manually write "DAW" on the prescription, so it is documented in writing.
2	Substitution allowed – patient requested product dispensed This value is used when the prescriber has indicated, in a manner specified by prevailing law, that generic or interchangeable biosimilar substitution is permitted, and the patient requests the brand or reference product.	The Pharmacy must document or have a computer date and time stamp on the prescription that the covered person requested the brand-name drug.
3	Substitution allowed – pharmacist selected product dispensed This value is used when the prescriber has indicated, in a manner specified by prevailing law, that generic or interchangeable biosimilar substitution is permitted, and the pharmacist determines the brand or reference product should be dispensed.	The use of this code may be restricted by benefit design for a brand-name drug with or without available generic or reference product biologics.
4	Substitution allowed – generic drug or interchangeable biosimilar not in stock (Note: For a generic drug shortage in the marketplace, see DAW Code 8.) This value is used when the prescriber has indicated, in a manner specified by prevailing law, that generic or interchangeable biosimilar substitution is permitted and the brand or reference product is dispensed since a currently marketed generic or interchangeable biosimilar is not stocked in the Pharmacy.	The use of this code may be restricted by benefit design for brand-name drug with or without available generic or reference product biologics.

Value	NCPDP description	Processing requirements
5	Substitution allowed – brand-name drug or reference product dispensed as a generic or interchangeable biosimilar This value is used when the prescriber has indicated, in a manner specified by prevailing law, that generic or interchangeable biosimilar substitution is permitted and the pharmacist is utilizing the brand or reference product as the generic or interchangeable biosimilar entity.	The use of this code may be restricted by benefit design for brand-name drug with or without available generic or reference product biologics.
6	Override This value is only used when other existing values do not meet the business need.	The use of this code may be restricted by benefit design for brand-name with or without available generic or reference product biologics.
7	Substitution not allowed – brand-name drug or reference product mandated by law This value is used when the prescriber has indicated, in a manner specified by prevailing law, that generic or interchangeable biosimilar substitution is permitted but prevailing law or regulation prohibits the substitution of a brand or reference product even though generic or interchangeable biosimilar versions of the product may be available in the marketplace.	Use of this code would be rare.
8	Substitution allowed – generic drug or interchangeable biosimilar not available in marketplace This value is used when the prescriber has indicated, in a manner specified by prevailing law, that generic or interchangeable biosimilar substitution is permitted and the brand or reference product is dispensed because the generic or interchangeable biosimilar is not currently manufactured, distributed or is temporarily unavailable.	This code should be selected when there is a market shortage of the generic drug or interchangeable biosimilar.
9	Substitution allowed by prescriber, but plan requests brand or reference product This value is used when the prescriber has indicated, in a manner specified by prevailing law, that generic or interchangeable biosimilar substitution is permitted, but the plan's formulary requests the brand or reference product. This situation can occur when the prescriber writes the prescription using either the brand, reference product, generic or interchangeable biosimilar name and the product is available from multiple sources.	DAW Code 9 is used when the plan formulary requires the brand or reference product for an interchangeable biosimilar to be dispensed, when the prescriber has not written the prescription as brand or reference product as medically necessary. DAW Code 9 is not appropriate on claim submissions for single source brand, single biologic, co-branded/co-licensed, generic or interchangeable biosimilar products.

Generic substitution

Generic drug standards

The Pharmacy must dispense a generic drug whenever permitted and in accordance with applicable laws.

The Pharmacy must stock a variety of generic drugs coinciding with the practices of prescribing providers and the benefit sponsor's drug formulary as indicated by the claims system response and other correspondence and the generic drug formulary of the state in which the Pharmacy is located.

Biosimilar drug standards

A biosimilar product is a biologic medication that is highly similar to and has no clinically meaningful difference from an existing Food and Drug Administration (FDA)-approved biologic, which is called a reference product. Only biosimilar products that are considered interchangeable biosimilars may be substituted for the reference product without obtaining prescriber authorization when allowed by applicable state law. Interchangeable biosimilars can be identified by use of the FDA's Purple Book.

Please visit **PrimeTherapeutics.com/Resources** for additional information on using the appropriate DAW/PSC codes.

Enhanced pharmacy programs

Vaccine administration

Pharmacies that dispense and administer vaccines must follow all applicable laws, regulations and guidelines governing the sale and administration of vaccines, including ensuring proper personnel compliance and licensing. Please refer to **Prime's website** for up-to-date vaccine program information.

"Vaccine" means a preparation that is used to stimulate the body's immune response against diseases or any other definition that is required by applicable law. "Vaccine administration fee" means a fee payable to the Pharmacy for administering a vaccine by the act of injection in accordance with applicable law. The Pharmacy must submit its claim for the vaccine administration fee to Prime electronically, along with the related ingredient cost submission and dispensing fee. In other words, the ingredient cost, dispensing fee and vaccine administration fee must be submitted to Prime as a single claim. Visit **Prime's website** for processing instructions, including software setup for the vaccine administration program.

Medication Therapy Management

Prime uses an internal team of clinicians and external Medication Therapy Management (MTM) vendors to provide annual comprehensive medication review (CMR) services for MTM-enrolled covered persons. Prime also provides quarterly, criteria-based targeted medication review services for MTM-enrolled covered persons.

Prime enrolls covered persons into the MTM Program who have multiple chronic diseases, are taking multiple Part D drugs and are likely to meet or exceed predetermined Part D drug costs and/or have been identified as an at-risk beneficiary (ARB). Criteria for enrollment into the MTM Program is established by CMS guidance. Eligible covered persons can complete a CMR or opt out of the program by calling Prime's MTM department at **866.686.2223**.

Medicare Part D Drug Management Program

Prime's Drug Management Program aims to mitigate current and prevent future nonmedical use and abuse of frequently abused drugs. Internal clinicians assess potential at-risk beneficiaries (ARBs) by performing reviews that meet or exceed the requirements and guidance set forth by CMS. If a member is deemed an ARB, one or more beneficiary-specific limitations are implemented, including POS, pharmacy and/or prescriber limitations. Members, prescribing providers and/or Pharmacies are notified of beneficiary-specific limitations and appeal information in notification letters.

Medicare Part D transition process

CMS requires that Medicare Part D benefit sponsors support an appropriate transition process to provide covered persons with a temporary supply of prescription drugs in certain circumstances, including, but not limited to:

- Current drug therapies not included in a covered person's new Medicare Part D benefit sponsor's drug formulary
- Current drug therapies subject to certain limits, such as a prior authorization (PA), step therapy (ST) or quantity limit (QL)

The transition process gives covered persons time to work with their prescribing provider to switch to a therapeutically equivalent medication or to obtain a drug formulary exception or PA.

Prescription drugs not on Medicare Part D benefit sponsor's drug formulary or subject to certain limits

When a covered person in their transition period (e.g., within the first 90 days of eligibility) presents a prescription for a Part D drug that is not on the Medicare Part D benefit sponsor's drug formulary or that is subject to certain limits, such as PA, ST or QL, the paid transition claim will return the applicable NCPDP Approved Message Code 004 to the Pharmacy, explaining that the drug was paid due to the standard transition benefit.

Supply limits

If the claim submitted for a days' supply is greater than what is allowed during the transition period, or if the covered person had already obtained a transition supply and the claim is rejected, the reject message to the Pharmacy will explain the reason. Messaging examples are provided below.

At retail, covered persons are allowed at least a one-month transition supply of a nonformulary drug or a drug subject to certain limits. LTC-covered persons are also allowed up to a one-month transition supply during their transition period. The exception to the days' supply limits is drugs packaged in such a way that they cannot be dispensed for fewer days than the benefit limit (e.g., Lupron Depot Inj. 11.25 mg is prepackaged in a three-month supply).

Pharmacies, including Extended Supply Network and mail order Pharmacies, may get a reject message indicating that a covered person may not obtain more than the days' supply limits noted above. However, a claim may require other corrections or override codes, which should be done prior to reducing the days' supply. The claim may allow benefits if the corrections are made without reducing the days' supply to accommodate the transition days' supply limit. If the claim remains rejected after all other corrections or overrides have been completed, action should be taken to resolve the transition days' supply reject indicated within the message.

Partial fills

Since a covered person may have received a partial fill during the transition period, it is important to reference the message indicating days' supply re-maining and check the covered person's history for the drug to see if the covered person is still eligible for any remaining authorized supply during the remainder of the transition period.

For instance, in the retail setting, a covered person may have received a nine-day transition supply. That covered person is still eligible for the remaining 21-day supply during the transition period.

Important notice — To meet CMS requirements, **covered persons in transition must leave the Pharmacy with the appropriate medications**. Covered persons who continue enrollment in a Medicare Part D benefit plan are eligible for a transition benefit within the first 90 days of the new year. Prime will provide a transition process consistent with the transition process required for new enrollees beginning each new year or those who make a transition prior to the beginning of the new year.

Status alerts

A primary goal of the transition process is to alert the covered person of the nonformulary status of their drug and if their drug is subject to PA, ST or QL. In these cases, Prime will use standard NCPDP codes indicating the payment of a claim is due to the transition benefit. Pharmacists receiving these codes must communicate the information to the covered person and suggest that the covered person contact their prescribing provider to switch to a formulary drug or request a drug formulary exception or PA. Covered persons will receive a letter from the benefit sponsor notifying the covered person how to proceed.

Sample POS messaging

Here are some examples of retail POS messaging during the transition period:

- If the claim rejects because the days' supply submitted is greater than the allowed days' supply for that drug during the transition period:
  - "MAX OF 30 DS DURING TRANSITION PERIOD. RESUBMIT W/LESSER DS. AUTH OR FORM ALT REQ. CALL **PRIME'S CONTACT CENTER** IF NEW/RE-ENROLLEE"
- If the claim rejects because the covered person has already received a full or partial transition supply during the transition period:
  - "AUTH OR FORM ALT REQ/NONFORM/UM MEDS. MAX 30 DAY SUPPLY IN TRANSITION PERIOD. <##> DAY SUPPLY REMAINS"
- When there is a paid claim, the NCPDP Approved Message Code 004 will be returned. Reason for and examples of LTC POS messaging during the transition period:
- If the claim rejects because the days' supply submitted is greater than the allowed days' supply for that drug during the transition period:
  - "MAX OF 31 DS/FILL IN TRANSITION PERIOD. RESUBMIT W/LESSER DS. AUTH OR FORM ALT REQ. CALL **PRIME'S CONTACT CENTER** IF NEW/RE-ENROLLEE"
- If the claim rejects because the covered person has already received a full or partial transition supply during the transition period:
  - "AUTH OR FORM ALT REQ/NONFORM/UM MEDS. MAX 31 DAY SUPPLY IN TRANSITION PERIOD. <##> DAY SUPPLY REMAINS"
- When there is a paid claim, the NCPDP Approved Message Code 004 will be returned.

There are additional benefits that apply to covered persons transitioning to or from LTC. Additional benefits include the following:

- The level of care change benefit applies to covered persons who switch care settings. This can occur when a covered person switches from LTC to retail, from retail to LTC, or from one LTC setting to another. Early refill edits are not used to limit appropriate and necessary access to Part D benefits. Such covered persons are allowed access to a refill upon admission or discharge. When there is a paid claim due to the level of care change transition benefit, the NCPDP Approved Message Code 012 will be returned, indicating:
  - "Level of Care Change"
- The emergency transition benefit applies to covered persons in the LTC setting. Since, as a matter of general practice, LTC facility residents must receive their medications as ordered without delay, Part D sponsors must also cover emergency supplies of nonformulary Part D drugs for LTC facility residents after the transition period.

- The emergency transition benefit allows up to a 31-day supply of Part D drugs that would otherwise reject as nonformulary or be subject to certain limits. When there is a paid claim due to the emergency transition benefit, NCPDP Approved Message Code 008 will be returned, indicating:
  - "Emergency Fill Situation"

Refer to **Prime's website** for Medicare Part D drug formulary listings.

Covered persons in transition must leave the Pharmacy with the appropriate medications. If the Pharmacy has questions regarding the transition process or claims processing, please call **Prime's contact center**.

Medicare Part D general guidelines and procedures

Pharmacies that provide prescription drug services to covered persons in an LTC facility must be familiar with the following guidelines:

- Claims must be billed in 31-day increments and no more than once per month unless the claim meets the short-cycle dispensing requirements.
- Seven-day unit packages must be logged and billed no more than once per month.
- The LTC facility must be documented on the prescription order for all dispensed controlled substances.
- Over-the-counter products must be dispensed in the original container and may not be priced higher than the shelf price.
- Items that are normally supplied by the LTC facility on a per-diem basis, such as test strips and syringes, are not billable to Prime.
- Unique dispensing methods (such as tray changes every two or seven days) do not justify additional dispensing fees. One dispensing fee per month is reimbursable except when the product is delivered to an LTC facility.
- If providing prescription drug services to covered persons residing in an LTC facility, the Pharmacy must maintain a delivery log to acknowledge delivery. The delivery log should include:
  - Prescription number
  - Date of fill
  - Delivery date and signature of covered person(s) receiving medication
  - Receipts and other documentation showing the copay (if applicable) was paid by the covered person or their representative

For the current LTC processing requirements, please visit **Prime's website**.

Medicare Part D short-cycle dispensing LTC guidelines and procedures

Pharmacies servicing LTC facilities must dispense solid oral doses of brand-name drugs to Medicare covered persons residing in LTC facilities in no greater than 14-day increments according to 42 CFR §423.154. Prime will reject LTC facility claims that are submitted with invalid or missing short-cycle claim combinations.

The following fields must be submitted on all LTC short-cycle claim combinations:

- NCPDP field 147-U7 pharmacy service type
- NCPDP field 307-C7 place of service
- NCPDP field 384-4X patient residence

Please visit Prime's website for detailed processing requirements.

Residence code	Code value
00	Not specified, other patient residence not identified below
01	Home
02	Skilled nursing facility
03	Nursing facility (LTC facility)
04	Assisted living facility
05	Custodial care facility (residential but not medical care)
06	Group home (e.g., congregate residential foster care)
07	Inpatient psychiatric facility
08	Psychiatric facility (partial hospitalization)
09	Intermediate care facility/individuals with intellectual disabilities
10	Residential substance abuse treatment facility
11	Hospice
12	Psychiatric residential treatment facility
13	Comprehensive inpatient rehabilitation facility
14	Homeless shelter
15	Correctional institution

Medicare Part B transition process

CMS requires that Medicare Part B plans support an appropriate transition process to provide covered persons who are undergoing an active course of treatment, including the use of durable medical equipment (DME), such as diabetic products and certain Part B drugs.

The transition process gives covered persons continuation of care and time to work with their prescribing provider to switch to a therapeutically equivalent DME or Part B drug or to get an exception to the preferred brand.

When a covered person in their transition period (e.g., within the first 90 days of eligibility or within the first 90 days of the calendar year) presents a prescription for a diabetic supply or certain Part B drugs that are not on the preferred list or require a PA, the paid transition claim will return the applicable NCPDP Approved Message Code 004 to the Pharmacy, explaining the product is covered under the standard transition benefit.

Supply limits

If the claim is submitted for a days' supply that is greater than what is allowed during the transition period, or if the covered person had already obtained a transition supply and the claim is rejected, the reject message to the Pharmacy will explain the reason. Messaging examples are provided below.

Covered persons are allowed at least a 90-day transition supply of a diabetic product or certain Part B drugs. The exception to the days' supply limits is a product packaged in such a way that it cannot be dispensed for fewer days than the benefit limit.

Pharmacies, including Extended Supply Network and mail order Pharmacies, may get a reject message indicating that a covered person may not obtain more than the days' supply limits noted above. However, a claim may require other corrections or override codes, which should be done prior to reducing the days' supply. The claim may allow benefits if the corrections are made without reducing the days' supply to accommodate the transition days' supply limit. If the claim remains rejected after all other corrections or overrides have been completed, action should be taken to resolve the transition days' supply reject indicated within the message.

Partial fills

Since a covered person may have received a partial fill during the transition period, it is important to reference the message indicating days' supply remaining and check the covered person's history to see if the covered person is still eligible for any remaining authorized supply of the product during the remainder of the transition period.

For instance, a covered person may have received a 30-day transition supply. That covered person is still eligible for the remaining 60-day supply during the transition period.

Important notice — To meet CMS requirements, **covered persons in transition must leave the Pharmacy with the appropriate products or drugs**. Covered persons who continue enrollment in a Medicare Part B benefit plan are eligible for a transition benefit within the first 90 days of the new year. Prime will provide a transition process consistent with the transition process required for new enrollees beginning each new year or those who make a transition prior to the beginning of the new year.

Status alerts

A primary goal of the transition process is to alert the covered person of the status of their product or drug. In these cases, Prime will use standard NCPDP codes to indicate that the payment of a claim is caused by the transition benefit. Pharmacists receiving these codes must communicate the information to the covered person and suggest that the covered person contact their prescribing provider to switch to a preferred product or request an exception for the product or drug. Covered persons will receive a letter from the benefit sponsor, notifying the covered person how to proceed.

Sample POS messaging

Here are some examples of POS messaging during the transition period:

- If the claim rejects because the days' supply submitted is greater than the allowed days' supply for that product during the transition period:
  - "MAX OF 90DS DURING TRANSITION PERIOD RESUBMIT W/LESSER DS. AUTH OR PREF PROD REQ. CALL **PRIME'S CONTACT CENTER** FOR SUPPORT IF NEW/RE-ENROLLEE"
- If the claim rejects because the covered person has already received a full or partial transition supply during the transition period:
  - "AUTH OR PREF PROD REQ. MAX 90 DAY SUPPLY IN TRANSITION PERIOD. <##> DAY SUPPLY REMAINS CALL **PRIME'S CONTACT CENTER** WITH QUESTIONS"

When there is a paid claim, the NCPDP Approved Message Code 004 will be returned.

Section 5: Responsibility of Pharmacy

Compliance with the Participation Agreement and Provider Manual

The Pharmacy is solely responsible for compliance with the terms of all applicable agreements and this Manual, as revised. Pharmacies are not entitled to seek any costs associated with these compliance obligations, including, but not limited to, credentialing or recredentialing, claims submission or reporting, under any circumstances. Except as explicitly identified within the Pharmacy Participation Agreement, if there is a conflict between the Participation Agreement and the Provider Manual, the Provider Manual will supersede.

Update information with the National Council for Prescription Drug Programs

The National Council for Prescription Drug Programs (NCPDP) requires that Pharmacies submit pharmacy information updates directly to NCPDP. To submit additions, changes, deletions, current address, fax number or phone number, visit NCPDP's website at **Online.NCPDP.org**.

Prime receives and incorporates weekly NCPDP updates into Prime's system, which include changes to a Pharmacy's address, email address, fax number, phone number and Pharmacy Chain/Pharmacy Service Administration Organization (PSAO) affiliation. Prime's system supports only one PSAO affiliation at this time.

Pharmacies must maintain current NCPDP profile information, including payee designation. Pharmacies must provide to Prime the following NCPDP fields:

- NCPDP relationship code (if applicable)
- NCPDP payment center code (if applicable)
- Payment center name (if applicable)
- Pharmacy tax identification number

Prime will remit payment to Pharmacies based on NCPDP payee designation and any applicable electronic funds transfer and 835 Health Care Electronic Remittance Advice forms submitted to Prime.

To ensure the integrity of Prime's data for covered persons to locate Pharmacies, Pharmacies must submit pharmacy information updates to NCPDP as soon as they are aware, but no later than seven days, of any change.

Office of Inspector General and GSA Exclusion and Preclusion List checks

CMS requires that all individuals and businesses that contract to provide Medicare prescription drug services make sure that everyone they employ is eligible to receive federal funds. Prime does not pay (either directly or indirectly) any individual or entity who has been excluded, suspended, precluded or otherwise declared ineligible from participating in any state or federal health care program (e.g., Medicare, Medicaid). Furthermore, Prime will reject a pharmacy claim for a prescription drug service that is prescribed by an individual on the Preclusion List.

The Pharmacy must ensure it does not employ, or contract with, any individual or business that is excluded, precluded or debarred from participation in Medicare or state health care programs. Exclusion and preclusion checks must be conducted prior to contracting or hiring and then monthly thereafter. If a Pharmacy or a specific pharmacy location is sanctioned by the Office of Inspector General (OIG), excluded or precluded from participation in federal health care programs, the Pharmacy must notify Prime immediately. Please see the following sources for more information:

- **OIG website**
- **System for Awards Management (SAM) website**
- **CMS Prescription Drug Benefit Manual, Chapter 9**
- **"Ineligible Person" means any individual or entity who:**

- As of the date such exclusion lists are accessed by the prescribing provider, is excluded, debarred, suspended or otherwise ineligible to participate in federal health care programs or in federal procurement or nonprocurement programs; OR
- Has been convicted of a criminal offense that falls within the ambit of 42 U.S.C. § 1320(a)-7(a) but has not yet been excluded, debarred, suspended or otherwise declared ineligible

Pharmacies have a continuing obligation to verify the identities and credentials of pharmacists and other providers. This includes checking or providing Prime with sufficient information to check the Social Security Administration Death Master File and verify provider identities.

Pharmacy's affiliation with the PSAO

For a copy of Prime's Pharmacy Participation Agreement, a Pharmacy should contact their PSAO unless applicable law indicates otherwise. Failure to obtain a copy of the Pharmacy Participation Agreement does not absolve a Pharmacy from complying with the standards, requirements and obligations set forth therein.

Pharmacies must notify NCPDP immediately upon change of affiliations with a PSAO. Prime is not liable under any circumstances for any losses suffered by a Pharmacy as a result of inaccurate, incomplete or other misinformation conveyed to Prime via the regularly received NCPDP interfaces. Prime reserves the right to request credentialing documentation from a PSAO, when applicable.

On a weekly basis, the PSAO is required to provide Prime a list of Pharmacies it intends to add to its organization. This information must be provided to Prime at least one week before the effective date of the Pharmacy's affiliation with the PSAO. Prime reserves the right to request additional documentation from the PSAO or Pharmacy prior to adding the Pharmacy to any network. The following information is required:

- PSAO affiliation code
- Pharmacy NCPDP, name, address and fax number
- Pharmacy ownership information (including name of registered owner or owner group and ownership interest)
- Name of Pharmacist in Charge (PIC)
- Name of any other staff pharmacists employed by the Pharmacy
- Pharmacy type (e.g., retail, compounding)
- The effective date of the PSAO and pharmacy affiliation
- Confirmation that the PSAO has verified the following:
  - Pharmacy is licensed in all applicable states in which it provides prescription drug services.
- Pharmacy has a full schedule Drug Enforcement Administration (DEA) certificate that is active and in good standing
  - Pharmacy has a physical location with a sufficient inventory that correlates to dispensing practices.
  - Each pharmacy owner, pharmacist and pharmacy technician has a current license and is not debarred from participating in any government health care programs.
  - Each Pharmacy has requisite insurance policies as outlined in the Pharmacy Liability Insurance section of the Agreement.
  - Each Pharmacy has processes and practices that are consistent with the Agreement.

Prime may decline or suppress new pharmacy affiliations or enrollments at Prime's discretion.

PSAOs must routinely monitor and conduct oversight of Participating Pharmacies. If a Pharmacy no longer meets Prime's credentialing requirements, the PSAO must notify Prime within two business days and promptly remove the Pharmacy from the affiliation. PSAOs must recredential Pharmacies at least every three years.

Failure by the PSAO to promptly remove a Pharmacy from affiliation or failure to recredential a Pharmacy in accordance with this Manual may result in the PSAO being held liable for any claims submitted by the Pharmacy that are noncompliant or suspected of fraud, waste or abuse (FWA).

Prime may request credentialing and recredentialing for any affiliated Pharmacy at any time.

Third-party payment reconciliation company

Pharmacies must update the 835 Health Care Electronic Remittance Advice (ERA) forms upon using a reconciliation company for the first time or upon changing the reconciliation company. Contact provider relations at **ProviderRelations@PrimeTherapeutics.com** to request the required ERA forms.

Pharmacy vendor relationships

All arrangements with switching and software vendors should be managed by Participating Pharmacies with their preferred vendor. This includes obtaining and maintaining compliance with applicable law for its own equipment, software and services necessary for claims and information transmittal, inclusive of any ongoing fees. This would include ensuring access to applicable claims processing systems in the same claims data format required under the Pharmacy's agreement and this Manual.

Re-creation fee

In the event the Pharmacy, or a reconciliation company, requests that Prime resubmit properly submitted remittance advice, Prime may charge the Pharmacy a $50 re-creation and resubmission fee ("re-creation fee"). Prime will separately invoice the Pharmacy for all applicable re-creation fees, which are due 30 days from the date of invoice.

Responsibilities of the Pharmacy for Medicare programs

Pharmacies in Prime's Medicare Network(s) must adhere to the guidelines outlined in the applicable Medicare services contract exhibits, which are part of Prime's Pharmacy Participation Agreement. A copy of Minimum Performance and Service Criteria for Prime's Medicare networks is available on **Prime's website**.

Pursuant to CMS regulations, a Pharmacy may offer a voluntary auto-ship program to Medicare beneficiaries if accompanied by the following protections and operational procedures:

- The Pharmacy must require that a covered person enrolls or opts in to an auto-ship program on a drug-by-drug basis only (each covered prescription) after the initial fill.
- The Pharmacy must obtain the covered person's consent to opt in to the auto-ship program after the initial fill. The Pharmacy may not assume or activate a covered person's opt-in at the same time as the initial fill for the prescription drug service.
- The Pharmacy must allow the covered person or their designee to opt out of the auto-ship program at any time.
- The Pharmacy must provide two separate successful and complete shipping reminders prior to auto-shipping the prescription drug service.
- The Pharmacy must cease auto-shipments upon becoming aware that the covered person has entered a skilled nursing facility, has elected hospice service, has died or the prescription drug service is now covered under Medicare Part A or B.

- The Pharmacy must provide a full refund for any prescription drug service dispensed under their auto-ship program that is not wanted by the covered person for any reason. The full refund must be applied for both new prescription drug services ordered by the prescribing provider and auto-shipped refills.
- The Pharmacy cannot require as a condition for a refund for a prescription drug service that the covered person must return unwanted medications.

These protections and procedures for CMS-authorized auto-ship programs help control FWA as required by 42 CFR § 423.504 and ensure that Medicare covered persons only receive new prescriptions and refills as requested.

Auto-ship procedures do not apply to retail or long-term care (LTC) Pharmacies that have refill reminder programs that require the covered person to pick up the prescription.

Pharmacies must (when instructed through POS messaging) include a copy of the Medicare Prescription Drug Coverage and Your Rights document with the covered person's prescription order. To find and print a copy of this CMS-required document (in **English** or **Spanish**), please visit **Prime's website**.

Pharmacies must comply with **CMS Medicare Marketing Guidelines**, when applicable. If Prime or a benefit sponsor identifies a communication that does not comply, Pharmacies must remove or revise the communication as requested by Prime or a benefit sponsor.

Pharmacy credentialing

Prime credentials Pharmacies for participation in networks administered by Prime. A new Pharmacy must complete a credentialing exhibit indicating that it has a business practice and processes which meet the terms and conditions of the Pharmacy Agreement and supply all supporting documentation requested during credentialing, including, but not limited to, standard operating procedures, copies of licenses and certificates, and pharmacy statements. Prime recredentials all Pharmacies at least once every three years. Prime follows nondiscriminatory practices in the credentialing process. Participation in Prime's Pharmacy Network(s) is not based on factors like race, religion, gender/gender identity, color, national origin, age or sexual orientation.

Recredentialing is a requirement for continued participation and occurs at least once every three years. Failure to complete the recredentialing application or supply all documentation Prime requests during the recredentialing may result in termination from participation in any or all networks administered by Prime or the Pharmacy Participation Agreement.

All Pharmacies must provide Prime with updated copies of the following documents upon expiration:

- Unrestricted Pharmacy License in all states in which the Pharmacy provides prescription drug services
- PIC license
- Full schedule DEA certificate that is active and in good standing
- Certificate of insurance with proof of general and professional liability insurance

Pharmacies must provide accurate information on their credentialing application and notify Prime, in writing, of any change to information submitted for credentialing or recredentialing within seven business days.

Pharmacies must meet credentialing criteria. Credentialing criteria are determined by Prime and benefit sponsors and are consistent with applicable law. These criteria include, but are not limited to, dispensing criteria, billing thresholds for mail order, compound prescription drugs, drugs not approved by the Food and Drug Administration (FDA), single-ingredient drugs, specialty drugs and products, and applicable clinical programming and reporting.

Credentialing criteria may be amended at any time. Pharmacies must continue to meet credentialing criteria to remain in network. To view pharmacy credentialing criteria, please visit **Prime's website**.

During credentialing, Prime reviews a Pharmacy's location to determine if it is located in either a federally defined or Prime-defined "heat zone." Heat zones are designated by CMS or Prime as areas that have potential for high rates of FWA. Additional documentation may be requested for review during credentialing to include, but not be limited to, dispensing records and wholesaler reports. The Pharmacy's location may impact the Pharmacy's eligibility for network participation.

- Pharmacies must maintain a full schedule DEA certificate that is active and in good standing at all times during participation.
- In the event a Pharmacy does not have a current full schedule DEA certificate that is active and in good standing at any time, including during times when such DEA certificate has been suspended or otherwise encumbered, Prime may terminate the Pharmacy's participation at Prime's sole discretion.

Prime reserves the right to request credentialing and recredentialing information from any Pharmacy at any time.

Prime reserves the right to decline or terminate all Pharmacies under the same ownership or control when the Pharmacy is determined to be in violation of the Agreement, this Manual or applicable law.

Chain and PSAO credentialing

Prime credentials chains and PSAOs for participation in networks administered by Prime. A new chain or PSAO must complete a credentialing exhibit and supply all supporting documentation requested during credentialing, including, but not limited to, standard operating procedures, copies of licenses, quality assurance program policies and pharmacy statements. Prime recredentials all chains and PSAOs at least once every three years. Failure to complete recredentialing may result in termination or participation in or more networks or termination of the agreement. As part of credentialing and recredentialing, a chain or PSAO must credential each Participating Pharmacy by verifying at least the following:

- Pharmacy has an unrestricted license in all applicable states within which it provides prescription drug services
- Pharmacy has a current, full and unrestricted DEA certificate for all scheduled controlled substances
- If a pharmacy is a retail Pharmacy, Pharmacy has a physical location with sufficient levels of inventory that correlate to dispensing practices; central fill pharmacies must maintain sufficient inventories and capabilities to meet the standard of practice applicable to the Pharmacy's dispensing
- Each Pharmacy owner, pharmacist and pharmacy technician(s) has a current license and is not debarred from participating in any government health care program
- Each Pharmacy has requisite insurance policies as outlined in the Pharmacy Liability Insurance section of the Agreement
- Each Participating Pharmacy has processes and practices that are consistent with the Agreement
- Whether Participating Pharmacy has any outstanding amounts owed to Prime

Annually, chains and PSAOs must complete a credentialing attestation of the following:

- Routinely monitors and conducts oversight of its Pharmacies. If a Participating Pharmacy no longer meets the requirements outlined above and within the Agreement, the Pharmacy has the responsibility to notify Prime within two business days and promptly remove the Participating Pharmacy from the Pharmacy Network(s).
- Prime shall recredential Participating Pharmacies at least every three years.
- Pharmacy must complete the Pharmacy Disclosure statement, when applicable.
- Pharmacy must update the Pharmacy Disclosure Statement promptly upon any change in the information contained therein and otherwise upon request from Prime.

Section 5: Responsibility of Pharmacy (continued)

- Pharmacy and any Pharmacy Professional shall maintain any license required by applicable state and/or federal law for its continued operation and performance under the Agreement. All licenses and/or certifications must be in good standing at all times during the term of the Agreement. Pharmacy represents and warrants that it and its Pharmacy Professionals are duly licensed in the jurisdictions in which it is located and in all locations in which it provides prescription drug services, as required by law.
- Pharmacy represents and warrants that it is not excluded from participation in any federal or state health care program under 42 U.S.C. section 1320a-7, as may be amended from time to time. Pharmacy further represents and warrants that none of its Pharmacy Professionals are excluded from participation in any federal or state health care program and that all Pharmacy Professionals are verified to ensure compliance with 42 U.S.C. section 1320a-7 prior to contracting or hiring and at least monthly thereafter to ensure that they have not been so excluded.
- **Reporting of disciplinary action, findings or indictments**. Pharmacy shall notify Prime immediately in writing if Pharmacy, Pharmacy owner(s), or Pharmacy staff receive any notices of adverse actions, including but not limited to, disciplinary actions, sanctions, citations, deficiency notices, orders, findings or indictments by state or federal governmental agencies. Upon request, Pharmacy agrees to provide Prime a written summary of the disciplinary action or indictment and actions taken in response, or as otherwise agreed to between Pharmacy and Prime in writing.
- **Required notification**. Pharmacy shall notify Prime immediately in writing if license(s) and/or permit(s) of Pharmacy, any Pharmacy Professional or any of its agents are suspended or revoked; are sanctioned by a federal or state, OIG or any other state agency or program (e.g. OIG, Board of Pharmacy); are excluded from participation in any federal or state health care program; or are placed on a Preclusion List, or as otherwise agreed to between Pharmacy and Prime in writing.
- **Pharmacy Liability Insurance**. Pharmacy, unless otherwise agreed to with Prime in writing, at its own expense shall hold and continuously maintain the following required insurance policies to provide coverage for the term of this Agreement with the following minimum limits of liability. The general liability policy must be primary and noncontributory, must name Prime Therapeutics LLC as an additional insured, and must contain a severability of interests or cross-liability clause. All required insurance policies shall provide waivers of subrogation in favor of, and shall hold harmless, Prime, its affiliates, subsidiaries, successors, members, partners, and their respective directors, shareholders, officers, agents and employees.

  Pharmacy shall furnish copies of said policies to Prime upon request, including, but not limited to, at the time of recredentialing, an audit or investigation by Prime, and Pharmacy's renewal of its policies. Pharmacy shall notify Prime in writing, in accordance with the notice procedures set forth herein, immediately upon receiving notice of any denial of, restriction on, reduction of, or cancellation, rescission, or termination of Pharmacy's Liability Insurance, except where such insurance is immediately replaced by equivalent insurance not subject to such denial, restriction, or cancellation, rescission, or termination.
- **Commercial General Liability**: Commercial General Liability insurance (including products liability, completed operations, contractual liability, broad form property damage and bodily and personal injuries, including death resulting therefrom) and with at least the following minimum required limits of liability:
  - Each occurrence $1 million
  - General aggregate $3 million

- **Professional Liability/Errors & Omissions/Malpractice**: Professional Liability/Errors & Omissions/Malpractice Liability Insurance, which shall include coverage for errors, omissions, misstatements and misrepresentations in connection with the preparation and submission of claims to Prime, with at least the following minimum required limits of liability:
  - Each claim $1 million
  - Aggregate $3 million
- Pharmacy shall also ensure that all pharmacists and other health care professionals employed or under contract with the Pharmacy to render prescription drug services to covered persons procure and continuously maintain such insurance, unless they are covered under the Pharmacy's insurance policy.
- Pharmacy participating in Prime Pharmacy Network(s) must complete and attest to FWA training and any other additional training as required by state and federal health care agencies or as requested by Prime on an annual basis. Failure to complete the annual credentialing attestation may result in termination of participation of PSAO-affiliated pharmacies in one or more networks or termination of the Agreement.

Ownership or control changes

Pharmacies and PSAOs must immediately notify Prime and/or PSAO, if applicable, in the event of a change of ownership and/or control. Any successor owner and/or operator must be credentialed by Prime and, if applicable, execute appropriate agreements with Prime for participation. Prime is not bound to any of its obligations under an agreement where the Pharmacy has assigned or subcontracted the Agreement or where ownership or control of the Pharmacy or any of its locations has changed. In such event, Prime has the right to immediately terminate the Provider Agreement.

Specialty pharmacy credentialing

Prime credentials specialty Pharmacies pursuant to specialty terms and conditions in addition to nonspecialty pharmacy credentialing criteria. Specialty terms and conditions include, but are not limited to, criteria related to clinical interventions and programming, care coordination, specialty pharmacy accreditation, specialty providers, clinical reporting and member experience reporting, in addition to other criteria to the extent consistent with applicable law. Pharmacies must maintain compliance with credentialing criteria for continued participation, including through recredentialing. Specialty terms and conditions are available to specialty Pharmacies by contacting Prime at **SpecialtyCredentialing@PrimeTherapeutics.com**.

Appropriate dispensing practices

Pharmacies must provide prescription drug services in a manner that complies with the terms of the Agreement, this Manual and all applicable laws and regulations, including, but not limited to, the following:

- Under the supervision of an appropriately licensed pharmacist
- Consistent with the covered person's benefit plan and the applicable drug formulary
- Consistent with POS messaging
- Safely, without engaging in conduct that would jeopardize the health, safety or welfare of a covered person
- According to the professional standards prevailing in the community at the time services are rendered

When dispensing medications, Pharmacies must be diligent in determining that claims are submitted for a valid use of a medication. Pharmacies must be aware of prescription orders that are prescribed and dispensed for dosage strengths and routes of administration that are not consistent with manufacturer prescribing information. When reviewing claims, auditors may request documentation to support appropriate medication dispensation based on standard industry practice.

Documentation of scientific evidence that meets expectations will demonstrate efficacy and safety for the requested use. The documented evidence must show:

- Consistent and adequate number of well-designed studies with a sufficient quantity of patients in relation to the incidence of the disease
- Publication in major peer-reviewed journals that only publish original manuscripts after the manuscripts have been critically reviewed by unbiased independent experts for scientific accuracy, validity and reliability
- Consistent results across all studies for specific diseases and treatments
- Positive health outcomes, including demonstration that the drug is as effective as or more effective than FDA-approved alternatives

Unacceptable dispensing practices

The following types of documentation do not meet standard industry practice:

- Clinical studies administered without direct correlation to intended use, strength, dosage form or route of administration
- Manufacturer-sponsored studies with results that have not been approved by the FDA
- Off-label use that does not have a level of evidence for the indication that is Micromedex DrugDex Class I or Class IIa level of evidence or a National Comprehensive Cancer Network category of evidence Class I or Class IIa
- Patient case reports
- Provider may not process automatic refills without verifying the covered person's days' of supply and supply on hand prior to dispensing, except when authorized under applicable law

Patient-prescribing provider relationship

Before dispensing a prescription, a Pharmacy must verify that there is a valid patient-prescribing provider relationship under applicable state or federal law and must confirm that the covered person knows about and has requested the medication.

Relationship between Pharmacy and covered person

The relationship between the Pharmacy and covered person is that of pharmaceutical provider and patient. The Pharmacy will perform all professional clinical pharmacy services and other services required to be provided under the Agreement, this Manual and all applicable laws, and it will be free to exercise its own judgment on all questions of professional Pharmacy practice. No provision of the Agreement, this Manual or any part of any benefit sponsor's benefit plan will be construed to require any pharmacist to dispense any medication or specific type of medication to any covered person if, in the pharmacist's reasonable professional judgment, such medication should not be dispensed to such person.

In addition, nothing in the Agreement or this Manual shall be construed to prohibit the Pharmacy from providing a covered person any information related to the covered person's prescription drug costs or benefit information as communicated to the Pharmacy through POS messaging.

Marketing and communications practices

Fraudulent, abusive or deceptive marketing tactics to obtain patients or prescriptions for patients, whether by the Pharmacy or a third party, are prohibited. The use of fraudulent, abusive or deceptive communication is also prohibited.

All marketing practices should be carried out according to federal, state and local laws, rules and regulations. It is the Pharmacy's responsibility to ensure claims for reimbursement are not being submitted in violation of this section and that all patient communications are in compliance with these requirements.

Pharmacies shall not engage in deceptive marketing practices, such as cold call telemarketing, online or in-person soliciting or recruitment practices, to obtain member information for the purposes of billing claims without the member's explicit knowledge of each individual claim submitted.

Pharmacy nondiscrimination

The Pharmacy must provide prescription drug services in a culturally competent manner. The Pharmacy must provide prescription drug services to all covered persons, including without unlawful regard to race, religion, gender or gender identity, color, national origin, age, sexual preference, disability, pregnancy, source of payment, physical or mental health status, socioeconomic status or participation in any preferred or nonpreferred provider network status.

More affordable drugs

Prime follows the requirements of 42 U.S.C.A. § 300gg-19b (2) (Patient Right to Know Drug Prices Act), 42 U.S.C.A. § 1395w-104 (Medicare Part D provisions), and state laws as applicable. Nothing in this Manual restricts a Pharmacy from informing a covered person and/or covered person's designee about their cost share for a drug, the difference between the covered person's out-of-pocket costs under their benefit plan and the cash price, or alternative drugs within the covered person's benefit plan that are more affordable. The Pharmacy shall not refuse to provide prescription drug services to any covered person on the basis of reimbursement, unless otherwise provided by applicable law.

Signature or delivery logs

The Pharmacy must maintain a paper or electronic signature log or delivery log whereby all covered persons (or their authorized agent) who receive a prescription drug service provide a signature, acknowledging receipt of the prescription drug service. Prescription numbers must be assigned in chronological order as prescriptions are received by the Pharmacy. At a minimum, signature logs must include the following:

- Covered person's name
- Prescription number
- Covered person's (or legal representative's) signature
- Date and time of sale
- Date and time of receipt by the covered person
- Covered person's cost-share receipt, evidencing the cost share was collected, when applicable
  - When cost share is not collected due to a copay assistance program, the Pharmacy must provide documentation supporting that the copay assistance program reimbursed the Pharmacy for the member cost share, upon request.

When off-site delivery is used to provide the prescription drug service, delivery carrier tracking numbers or confirmations must include the required signature log elements above. For covered persons residing in residential care facilities that administer medications to the covered person, medication administration records may be required to support delivery of the medication to the patient.

Prime may request documentation supporting prescription order receipt by covered persons, including, but not limited to, signature and/or delivery logs for prescription drug service(s) at any time.

LTC and home infusion annual validation process

Prime requires each Pharmacy that participates in LTC or home infusion (HI) Pharmacy Networks to annually validate that the Pharmacy complies with participation guidelines outlined in the applicable LTC and HI Pharmacy Networks.

Failure to validate may result in termination from LTC or HI Pharmacy Networks.

Termination appeals

Appeals must be submitted in writing and include the Pharmacy's name and an explanation of the appeal. Prime accepts appeals within the applicable appeal period:

- Appeals of 90-day terminations within 30 days from the date of notification of termination or an extended time as required by law to submit a termination appeal
- Appeals of 10-day breach terminations within the noticed 10-day appeal period
- Appeals of 30-day breach terminations within 14 days
- Appeals of five-day participation terminations or immediate terminations within the noticed five-day appeal period

Terminations will be deemed finalized if an appeal is not received from the Pharmacy within the applicable appeal period or an extended time frame as required by law. Pharmacy termination appeals must be submitted in writing to the Provider Relations department by fax at **877.823.6373** or by email to **Termination@PrimeTherapeutics.com**.

Prime reserves the right to terminate a Pharmacy from any agreement or Prime's Network(s) for up to five years.

Confidentiality and proprietary rights

Confidentiality

Confidential information means any nonpublic, confidential, proprietary or trade secret information disclosed or made available, either directly or indirectly, during an audit or the course of the Agreement. The pricing terms of the Agreement, including all exhibits to the Agreement, are proprietary and confidential.

- The Pharmacy must not sell, assign, transfer, disclose or give confidential information to any third party without Prime's prior written consent.
- No confidential information may be quoted or attributed to the Pharmacy or Prime without Prime's prior written consent.
- The Pharmacy must use all necessary security procedures to protect confidential information from improper access or disclosure.
- The Pharmacy must maintain the confidentiality of a covered person's personal profile, records and protected health information as required by applicable law, state privacy laws and the Health Insurance Portability and Accountability Act of 1996, as amended. The Pharmacy may not use the information provided by covered persons or any information obtained through performance of the Agreement for any purpose not related to the Agreement, except to the extent such use is required by applicable law. The Pharmacy must establish privacy and security safeguards in accordance with applicable law and as appropriate and necessary.
- The Pharmacy must promptly notify Prime if it becomes aware of any unauthorized access, use or disclosure of confidential information.
- Nothing in this Manual restricts the Pharmacy from informing a covered person and/or covered person's designee about the cost share for a drug, alternative drugs within the covered person's benefit plan or prior authorization requirements for a prescribed drug. This Manual does not restrict the Pharmacy from providing information to state and federal pharmacy benefit management regulators.

Proprietary rights

Except as required to fulfill the Pharmacy's obligations under the Agreement, the Pharmacy has no right to use, reproduce or adapt any information, data, work, compilation, computer programs, Manual process or invention obtained from, provided by or owned by Prime or any benefit sponsor (including, but not limited to, products, programs, services, business practices and procedures) without Prime's prior written consent.

Prime has the right to disclose, use, reproduce and/or adapt any information or data obtained from the Pharmacy in any manner deemed appropriate, even if such use is outside the scope of the Pharmacy Participation Agreement, provided such use is in accordance with applicable law.

Recall notices and expired medication

The Pharmacy must monitor and respond to all recall notices and remove any impacted drugs from the Pharmacy's inventory immediately or as otherwise indicated in the recall notice. The Pharmacy must notify any covered persons who received recalled drugs and work with the prescribing provider and covered person to provide an alternative medication, as applicable, and document all actions taken. Additionally, the Pharmacy must maintain and document a process to ensure all expired drug products are removed from the Pharmacy's stock.

Manufacturer assistance reporting

Some benefit plans limit or exclude direct manufacturer assistance amounts from a covered person's annual limitation on cost sharing. To comply with these benefit plans, the Pharmacy must provide Prime with information on direct manufacturer assistance, including, but not limited to, coupons, such as those through RelayHealth or other switch operators and manufacturer-sponsored copay assistance programs. To view the specific manufacturer assistance reporting requirements, please visit **Prime's website**.

Section 6: Pharmacy oversight

Pharmacy oversight

Pharmacy oversight is a critical component of responsible pharmacy benefit management. Prime operates a pharmacy oversight program to detect inaccurate payments, drug waste, fraudulent claims or other benefit coverage abuses. As part of Prime's fraud, waste and abuse (FWA) program, Prime regularly samples and reviews claims submitted by Pharmacies.

Prime conducts daily claim reviews, desk audits, on-site audits and investigations ("oversight activities") to monitor compliance with state and federal regulations, Prime's Pharmacy Participation Agreement ("Agreement") and this Manual. These activities verify the integrity of claims submitted to Prime and payments made to Pharmacies. Through these oversight activities, Prime reviews the accuracy of the claim information submitted to Prime to identify potential FWA or otherwise improper prescription drug services or claims activity.

Findings related to Prime's oversight activities may result in payment suspension, Pharmacy Payment Recoupment, claim adjustment, remediation, termination from one or more networks and termination of the Agreement. For purposes of this Pharmacy Oversight section, please see the specific criteria found in the guidelines located on **Prime's website**.

Education

Prime provides information to Pharmacies through the Prime Perspective newsletter, direct correspondence, updates to this Manual, as revised, and resources provided on **Prime's website**. These documents provide information and tools to Pharmacies to strengthen documentation and billing practices, prepare for Prime audits, respond to Prime investigations and reduce common billing errors.

Access to pharmacy records

Pharmacies must allow Prime adequate access to records related to prescription drug services provided under the Agreement, consistent with applicable law. This includes, but is not limited to:

Wholesaler invoices and pedigrees (pricing may be redacted if appropriate)

- Prescription orders
- Signature log/delivery log
- Licensing
- Proof of insurance
- Dispensing history
- Proof of copay collection
- Business agreements or contracts with prescribing providers
- Bill of sale documentation regarding Pharmacy purchase, when applicable
- Past and current employee lists
- Standard operating procedures

Prime reviews these records to compare the submitted claim information to the original source documentation, such as the prescription order and other relevant documentation, to confirm the accuracy and legitimacy of the claim submitted to Prime.

Pharmacies must not photograph or record (either audio or video) interactions with Prime personnel, including telephone discussions, on-site audits, security camera footage or other interactions without Prime's prior written consent. Such activity may result in termination of the Agreement.

Expenses

Pharmacies may not charge Prime for personnel time involved in responding to Prime's oversight activities. Each Pharmacy is responsible for its own expenses, including production of any records it provides to Prime.

Prescription requirements

Prescription hard copies are written prescriptions, refill authorizations, institutional orders, verbal or telephoned orders, facsimile (fax) orders, prescription transfers and electronic prescriptions that the Pharmacy relies on at the time of dispensing. To qualify as an electronic prescription, the electronic prescription must be noted prior to dispensing and must clearly record, in a manner that cannot be altered, the system-assigned user, date and time stamp to take the place of hard-copy documentation.

The Pharmacy must retain all documentation related to a prescription claim in accordance with the Agreement and applicable state and federal laws.

A prescription is considered valid when the original prescription order contains the following information at the time of dispensation:

- Full name, address and date of birth of the covered person
- Date of issuance
- Full name, National Provider Identifier (NPI) and telephone number of the prescribing provider and, if the prescription is for a controlled substance, the prescribing provider's Drug Enforcement Administration (DEA) number. If the prescribing provider did not include their NPI/DEA number(s) on the prescription hard copy, then the Pharmacy is responsible for acquiring the prescribing provider identification (ID) and/or the prescribing provider's DEA number either from the Pharmacy's claims system or by contacting the prescribing provider.
- The Pharmacy must document the correct prescribing provider ID on the prescription hard copy or on a prescription label affixed to the back of the prescription hard copy.
- Name of medication and strength prescribed
- Quantity authorized by the prescribing provider
- **Specific dosage change** — The medication dispensed to the covered person must be labeled with the prescribing provider's direction for use. The Pharmacy must obtain specific directions for use to accurately dispense the prescription. Directions must be more specific than "use as directed." The direction "as directed" is not permitted. Directions may be obtained through direct communication with the prescribing provider and must be documented on the prescription hard copy. The medication dispensed to the covered person must be labeled with the specific directions for use obtained from the prescribing provider. For drugs that are administered on a sliding scale, such as insulin, the Pharmacy must obtain and document the dosage range or maximum per day prior to dispensing.
- **Substitution instructions with appropriate documentation** — When medically necessary, the prescribing provider may write "dispense as written" on the prescription or, in the case of a telephoned prescription order, the pharmacist must write "dispense as written" on the telephoned prescription order. If a covered person requests a brand-name drug, the Pharmacy must document the request on the prescription order.
- **Refill** — If the prescribing provider does not indicate refills, the Pharmacy should presume that no refills are authorized. If refills are added to a prescription, the Pharmacy must retain written documentation of the authorization and assign a new prescription number.

- **Prescription number** — The prescription hard copy must be labeled with the corresponding prescription number. If the prescription is for a drug under a federally regulated program, including, but not limited to, iPLEDGE or S.T.E.P.S. Data 2000, the Pharmacy must document the authorization number obtained from the program on the prescription hard copy before dispensing.
- Documentation of the date the prescription was received and the name of the caller for verbal or telephoned prescription orders, changes to prescription order or clarification to any order.
- Prescription hard copies missing one or more of the required elements may be considered invalid.

Prescription label requirements

The prescription label must contain the following elements, in addition to other elements required by state and federal guidelines:

- Full name of covered person
- Full name of prescribing provider
- Full name and strength of medication dispensed
- Quantity of medication dispensed
- Specific directions for use
- Prescription number
- Number of refills authorized
- Date medication was dispensed

Product purchase requirements

Pharmacies must purchase all products and supplies dispensed to covered persons from authorized traders, in compliance with federal law. Product and supply orders must be tracked using verifiable invoices and pedigree invoices when required by applicable law. Prime reserves the right to reject documentation from any authorized trader at any time when the invoice documentation cannot be verified or does not comply with applicable law.

Purchase invoices and pedigrees

Prime may request that the Pharmacy authorize their wholesaler(s) or manufacturer(s) to submit invoices and pedigrees to Prime to verify purchase and demonstrate that the products billed to Prime were purchased from an acceptable source. The Pharmacy must promptly comply with such request. Wholesaler invoices received must be verifiable. Pharmacies are responsible for validating that each wholesaler can produce valid pedigree documentation.

Review of claim submission

Prime will, at a minimum, verify the following claim elements when evaluating a prescription:

- **Covered person** — The prescription must contain the full name of the covered person and the correct covered person ID card number.
- **Date of issuance** — The date of issuance must be on the prescription.
- **Drug name and strength** — The National Drug Code (NDC) on the claim must correspond with the specific drug and strength prescribed and dispensed. Reasonable efforts must be made to select the most cost- effective form of a prescribed drug or generic equivalent. The Pharmacy must submit the originally prescribed product to determine if the drug is covered by the covered person's benefit plan.

- **NDC** — The NDC on the claim must correspond to the NDC used to dispense the prescription.
- **Price** — The accuracy of the calculating and submitting price is based on the NDC and quantity used to dispense the product.
- **Product Selection Code (PSC)** — PSC submissions will be verified. When the covered person requests the brand-name drug, the Pharmacy must document the covered person's request on the original hard copy and submit the claim with a DAW-2. If the generic is not available to the market, the Pharmacy must document on the original hard copy and submit the claim with a DAW-8.
- **Quantity** — The Pharmacy must dispense the quantity as written and supported by the dosing directions unless the quantity written exceeds the covered person's benefit plan, the quantity written is for greater than the amount needed for the time frame needed based on use instructions (e.g., writing for 20 doses per month when directions are to infuse three times weekly) or the quantity written is intended to be dispensed only if certain situations occur (e.g., hemophilia bleed dose replacement upon submission of infusion records). The Pharmacy must comply with POS messaging, including, but not limited to, messaging regarding the covered person's benefit plan limit, and must document the reason for dispensing a lesser quantity on the original prescription. If the POS messaging on the claim requires a prior authorization (PA), the Pharmacy must follow POS messaging and must not reduce the quantity. To prompt accurate POS messaging, the Pharmacy must accurately represent the days' supply based on the quantity dispensed and directions for use on the prescription order.
- **Days' supply** — The Pharmacy must submit the correct days' supply, based on directions for use. The Pharmacy must submit the number of consecutive days the prescription drug will last. Overstating the days' supply may impact future refills, whereas understating the days' supply may exceed the covered person's benefit plan. The most common days' supply errors occur when dispensing inhalers, insulin and medications with intermittent dosing. The Pharmacy must submit the correct days' supply based on the quantity dispensed and the directions for use on the prescription order. For examples of common billing errors, visit Prime's website.
- **Refill instructions** — Refill history must be reviewed to confirm that the prescription was not refilled in excess of the prescription order. If additional refills are authorized, the Pharmacy must obtain the appropriate prescription order based on the drug class.
- **Auto-ship refills** — Pharmacies must obtain patient consent prior to enrolling a prescription in an auto-ship refill program.
- **Claim edits** — If the Pharmacy receives specific messaging when a claim is submitted, the Pharmacy must ensure that documentation is maintained to support the use of dynamic PA, drug utilization review (DUR) overrides and Submission Clarification Codes.
- **Prescribing provider ID number** — The Pharmacy must enter the correct and valid prescribing provider's ID number on the claim submission.
- **Overpayment** — Any overpayments made by Prime to Pharmacy for any reason are to be refunded by Pharmacy to Prime within 14 days of the date Prime discovered that they had made an overpayment or of the date of receipt of Pharmacy's request for refund, whichever date is earlier. Examples of overpayments include, but are not limited to, payment for a noncovered person, duplicate payment, payment for services not rendered or payment processing error. If Pharmacy fails to refund the overpayment, Prime may withhold from any amounts due Pharmacy an amount equal to the overpayment.

Prime relies on the original documentation provided in an audit or investigation. Documentation that conflicts with or is inconsistent with the documentation provided in response to an audit or investigation will not be accepted during the appeal process.

Common billing errors

- **Quantity dispensed** — Overstating the days' supply may impact future refills, whereas understating the days' supply may exceed the covered person's benefit plan, all while assessing less copay than is applicable. The Pharmacy must submit the correct days' supply, based on directions for use and benefit limitations (e.g., incorrectly calculating the days' supply for eye drops. Please note that most eye drops are based on an average of 15 drops/mL for solution and 12 drops/mL for suspension unless manufacturer-supplied data suggests otherwise).
- **Reversal of claims** — All prescriptions not received by the covered person within 14 days of claim submission must be reversed through the electronic claims system.
- **Use as directed** — The Pharmacy must determine the specific dosing directions to accurately calculate the days' supply and correctly submit the claim to Prime. The Pharmacy must contact the prescribing provider to clarify any ambiguous directions (such as "use as directed," no directions documented, or "as needed") and document the prescribing provider's instructions on the prescription hard copy. If the prescribing provider is unavailable, communication with the covered person is acceptable and must be documented.
- **One prescription for the entire family** — Prescriptions written for an entire family on one prescription form must be processed as separate claim(s) for each covered person.
- **Early fill due to max benefit supply** — Prescriptions dispensed with altered days' supply due to a maximum days' supply benefit must be filled in alignment with directions for use.

For examples of commonly misbilled medications, visit **Prime's website**.

Unacceptable billing practices

The following are examples of unacceptable and, in some cases, fraudulent practices, that include, but are not limited to:

- Billing for a legend or over-the-counter drug without a prescription or benefit-sponsored voucher except where required by law
- Submitting incorrect information on claims that may lead to inappropriate bypass of benefit exclusions, DUR messages or other benefit plan edits
- Billing for a quantity of a legend drug that is different than the quantity dispensed
- Billing for a quantity of a legend drug that exceeds the total prescribed quantity
- Billing for a higher-priced drug when a lower-priced drug was prescribed or dispensed
- Billing multiple loading doses instead of the appropriate subsequent maintenance doses
- Billing a maintenance dose concomitantly with a start kit or loading dose
- Dispensing a generic drug but billing for the brand-name drug
- Submitting claims with an NDC other than the NDC from the package from which the product was dispensed
- For general long-term care (LTC) dispensing, billing more than once per month for federal legend drugs for covered persons in an LTC facility where short-cycle dispensing is not allowed
- Dispensing drugs that are solid oral dose brand-name drugs in greater than 14-day increments for short-cycle dispensing
- Overriding DUR rejects without properly resolving and documenting the resolution
- Failing to provide documentation to support the need for refilling a prescription prior to when the benefit limit has been met

- Incorrectly billing Medicare Part A– or Part B–eligible drugs to Medicare Part D
- Billing compound products in a manner inconsistent with Prime's credentialing criteria or the compound billing requirements described in the Compound Drugs Billing Guidelines of this Manual
- Applying an expiration date on the prescription order that is earlier than the date the product expires according to the manufacturer
- Misrepresenting or failing to report an accurate usual & customary
- Billing the covered person for any associated audit and/or investigation recovery
- Misrepresenting or failing to report an accurate origin code
- Billing for drugs that the Pharmacy never purchased
- Billing for drugs associated with wholesaler invoices that the respective wholesaler denies providing to the Pharmacy because the drugs were not purchased from the wholesaler
- Billing for drugs from a wholesaler that cannot provide drug ancestry or pedigree documentation to support the legitimate purchase record of the drug
- Submitting a claim for a drug not approved by the Food and Drug Administration (such as compound kits and patches)
- Billing for a greater vial size than what is necessary to supply the ordered dose
- Billing for drugs that are cyclic as continuous days' supply (e.g., 28-day cycle billed as 21 days)
- Billing for weight-based drugs without weight dosing calculations
- Failing to implement documentation or process changes communicated in a previous audit
- Billing high-cost products when lower-cost equivalent products are available
- Billing the same drug in two different dosage forms concomitantly without documentation of medical necessity
- Billing for drugs that the covered person did not authorize or receive
- Billing for a medication when Pharmacy is aware member has large remaining quantity
- Billing for drugs that the prescribing provider did not order
- Billing for Pharmacy preselected services and/or products
- Billing for services and/or products that are not clinically appropriate
- Billing for drugs that are adulterated in the delivery process
- Billing for drugs utilizing another Pharmacy's credentials
- Submitting claims at multiple locations and/or under multiple networks in a manner to obtain favorable pricing without consulting the covered person
- Billing in a manner to bypass network contract status
- Billing for drugs when the covered person and the prescribing provider did not have a valid patient-prescribing provider relationship
- Billing for drugs when the Pharmacy does not have a valid prescription order
- Billing for a therapeutic interchangeable medication without contacting the prescribing provider before the claim is submitted to confirm the interchange
- Billing for prescriptions during posted business hours when the Pharmacy is not physically open
- Mail-order Pharmacies running overnight batch billing is not considered an immediately unacceptable billing practice, but may be reviewed for potential audit
- Billing for prescriptions to bypass POS edits or messaging

Recovery of Pharmacy Payments

Prime may suspend and collect improper payments paid to Pharmacies in a manner determined by Prime in its sole discretion, consistent with applicable law.

Pharmacies will be informed of payment offsets through remittance advice. Pharmacies will receive a report of claim adjustments performed directly by Prime.

In cases where a claim or claims have been previously paid by Prime, and the Pharmacy reverses the claim or claims, the Pharmacy is responsible for any outstanding balance for prior payment on claims later reversed.

Payments for paid claims will be paid first to any outstanding balance owed, consistent with applicable law.

Reasons for audits and oversight activities

Prime conducts audits to ensure the integrity of prescription drug services and compliance with applicable requirements. Audits may be initiated for any of the following nonexclusive reasons:

- Request or inquiry by a benefit sponsor, covered person or government agency
- Pharmacy billing history
- Pharmacy does not respond to Prime's requests for documentation
- Prime identifies billing issues through claim reviews
- Referral from Prime's fraud tip hotline or other sources that indicate potential FWA
- Routine audit of Pharmacies selected on a random basis

Audit and oversight activity time frames

Claims selected for review through the daily claims review process generally include prescriptions billed to Prime within the previous 14 days. Historical claim audits generally include prescriptions billed to Prime within the previous 12 months. Standard on-site audits generally include prescriptions billed to Prime within the previous 24 months, or other time periods provided for by applicable law. However, Prime has the right to audit or investigate claims for up to seven years from the date of the prescription drug service for commercial claims and up to 10 years from the date of prescription drug service for government program claims, or as otherwise permitted by law.

Types of audit and oversight activities

Daily claim reviews

Prime monitors claims data to identify potential billing and compliance errors on a prepayment basis (before the Pharmacy is reimbursed). When Prime identifies potential pharmacy errors, Prime may instruct the Pharmacy to correct the claim. If the Pharmacy does not respond to Prime's request to correct a claim, or otherwise fails to correct improperly billed claims, Prime may resubmit or reverse impacted claims in its sole discretion. Failure to participate may result in an audit, investigation or further remedial actions.

Desk audits

Prime also conducts pharmacy audits. If a claim is identified for audit review, Prime will contact the Pharmacy by telephone, email, fax or mail regarding the claim. Requested documentation may include, but is not limited to:

- Photocopies of the original prescription order, front and back
- Signature or delivery logs

- Receipts and other documentation showing the copay/cost share (if applicable) paid by the covered person or their representative
- Tracking number from delivery log, which must link to the prescription number, date of service and delivery date
- Computer records
- Wholesaler, manufacturer or return vendor invoices
- Pedigree invoices or documentation to confirm traceability of the medication from the manufacturer
- Compound information, including all ingredients with NDCs and quantities used to prepare the compound claim
- Dispensing logs
- Bleed and dispensing logs for hemophilia products
- Documentation to include patient's on-hand quantities of prescriptions for prophylactic and as-needed doses
- Weight-based dosing documentation
- Prescription label
- Pharmacy and Pharmacist-in-Charge (PIC) liability insurance
- Professional insurance information
- Proof of FWA training
- License information
- Bill of sale
- Documentation to support appropriate dispensing of medications based on standard industry practice
- Attestation of compliance with specific state and federal statutes, regulations and Centers for Medicare & Medicaid Services (CMS) guidance

If a Pharmacy processes LTC facility claims, the following additional information may also be requested:

- Demographic information of any LTC facility the Pharmacy services during the period under audit or investigation
- Medication administration records of the Pharmacy and the LTC facility
- LTC facility census information for the covered person during the audit or investigation that provides information on Medicare Part A stays

Prime will provide the Pharmacy with a due date for submitting audit/oversight review documentation. The Pharmacy may fax, mail or email requested documentation.

Prime communicates with Pharmacies throughout the claim audit/oversight review process and before claim adjustments are made. Pharmacy audit result letters will indicate finding code(s) respective to each audited claim. Please visit **Prime's website** for information on finding codes, including applicable description, pharmacy instruction and acceptable mitigating documentation that Prime may accept when a finding is contested. Any and all materials submitted to Prime will be reviewed before a final determination is made.

The additional information is reviewed through the claim audit/oversight review grievance process within 14 calendar days, or as otherwise provided by law. Pharmacies should provide any additional documentation to the auditor via fax or email.

Prime pharmacy claims audit fax:
877.825.7404
877.263.5543

Email: **PharmacyAudit@PrimeTherapeutics.com**

Corporate address:
Prime Therapeutics LLC
ATTN Pharmacy Audit 2900 Ames Crossing
Suite 200
Eagan, MN 55121-2498

A Prime auditor will review the requested claims to verify that the claims have been submitted in compliance with the Agreement and this Manual, as revised. Pharmacies will receive a claim adjustment report for any claims Prime adjusts directly.

On-site audits

Pharmacies selected for an on-site audit may receive advance written notice from Prime. Prime may conduct an on-site audit without advance notice as allowed by law. If the Pharmacy cannot accommodate an on-site audit on the scheduled date, the Pharmacy may request an alternative arrangement in advance of the on-site audit date. Prime will consider such requests on a case-by-case basis.

On-site audits are conducted during regular business hours. Prime makes reasonable efforts to minimize disruption to all areas of the Pharmacy. Pharmacies are expected to provide Prime access to the Pharmacy, and documentation supporting claims submitted during the audit period should be readily retrievable and accessible.

Pharmacies are also expected to be adequately staffed during the audit and to have a representative (either pharmacist or technician) available to respond to questions and retrieve specific prescription hard copies and supporting documentation that may be requested.

While on-site, the auditor will observe Pharmacy practices and review all related documentation. The auditor may ask to observe the Pharmacy's dispensing practices, including a review of prescriptions pending member pickup. An interview will be completed with Pharmacy personnel, preferably with the PIC.

Requested documentation may include, but is not limited to:

- Photocopies of the original prescription order, front and back
- Prescription label
- Signature or delivery logs
- Receipts and other documentation showing the copay (if applicable) paid by the covered person or their representative
- Tracking number from delivery log, which must link to the prescription number, date of service and delivery date
- Bleed and dispensing logs for hemophilia products
- Documentation to include patient's on-hand quantities of prescription for prophylactic and as-needed doses
- Weight-based dosing documentation
- Computer records

- Wholesaler, manufacturer and return vendor invoices
- Pedigree invoices or documentation to support wholesaler(s) purchases to confirm traceability of medication from the manufacturer
- Compound information, including all ingredients with NDCs and quantities used to prepare the compound claim
- Pharmacy and PIC liability insurance
- Professional insurance information
- License information
- Proof of annual FWA training
- Pharmacy bill of sale, if applicable
- Documentation to support appropriate dispensing based on standard industry practice
- Attestation of compliance with specific state and federal statutes, regulations and CMS guidance

If a Pharmacy processes LTC facility claims, the following additional information may also be requested:

- Demographic information of any LTC facilities serviced by the Pharmacy during the period under audit or investigation
- Medication administration records of the Pharmacy or the LTC facility
- LTC facility census information for the covered person during the audit or investigation that provides information on Medicare Part A stays

On-site audits will involve the disclosure of covered persons' protected health information for the purpose of disclosure of treatment, payment or health care operations. For Prime and the Pharmacy to remain Health Insurance Portability and Accountability Act (HIPAA) compliant, a Pharmacy staff person is required to retrieve documentation, and the auditor must be present to observe the documentation retrieval.

Pharmacies may not refuse to comply with an on-site audit on the grounds that it violates HIPAA or other relevant privacy laws.

A Prime auditor will review the claims for accuracy and compliance with the Agreement and this Manual, as revised.

Audit documentation, including prescriptions and supporting documentation, may be photographed, or copies will be requested by the auditor as necessary.

When the audit is complete, the auditor will provide general feedback and education verbally while on site at the Pharmacy.

On-site audits will be conducted in accordance with applicable law. Pharmacies must cooperate with an on-site audit or investigation.

Reporting on-site audit results

Following the on-site audit, Prime will provide the Pharmacy with a written preliminary audit report, which will include details of any discrepancies or relevant audit findings, as required by applicable law.

Results include the details of any issues of noncompliance with:

- Federal and state regulations
- The Pharmacy Participation Agreement
- Prime's Provider Manual
- Discrepancies between the original prescription order documentation available at the time of dispensing and the Pharmacy's claim submission

The Pharmacy will be provided a date by which additional documentation supporting the claims may be provided to Prime. Prime will review additional documentation received. A final audit report will be issued to the Pharmacy after review of the additional documentation received or after the due date to provide additional documentation has passed.

Audit appeal process

Pharmacies have 30 days from the date Prime issues the final audit report to submit an appeal or an extended time frame as required by law or regulation.

Appeals must be submitted in writing and include the Pharmacy's name, the claims/prescriptions appealed, any additional documentation not provided at the time of audit and an explanation of the appeal. Please see the Pharmacy Audit Guidelines for post-audit documentation accepted by Prime. Audit findings, including associated recoveries, will be deemed finalized if an appeal is not received from the Pharmacy within 30 days from the date of notification of the audit findings or an extended time frame as required by law or regulation.

Documentation provided by the Pharmacy as part of its audit appeal may result in additional findings. Appeal results are considered final. For a copy of Prime's Pharmacy Audit Guidelines and Appeal form, visit **Prime's website**.

- Documentation that conflicts with the initial documentation submitted will not be accepted during the appeal process.
- Prescribing provider or covered person attestations received to support the manner in which a claim is submitted must be received directly from the prescribing provider or member.
- Appeals received after the due date will not be considered.

If applicable state law allows, the Pharmacy has the right to request an independent third-party review of the final audit findings. The cost of the independent third-party review is dictated by the applicable state law. The Pharmacy can request an independent third-party review within 30 days after all internal appeal processes have been exhausted unless specified by state law. The request must be received in writing to **PharmacyAudit@PrimeTherapeutics.com**.

Corrective action plan

Pharmacies may be placed on a corrective action plan, as determined by Prime in its sole discretion. Pharmacies subject to a corrective action plan are monitored to determine whether the identified issues have been remediated. If issues are not resolved to Prime's satisfaction, Prime may take additional remedial action, as permitted by the Agreement. Failure to comply with the terms of the corrective action plan may result in termination of the Agreement.

Pharmacy investigations

Prime may conduct an investigation of any Pharmacy when Prime suspects or identifies potential FWA activity. During an investigation, Prime may request access to the Pharmacy's facilities, personnel and documentation to support claims submitted to Prime during the period under investigation.

Pharmacies may not receive notification in advance of an on-site investigation. Timing of communications and reports to the Pharmacy may vary. Prime may record (either audio or video) interviews in person or by telephone for fraud investigations, as permitted by law. Prime will issue applicable reporting to the Pharmacy throughout the investigative process. Prime reserves the right to terminate all Pharmacies under the same ownership or control based on the results of an investigation.

Pharmacies must comply with any investigation Prime conducts.

Remediation action

Pharmacy audits and investigations may identify a Pharmacy's failure to comply with Prime's terms and conditions. As noted in the introduction of this Manual, failure to comply with Prime's contractual terms and conditions, including, but not limited to, those described in this Manual, as revised, may result in placement on a corrective action plan, payment suspension, full or partial financial recoupment, termination from participation in any network, termination of the Agreement or other remediation actions, as determined by Prime. A Pharmacy may be immediately terminated from any network or the Agreement upon Prime's receipt of any evidence of a Pharmacy engaging in FWA.

Section 7: Medicaid requirements

Medicaid Pharmacy Program inquiries

For general pharmacy inquiries related to each state's Medicaid Program, please call:

- BCBSMN Blue Plus: **800.648.2778**
- BCBSIL Community Health Plans: **855.457.0173**
- BCBSNM Turquoise: **888.840.3044**
- BCBSTX Children's Health Insurance Program (CHIP): **855.457.0403**
- BCBSTX State of Texas Access Reform (STAR): **855.457.0405**
- BCBSTX STAR Kids (Travis service area): **855.457.0757**
- BCBSTX STAR Kids (MRSA Central service area): **855.457.0758**
- Community Care Plan: **800.424.7897**
- EmblemHealth: **866.799.79196**

General Medicaid requirements

Pharmacy disclosure statement

Pharmacies that participate in the Medicaid Program must complete the Pharmacy Disclosure Statement to comply with federal and state regulations. Pharmacies must complete Prime's Pharmacy Disclosure Statement when requested and, if there is any change in ownership, the Pharmacy must submit a new Pharmacy Disclosure Statement.

Payer of last resort

Under federal regulations, including 42 CFR § 433 Subpart D and 42 CFR § 447.20, the Medicaid Program is generally the payer of last resort. That is, Medicaid is properly responsible for payment of enrollees' costs, including prescription drug costs, only after all third-party sources have met their legal obligations.

Appendix A-1: Illinois Medicaid requirements

Illinois Medicaid requirements

All prescribing providers and pharmacies must be enrolled through the IMPACT (Illinois Medicaid Program Advanced Cloud Technology) system (**1.877.782.5565**; **Impact.Illinois.gov**).

Automatic refills

Pharmacies in Prime's Illinois Medicaid Network are not allowed to use automatic refills. Pharmacies must verify that all prescription drug services refills are initiated by a request from the prescribing provider, covered person or other person acting as an agent of the covered person, for example, a family member.

Any prescription drug services with remaining authorized refills do not constitute a request to refill the prescription. The Illinois Department of Healthcare and Family Services (HFS) will not reimburse a Pharmacy for any prescription drug service that has been filled using an automatic refill process. The Pharmacy must reverse claims for prescription drug services that have been filled using automatic refills and inadvertently billed to HFS. The auto refill prohibition does not apply to medications that are dispensed to residents of LTC facilities or community-based living arrangements such as CILA, SLF or sheltered care facilities.

Prorated claims and synchronized fills

Prime will be able to process prorated claims and synchronize fills for Illinois Medicaid covered persons when the Pharmacy fulfills the synchronization claim submission requirements, as follows:

- Drugs eligible for synchronization are maintenance drugs
- Compounds are excluded
- A Submission Clarification Code (SCC) is required; valid SCC codes are 47 and 48

Emergency prescription supply

In emergency situations, after hours or on weekends, Pharmacies are authorized to dispense a 72-hour emergency supply of any non-specialty medication without a PA. Pharmacies should submit all the following values:

- "2" in field 461-EU (PA Type Code)
- "88888888872" in field 462-EV (PA Number Submitted)
- "3" in field 405-D5 (Days' Supply) in the claim segment of the billing transaction
- Quantity dispensed and submitted in field 442-E7 (quantity dispensed) should equal the quantity necessary for a three-day supply according to the directions for administration given by the prescribing provider up to a maximum daily dose of 4.000.

The Pharmacy should dispense a 72-hour emergency supply of a prescribed drug that is appropriate for the member's medical condition where delay could cause harm. This applies to all prescribed, non-specialty, items on the IL Medicaid Preferred Drug List (PDL) formulary and considered to be an emergency in the judgment of the dispensing pharmacist.

A Pharmacy can dispense a product that is packaged in a dosage form that is fixed and unbreakable (e.g., an albuterol inhaler) as a 72-hour emergency supply. The 72-hour emergency supply is not applicable if PA denial is on record. A member is allowed one grace fill over a period of 30 days per product. If the member meets that limit, any subsequent emergency fill attempt will reject with "ONLY ONE GRACE FILL ALLOWED. A PRIOR AUTHORIZATION IS REQUIRED."

Appendix A-2: Minnesota Medicaid requirements

Minnesota Medicaid requirements

Automatic refills

Minnesota Health Care Programs (MHCP) does not allow automatic refills for Medicaid members. The Pharmacy may not contact the covered person to initiate a refill unless it is part of a good faith clinical effort to assess the covered person's medication regimen. Prescription refills are not eligible for payment without an explicit request from a covered person or authorized caregiver.

A prescribing provider or other authorized agent of a facility may initiate a request for refill for a covered person residing in a skilled nursing facility, group home or assisted living arrangement.

Medicaid Provider Number

In accordance with federal law under the 21st Century Cures Act, the Minnesota Department of Human Services (DHS) is mandated to enroll all Medicaid providers, including those participating in fee-for-service and managed care organization (MCO) networks. As such, any pharmacy delivering Prescription Drug Services through the Minnesota Medicaid program must be formally enrolled as a Medicaid provider with the State of Minnesota.

Pharmacies are required to notify Prime in writing immediately upon cancellation, revocation, suspension, or any other termination of their Medicaid Provider Number. Failure to provide timely written notification may result in immediate removal from the Minnesota Medicaid Network administered by Prime and utilized by Blue Cross Blue Shield of Minnesota.

Do not accept cash payment

As a general reminder, Pharmacies may not accept a cash payment from a covered person or from someone paying on behalf of the covered person for any MHCP prescription drug service.

The Pharmacy may accept a cash payment for a noncovered prescription drug if all of the following apply:

- The covered person is not enrolled in the Minnesota Restricted Recipient Program (MRRP).
- All available covered alternatives have been reviewed with the covered person.
- The Pharmacy obtains a covered person signature on the Advance Member Notice of Noncovered Prescription form (DHS-3641).
- The prescription is not a controlled substance.
- The prescription is not for gabapentin.

MHCP will not authorize the Pharmacy to accept cash if the medication requires prior authorization or is subject to a quantity limit and the prescribing provider has not attempted to obtain the prior authorization or authorization to exceed the quantity limit. MHCP will authorize cash payment if the Pharmacy and covered person complete their sections of the DHS-3641 and the prescribing provider also confirms the following:

- Covered alternatives are not viable options for the covered person.
- The prescribing provider is aware that he or she is seeking authorization for the Pharmacy to charge the covered person for the medication.
- The prescribing provider is aware of the last time the medication was filled for the covered person, if applicable.
- The prescribing provider attests that allowing the covered person to purchase the medication is medically necessary.

Appendix A-2: Minnesota Medicaid requirements (continued)

The prescribing provider must sign the DHS-3641, send the completed form to the Pharmacy and retain a copy of the completed form in the covered person's medical record. The Pharmacy must also retain a copy of the completed form as documentation of approval from MHCP to accept cash payment on the date of service. The completed DHS-3641 is authorization from MHCP to accept cash payment on the date of service; the Pharmacy does not need to submit a copy to MHCP, unless requested. Neither the prescribing provider nor Pharmacy need to call MHCP for additional authorization.

If a covered person's MHCP eligibility status is in question and the covered person offers a cash payment for prescription drug services, the Pharmacy must verify eligibility through Minnesota Information Technology Services (MN-ITS) or Eligibility Verification System (EVS). If the person does not have coverage through MHCP, the Pharmacy may accept cash as payment.

If the covered person is covered by MHCP, do not accept cash payment from the covered person for the prescription if the covered person is enrolled in MRRP.

If you have questions regarding claims processing, please call **Prime's contact center**.

For further information on Minnesota's Medicaid regulations, visit **Minnesota Department of Human Services**.

Controlled Substance or Gabapentin

The Pharmacy may accept cash payment for a controlled substance or gabapentin only if the Pharmacy has received an Advance Member Notice of Noncovered Prescription (DHS-3641) (PDF) signed by the prescribing provider and all criteria have been met for a covered person who is not enrolled in MRRP.

Providers must follow all Prescription Drug Monitoring Program reporting requirements as outlined in MN Statute 2004 section 152.126.

Prorated claims and synchronized fills

Prime will process prorated claims and synchronize fills for Minnesota Medicaid covered persons when the Pharmacy fulfills the synchronization claim submission requirements, as follows:

- Eligible claims are less than a 28-day supply.
- The copay proration will be based on the benefit maximum days' supply of 34.
- Drugs eligible for synchronization are maintenance drugs.
- Compounds are excluded.
- DEA Schedule II, III and IV are all excluded.
- A Submission Clarification Code (SCC) is required; valid SCC codes are 47 and 48.
- Each drug is allowed up to one copay proration per 365-day period.

National Provider Identifier (NPI)

The Pharmacy must submit either the prescribing provider's NPI or Pharmacy's NPI for over-the-counter (OTC) Medicaid claims. For all other Medicaid claims, the Pharmacy must submit the prescribing provider's NPI.

Appendix A-3: New Mexico Medicaid requirements

New Mexico Medicaid requirements

National Provider Identifier (NPI) and enrollment

All prescribing providers must be enrolled in the New Mexico Medicaid Program. The Pharmacy must submit the prescribing provider's NPI for all Medicaid claims.

Pharmacists with prescriptive authority consult fee

Pharmacists with prescriptive authority who provide extended counseling to covered persons are able to submit for reimbursement in 15-minute intervals. Reimbursement will also include the cost of the drug, the dispensing fee and a clinical service payment for prescribing the drug. Documentation of clinical encounters will be required.

This will apply to the following drug classes:

- Hormonal contraception
- Tobacco cessation
- Immunization
- Naloxone
- HIV PEP therapy
- TB testing
- Group A strep therapy
- Covid-19 oral therapy
- Influenza oral therapy

Billing will be submitted with DUR codes:

- Reason: PP
- Professional: PEResult: 1B

Level of Effort (LOE): varies
Level of Effort 1 = 0–15 minutes counseling
Level of Effort 2 = 16–30 minutes counseling
Level of Effort 3 = 31–45 minutes counseling
Level of Effort 4 = 46–60 minutes counseling

Prorated claims and synchronized fills

Prime will be able to process prorated claims and synchronize fills for New Mexico Medicaid covered persons when the Pharmacy fulfills the synchronization claim submission requirements, as follows:

- Drugs eligible for synchronization are maintenance drugs.
- Compounds are excluded.
- No Submission Clarification Code (SCC) is required.

Appendix A-3: New Mexico Medicaid requirements (continued)

Prescription origin code

Pharmacy must use the prescription origin code for all New Mexico Medicaid claim submissions. The prescription origin code should be placed in the 419-DJ field using one of the following values:

1 Written
2 Telephone
3 Electronic
4 Facsimile (fax)
5 Pharmacy

The value of blank or zero will be rejected for any new prescription number and is also unacceptable on refills. New York Medicaid requirements

Appendix A-4: New York Medicaid requirements

New York Medicaid requirements

Medicaid Provider Number

As required by applicable law, in order for a Pharmacy to provide prescription drug service under the New York Medicaid Program, a Pharmacy must be enrolled as a Medicaid provider with the state of New York. A Pharmacy must notify Prime immediately in writing if its Medicaid Number is canceled, revoked, suspended, or otherwise terminated. Failure to immediately notify Prime in writing of any such action may result in immediate termination from the Medicaid Network.

Appendix A-5: Texas Medicaid requirements

Texas Medicaid requirements

Prime is the pharmacy benefit manager for Blue Cross and Blue Shield of Texas, a managed care plan that provides services for covered persons participating in the Texas Medicaid plans. The terms and conditions of this section titled "Texas Medicaid Requirements" apply to Pharmacies that provide prescription drug services to covered persons in the Texas Medicaid Network.

Automatic refills

For automated refill orders for covered products, the provider must confirm with the member that a refill, or new prescription received directly from the physician, should be delivered. Further, the provider must complete a drug regimen review on all prescriptions filled as a result of the auto-refill program in accordance with 22 Tex. Admin. Code § 291.34. The member or medical consenter must have the option to withdraw from an automated refill delivery program at any time.

National Provider Identifier (NPI)

The Pharmacy must submit the prescribing provider's NPI for all Medicaid claims.

Pharmacy credentialing

For entry into the Texas Medicaid Network, a Pharmacy must fill out a credentialing application and provide the following documents:

- Pharmacy License number
- Pharmacist-in-Charge (PIC) license number
- DEA Certificate
- Certificate of Insurance with proof of General and Professional Liability Insurance
- Pharmacy Disclosure Statement

Within 15 days of receiving a fully completed credentialing application from the Pharmacy, Prime will assess and verify that the pharmacy name, pharmacists and the pharmacy owner are not excluded or debarred. Prime uses the **Texas State Board of Pharmacy website** as the primary source of validation to verify that all Pharmacies' and pharmacists' licenses are active and no disciplinary actions exist on file. If Prime finds a disciplinary action, Prime will conduct further assessment.

All Pharmacies in the Texas Medicaid Network must provide Prime with the documents listed above on an annual basis.

Documentation

Specific to the Texas Medicaid Program, per 22 Tex. Admin. Code § 291.34, the Pharmacy must document verbal changes and clarifications to the prescribing provider's prescription order on the original hard copy or electronically noted in the Pharmacy's online system prior to dispensing. When a claim requires a prior authorization, the Pharmacy must request the prescribing provider obtain a PA. The Pharmacy must note electronic documentation prior to dispensing and must identify a system-assigned user, time stamp to take the place of hard copy documentation. When additional refills are ordered, the Pharmacy must assign a new prescription number and appropriately document it on a hard copy.

Compound drugs billing guidelines

Pharmacies must submit compound drugs through the Prime point-of-sale (POS) system using the following directions:

- Flag the compound as a compound drug in the Pharmacy's system prior to adjudication.
- Submit a zero in the NDC portion of the claim using the Compound segment.
- Enter the qualifier, NDC, quantity, cost and cost basis for each ingredient in the compound.

Appendix A-5: Texas Medicaid requirements (continued)

- Submit the final product quantity (the quantity of the finished compound product).
  - For a liquid, submit the number of milliliters of the finished compound product.
  - For capsules, submit the total number of capsules being dispensed.
  - For creams or ointments, submit the total number of grams being dispensed.
- Submit the total ingredient cost, including OTC ingredients. For total ingredient cost, multiply the quantity used for the individual ingredient and the AWP for the individual ingredient according to the pricing source at the time of dispensing for each eligible ingredient used. Then, add all individual ingredient costs.
  - Plan-excluded drugs and invalid NDCs are not eligible for reimbursement.
  - Eligible OTC ingredients may be covered by the benefit plan.
  - Eligible ingredient costs do not include costs for labor, equipment, professional fees or flavoring.
- Maintain compound log documentation to document quantities and NDCs of the ingredients used to prepare the compound. NDCs submitted for the compound must be the exact formulation of what is dispensed in the compound.
- Prime will accept a multi-ingredient compound submission using NCPDP's compound segment for up to 25 ingredients.
- The Pharmacy must submit 420-DK Submission Clarification Code (SCC) for all compounds to allow payment of all covered ingredients, including OTC products. The Pharmacy must follow POS messaging to determine if the ingredients submitted require a PA prior to submitting SCC 8.

Pharmacies are expected to observe applicable state and federal laws, relevant U.S. Pharmacopoeia (USP) Chapter Guidelines, professional standards and FDA communications when preparing and dispensing compound drugs. Evidence of unprofessional or unsafe compounding found during the pharmacy audit process or otherwise may be reported to the applicable state Board of Pharmacy or the FDA and may result in termination of the Pharmacy Participation Agreement.

The following are examples of compound drugs that benefit design may not cover:

- Modified-release compounds (based on covered person benefit design)
- Any compound that contains active ingredients not approved by the FDA
- A compound for which the stability is unknown at the time of dispensing or cannot be determined by referring to USP-approved reference material
- Experimental or investigational items, products or services
- Any finished product intended to address a covered person's medical diagnosis but the diagnosis does not support the need for the finished product (i.e., a sugar-free product)
- Any compound that differs from the equivalent commercial form only by the addition of cosmetic agents or agents intended to produce a cosmetic effect

A Pharmacy cannot submit the following drugs to Prime as a compound drug:

- Reconstituted nonsterile products, to which only water, alcohol or sodium chloride solution are added to the active ingredient (e.g., children's antibiotic suspensions)
- Any prescription that is subdivided into unit dose(s)
- Injectable drugs that are drawn into syringes for administration
- Any compound that has an equivalent commercial form, except in some limited situations in which the compound is preferred according to the benefit plan

Appendix A-5: Texas Medicaid requirements (continued)

Prime also considers the following practices to be unacceptable when billing for compound drugs:

- Billing for a different NDC than what was used in the compound
- Billing for the full package size when only a partial amount was dispensed to the patient
- Billing for a different dosage than what was used in the compound
- Billing for a quantity other than what was used to prepare the compound
- Any compound to which active ingredients are added that were not part of the prescription order
- Not following POS messaging, including, but not limited to, messaging for rejected claims
- Obtaining changes to prescription orders to avoid POS messaging
- Billing claims in a manner that bypasses system messaging requiring further review

Example: billing claims multiple times in a month to avoid obtaining a PA or reaching plan dollar thresholds
If you have questions regarding compound drugs, please call **Prime's contact center** as follows:

- STAR covered persons at **855.457.0405**
- CHIP covered persons at **855.457.0403**
- STAR Kids (in the Travis service area) at **855.457.0757**
- STAR Kids (in the MRSA Central service area) at **855.457.0758**

Maximum allowable cost (MAC) and appeals

To place a drug on Prime's Texas Medicaid MAC list, the drug must be "A" or "B" rated in the most recent version of the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the Orange Book. The drug must also:

- Have an "NR" or "NA" rating or a similar rating by a nationally recognized reference
- Be generally available for purchase by Pharmacies in the state of Texas from national or regional wholesalers
- Not be obsolete

Prime reviews MAC pricing a minimum of once every seven days or in accordance with applicable law. This ensures the MAC price of every drug is based on the current market price of available therapeutically equivalent drugs. A Pharmacy may challenge a listed MAC price for a drug by submitting an invoice and claim information of the MAC drug being appealed. Prime will respond to a challenge in the time period required by applicable law or no later than 15 days after the date the challenge is made. If the challenge is successful, the MAC price for the drug will be adjusted on the date the challenge is resolved and will be applicable to all similarly situated Pharmacies as determined by Prime. If the challenge is denied, Prime will provide a reason for the denial.

If a Pharmacy would like access to Prime's MAC lists, weekly MAC changes, MAC pricing appeals process and the sources used to determine MAC pricing, please refer to **Prime's website** for registration instructions. After network participation is verified, the Pharmacy will receive a secure username and password via email to access Prime's MAC lists.

Prescription drug benefits

Prime uses the Texas Vendor Drug Program (VDP) Preferred Drug List.

Appendix A-5: Texas Medicaid requirements (continued)

How to use the drug list

The Drug List lists the brand name and generic name of a given drug. If a medication does not appear on this Drug List, the medication is not covered under the pharmacy benefit. In some instances, a medication may require a prior authorization (PA). A PA request must be completed by the prescribing provider and submitted to Prime before the prescription may be filled.

To obtain the PA form for medications requiring PA, please call **Prime's contact center** as follows:

- STAR covered persons at **855.457.0405**
- CHIP covered persons at **855.457.0403**
- STAR Kids (in the Travis service area) at **855.457.0757**
- STAR Kids (in the MRSA Central service area) at **855.457.0758**

You may search the Drug List at the **Texas Vendor Drug Program**.

Prior authorization (PA)

PA is designed to encourage appropriate use of medications. Select medications may require a PA. A medication must be used only for FDA-approved indications according to Prime's medical necessity guidelines. The Pharmacy should not request changes to a prescription for the sole purpose of avoiding POS messaging. For example, if a Pharmacy receives a POS message indicating a PA is required, or that it must call **Prime's contact center**, the Pharmacy is expected to follow the POS messaging and **Prime's contact center** instructions. The Pharmacy may contact the prescribing provider for further clarification or additional information about the prescription as needed. If a medication requires PA, the prescribing provider must complete a PA request and submit it to Prime.

To obtain a PA form, the Pharmacy may call **Prime's contact center** as follows:

- STAR covered persons at **855.457.0405**
- CHIP covered persons at **855.457.0403**
- STAR Kids covered persons (in the Travis service area) at **855.457.0757**
- STAR Kids covered persons (in the MRSA Central service area) at **855.457.0758**
- **CoverMyMeds**

Submit all PA fax forms via fax to **877.243.6930**.

Emergency prescription supply

A Pharmacy will receive a rejection of "PA Required" for a non-preferred drug that has not been prior authorized. The message will indicate that the drug is non-preferred and that the prescribing provider should call Prime's PA line at 855.457.0407 to initiate a PA request.

If the Pharmacy is unable to override, simply call Prime's contact center — available 24 hours a day/7 days a week — for assistance:

- STAR covered persons at **855.457.0405**
- CHIP covered persons at **855.457.0403**
- STAR Kids covered persons (in the Travis service area) at **855.457.0757**
- STAR Kids covered persons (in the MRSA Central service area) at **855.457.0758**

In emergency situations, after hours or on weekends, Pharmacies are authorized to dispense a 72-hour emergency supply of any non-preferred medication without a PA. Pharmacies should submit all the following values:

- "8" in field 461-EU (PA Type Code)

- "801" in field 462-EV (PA Number Submitted)
- "3" in field 405-D5 (Days' Supply) in the claim segment of the billing transaction
- The quantity dispensed and submitted in field 442- E7 (quantity dispensed) should equal the quantity necessary for a three-day supply according to the directions for administration given by the prescribing provider

A Pharmacy must provide a 72-hour emergency supply of a prescribed drug when a medication is needed without delay and PA is not available. This applies to all drugs requiring a PA, either because they are non-preferred drugs on the Preferred Drug List or because they are subject to clinical edits. However, it does not apply to any drug not considered to be an emergency in the judgment of the dispensing pharmacist.

In accordance with 1 Tex. Admin. Code § 354.1832, a Pharmacy will be authorized to dispense a 72-hour emergency supply any time a PA cannot be resolved within 24 hours for a medication on the Vendor Drug Program formulary that is appropriate for the member's medical condition and where delay could cause harm. If the prescribing provider cannot be reached or is unable to request a PA, the Pharmacy should submit an emergency 72-hour prescription.

A Pharmacy can dispense a product that is packaged in a dosage form that is fixed and unbreakable (e.g., an albuterol inhaler) as a 72-hour emergency supply. The 72-hour emergency supply is not applicable if PA denial is on record.

Quantity supply limits

Blue Cross and Blue Shield of Texas (BCBSTX) allows up to a 34-day supply of nonmaintenance medication, and up to a 93-day supply of maintenance medication at retail or a mail order Pharmacy. If a medical condition warrants a greater quantity supply than the defined limits, a PA will ensure access to the prescribed quantity. Prior to dispensing, the prescribing provider must submit a PA request to Prime to determine medical necessity..

Dose optimization

The dose optimization program, or dose consolidation, is an extension of the quantity supply program, which helps increase patient adherence with drug therapies.

This program works with the covered person, the covered person's physician or health care provider and the pharmacist to replace multiple doses of lower-strength medications where clinically appropriate with a single dose of a higher-strength medication (only with the prescribing provider's approval). Prior to dispensing multiple doses of the lower-strength medications, the prescribing provider must submit a PA request to Prime to determine medical necessity.

Medically necessary nonformulary drugs

Prior to dispensing medically necessary nonformulary medications, the prescribing provider must submit a PA request to Prime to determine medical necessity. In the event a circumstance occurs in which a nonformulary drug has been identified as the only medically necessary and available recourse, Prime may submit a request to Vendor Drug Pharmacy (VDP) Operations for nonemergency situations. The request must include the following information:

- Member's name
- Medicaid ID
- Drug name
- Pharmacy
- Prescriber
- A detailed description of the circumstance

- Confirmation the case was reviewed by clinical staff

VDP Operations must approve the request before the claim can be submitted. Once approved, Pharmacies must submit the following values:

- "7" in field 420-DK (Submission Clarification Code)
- "Q" in field 257 (formulary status)

This process is intended to help address access to care concerns in non-emergency situations only.

Benefit exclusions

Benefit exclusions are services that are not covered under the covered person's benefit plan. These include but not limited to:

- Medications used for infertility treatment
- Medications used for erectile dysfunction
- Cosmetic and hair growth medications
- Dietary supplements
- Drugs not approved by the FDA
- OTC drugs for CHIP/CHIP Perinate covered persons (with the exception of mosquito repellants, OTC insulin and diabetic supplies on the formulary)
- Contraceptive agents used for family planning for CHIP/CHIP Perinate

Where prescription drug services are filled

Prescription drug services can be filled at Pharmacies participating in the Texas Medicaid Network. A list of Pharmacies in the Texas Medicaid Network can be found in the **BCBSTX Provider Directory**. To verify Pharmacy Network participation or BCBSTX drug coverage, please call **Prime's contact center** as follows:

- STAR covered persons at **855.457.0405**
- CHIP covered persons at **855.457.0403**
- STAR Kids (in the Travis service area) at **855.457.0757**
- STAR Kids (in the MRSA Central service area) at **855.457.075 8**

Prime's information for claims processing

BIN 011552
PCN TXCAID

The Group number is not required for STAR and CHIP claims processing.

Member eligibility

A Pharmacy should verify the covered person's Medicaid coverage at the time of service.

A Pharmacy can verify eligibility by calling the Texas Medicaid Healthcare Partnership (TMHP) at **800.925.9126** or by going to TexMedConnect on the **TMHP website** and checking the covered person's Medicaid ID number (PCN).

Covered persons may call BCBSTX customer service at **888.657.6061** with eligibility-related questions. If a covered person is unaware of which program they are enrolled in, the covered person may contact the Medicaid Managed Care enrollment broker. Covered persons may call the Medicaid Client Line at **800.964.2777** for assistance with eligibility-related issues.

Appendix A-5: Texas Medicaid requirements (continued)

Cost to member

Member type	Copay for up to 34-day supply
STAR	No copay
CHIP < 100% Federal Poverty Level (FPL)	$0 for generic/$5 for brand
CHIP 101% – 151% FPL	$0 for generic/$5 for brand
CHIP above 151% – 186%	$10 for generic/$35 for brand; $25 cap for insulin
CHIP above 186% – 201% FPL	$10 for generic/$35 for brand; $25 cap for insulin
CHIP Perinate	No copay
CHIP American Indians & Alaska Natives (AIAN)	No copay
CHIP No Cost Share	No copay
STAR Kids	No copay

Advance directives

The Pharmacy must comply with the requirements of state and federal laws, rules and regulations relating to advance directives according to 42 CFR § 489, Subpart I.

Child protection

The Pharmacy must testify in court as needed for child protection litigation if requested by Texas Health and Human Services Commission (HHSC).

Cancellation of product orders

In the event a Pharmacy in the Texas Medicaid Program offers delivery services for covered product(s), such as durable medical equipment (DME), home health supplies, outpatient drugs or biological products, and the covered person requests in written or oral representation to reduce, cancel or stop delivery of the covered product(s), the Pharmacy must maintain records documenting the request.

Coordination of benefits

The Pharmacy must perform coordination of benefits in accordance with **TX Uniform Managed Care Contract Sections 8.2.8 and 8.4.3** and **HHSC Uniform Managed Care Pharmacy Claims Manual, Chapter 2.2 Section V(3)**.

Tuberculosis (TB)

Any covered person who may be or is at risk for exposure to TB must be screened for TB. An at-risk covered person is a person who is susceptible to TB because of the association with certain risk factors, behaviors, drug resistance or environmental conditions. The Pharmacy must consult with the local TB control program to ensure that all services and treatments comply with the guidelines, policies and standards recommended by the American Thoracic Society (ATS), the Centers for Disease Control and Prevention (CDC) and Texas Department of State Health Services (DSHS).

Noncovered services

If a Pharmacy receives a request for noncovered prescription drug service for a covered person, the Pharmacy must inform the covered person of the cost and obtain a signed private pay form from the covered person prior to rendering the services. The private pay form may be found in the **TMHP Provider Enrollment and Responsibilities Manual**.

Appendix A-5: Texas Medicaid requirements (continued)

Delivery service

If a Pharmacy elects to provide delivery services to covered persons under the Texas Medicaid Network, the Pharmacy may not charge the covered person a delivery fee. The Pharmacy must adhere to the state's delivery incentive requirements found on the Pharmacy Provider Enrollment Application. If a Pharmacy is in violation of this requirement, Prime, benefit sponsor or HHSC reserves the right to terminate the Pharmacy from the Texas Medicaid Network.

Covered person protections

If a Pharmacy is aware of any reports to authorities on abuse, neglect or exploitation of a covered person, the Pharmacy must notify Prime of any such reports, including, but not limited to, the Pharmacy's self-reports and reports made by others.

Durable medical equipment

If a Pharmacy processes or intends to process a durable medical equipment (DME) prescription, Prime encourages the Pharmacy to become Medicaid-enrolled as a DME provider. Please refer to the State of **Texas' Vendor Drug Program (VDP**) to request a DME application. To be listed as a DME provider, the Pharmacy must be a VDP Pharmacy and attested with Texas Medicaid and Healthcare Partnership (TMHP).

Prorated claims and synchronized fills

Prime will be able to process prorated claims and synchronize fills for Texas Medicaid covered persons when the Pharmacy fulfills the synchronization claim submission requirements, as follows:

- The copay proration will be based on the benefit maximum days' supply of 34.
- Drugs eligible for synchronization are maintenance drugs.
- Compounds are excluded.
- A Submission Clarification Code (SCC) is required; valid SCC codes are 47 and 48.

Important toll-free contact numbers

Prime's contact center is available 24 hours a day/7 days a week:

- BCBSTX STAR covered persons: **855.457.0405**
- BCBSTX CHIP covered persons: **855.457.0403**
- BCBSTX STAR Kids covered persons (Travis service area): **855.457.0757**
- BCBSTX STAR Kids covered persons (MRSA Central service area): **855.457.0758**

Pharmacy prior authorization is available 24 hours a day/7 days a week:

- BCBSTX STAR covered persons: **855.457.0405**
- BCBSTX CHIP covered persons: **855.457.0403**
- BCBSTX STAR Kids covered persons (Travis service area): **855.457.0757**
- BCBSTX STAR Kids covered persons (MRSA Central service area): **855.457.0758**
- Pharmacy prior authorization fax: **877.243.6930**

Appendix A-6: Florida Department of Health Drug Assistance 340B Program

Florida AIDS Drug Assistance Program requirements

Florida Department of Health Aids Drug Assistance 340B Program requirements

Florida's Ryan White AIDS Drug Assistance Program (ADAP) is a program that provides medications to uninsured or underinsured individuals living with HIV/AIDS disease, authorized under 42 U.S.C. § 300ff-

26. FL ADAP is a statewide, federally funded prescription medication program for low-income people living with HIV.

Pharmacy Provider Manual adds to the network

There may be situations where the Pharmacy may need to be manually added to the provider network. In those situations, approval is required from the Department of Health (DOH). The DOH will contact Prime directly for a manual entry to the system.

340B and FL ADAP pharmacy compliance audits

Audit purpose and policy

Prime has contracted with the State of Florida DOH for the provision of 340B PBM and pharmacy network services for uninsured ADAP-eligible clients. This contract includes a requirement to perform independent audits of each 340B contracted Pharmacy in the PBM network for compliance with the 340B Drug Pricing Program and FL ADAP requirements. Annually, the Prime audit team performs independent on-site audits of each 340B contracted Pharmacy in the PBM network for compliance with the 340B Drug Pricing Program, FL ADAP requirements and the contract between the contracted Pharmacy and Prime. The objective of audits is to observe compliance with 340B guidance, FL ADAP requirements and the contract between the Pharmacy and Prime.

Access to records

Please note that all claims submitted to Prime are subject to audit, regardless of the final claim status. This includes claims that are paid, reversed, denied and rejected. Pharmacies are expected to maintain and make available to Prime all appropriate documentation and records that support a claim or an element of a claim. This includes transaction logs and records, receipts of payment and other records.

Documentation should not be altered or created in preparation for an audit. If a Pharmacy is missing documentation, the Pharmacy should contact the auditor and provide an explanation for the missing documentation.

Denying access to records or failing to respond to any audit request will be treated as a failure to comply with an audit. If a Pharmacy fails to comply with an audit, Prime may take additional disciplinary actions, including, but not limited to, referring the Pharmacy to an external oversight agency, recovering any overpayments associated, implementing corrective action or terminating the Pharmacy from the network.

Audit process

All audits will be conducted in accordance with applicable contractual and regulatory requirements. Audits will include the following steps:

- Advance notice will be provided to Pharmacies unless suspected fraud has been identified. When suspected fraud has been identified, no advance notice is required. Prime will work with Pharmacies to make reasonable accommodations when scheduling on-site audits and to ensure minimal disruption to pharmacy operations during the audit process.
- A list of documentation required for the review will be provided (along with the required time frame).

Appendix A-6: Florida Department of Health Drug Assistance (FL ADAP) 340B Program (continued)

- We will review the records to ensure their accuracy and compliance with the 340B Drug Pricing Program and the contract between contracted Pharmacy and Prime. When on site, we may also interview staff, review policies and procedures and other relevant documentation and will observe staff interactions with customers. Our audit staff will comply with all applicable privacy regulations.
- Once records have been reviewed, a preliminary report of the findings is provided. It will include a detailed list of the discrepancies found, a reference to the contractual or regulatory requirement(s) in question and guidelines for any opportunity to contest the initial findings. Some findings may not allow for submission of additional documentation because of their nature (e.g., wrong patient or prescriber selected).
- The audit will be closed and a final report issued once the additional documentation has been reviewed or the time to submit additional documentation has passed. Any changes to the preliminary results based upon the review of additional documentation will be reflected in the final report.
- A Pharmacy may be subject to a corrective action plan if a deficiency is identified that requires follow-up and/or additional action.

Rebate

340B Pharmacies buy medications at a discounted rate; therefore, no 340B rebate is allowed. The ADAP Program will submit for any available additional rebates from drug manufacturers, including rebates, to reduce the net cost of drugs reimbursed through the PBM to the ADAP price negotiated with the manufacturer.

General claim billing information

340B billing requirements

Pharmacies participating in the 340B Program shall comply with all requirements of the notice regarding 340B Drug Pricing Program – Contract Pharmacy Services published in the Federal Register, Vol. 75, No. 43, Friday, March 5, 2010. Pharmacies shall also comply with all updates to requirements issued by Health Resources and Services Administration regarding operation of a 340B-contracted Pharmacy.

340B-contracted pharmacy requirements

Each 340B-contracted Pharmacy should, at a minimum:

- Monitor utilization data to identify any incomplete HIV antiretroviral treatment regimen and notify the prescribing health care practitioner of the incomplete regimen prescribed to an eligible client.
- Monitor utilization data for any inappropriately prescribed or excessive dosages of prescribed medication.
- Notify the prescribing health care practitioner of the inappropriate or excessive dosage of medication prescribed to an eligible client.
- Maintain a Community Pharmacy Permit in accordance with section 465.018, Florida Statutes, from the Florida Board of Pharmacy. Ensure the Community Pharmacy Permit is not suspended or revoked at any time during the contract term.
- Ensure pharmacy staff comply with the requirements of the Florida Pharmacy Act set forth in Chapter 465, Florida Statutes, and the requirements of the Florida Board of Pharmacy.
- If located outside of Florida and which ships, mails or delivers, in any manner a dispensed medicinal drug into Florida, comply with the requirements set forth in section 465.0156, Florida Statutes, and the requirements of the Florida Board of Pharmacy.

Appendix A-6: Florida Department of Health Drug Assistance (FL ADAP) 340B Program (continued)

- Comply with all requirements of the Notice Regarding 340B Drug Pricing Program – Contract Pharmacy Services published in the Federal Register, Vol. 75, No. 43, Friday, March 5, 2010, in Exhibit 4.
- Comply with all updates to requirements issued by the Health Resources and Services Administration regarding operation of a 340B-contracted Pharmacy.
- Dispense all medicinal drugs on the ADAP formulary to eligible clients within 48 hours of receipt of a new prescription or refill authorization.
- Place all chronic condition medications on automatic refill, and request refills from the prescribing health care practitioner when needed, no less than five days prior to the refill due date. Contact eligible clients to arrange for delivery or medication pick up.
- Notify the prescribing health care practitioner via fax or phone call when eligible clients cannot be reached to arrange for delivery or do not pick up their medications at least 72 hours before they are expected to run out of medication.
- Notify the prescribing health care practitioner and the eligible client of receipt of a new prescription for a drug that is not on the ADAP formulary. Document rejection of claim for the nonformulary drug in the eligible client's file. Provide ADAP formulary therapeutic alternatives (if available), or identify another payer source (e.g., case manager, patient assistance program) if no therapeutic alternatives are on the ADAP formulary.
- Transfer prescriptions at the eligible client's request to another 340B contracted Pharmacy within the PBM network in accordance with applicable state and federal statutes, rules or codes. This may also require the prescription to be transferred, filled and transferred back.
- Identify HIV antiretroviral treatment regimens that are potentially inappropriate (e.g., incomplete or combinations not recommended). Notify the prescribing health care practitioner within 48 hours of receipt of prescriptions and prior to dispensing the medications to appropriately resolve the issues. If unable to contact the health care practitioner, notify the Department of the issue.
- Notify the prescribing health care practitioner at the time of dispensation of the last available fill of a prescription by their preferred method (i.e., ePrescribing, fax, or phone) regarding refills of any medications that do not have refills remaining.
- If outsourcing the filling of any prescriptions, maintain a direct and uninterrupted transfer process to the eligible client and prescriber. Obtain prior eligible client approval if transferring the prescription to another Pharmacy, and check for drug-drug interactions among those filled at both pharmacies.

Provider reimbursement rates

Pharmacy reimbursement note:

For all claims, 340B stock must be used. The stock is replenished and pharmacy providers will be reimbursed a dispensing fee.

- The Department mandates a 15-day adjudication delay in addition to the 90-day replenishment window. The 15-day time frame ensures claims are fully adjudicated before replenishment.
- In the event any NDC cannot be fulfilled through replenishment within 90 days from date of service, the claim will be reimbursed at wholesale acquisition cost (WAC) plus the applicable administrative fees.
- For pharmacies that cannot ingest WAC, the Department will reimburse the average wholesale price for unreplenished items.

Prime will provide reporting to identify and assist with reversing and reprocessing the claims.

When usual and customary is not submitted on claim, claim will deny with NCPDP error code DQ-M/I "Usual and Customary Charge."

Appendix A-6: Florida Department of Health Drug Assistance (FL ADAP) 340B Program (continued)

Shipping

Providers will only be paid one shipping fee of up to $15.00 for each order shipped by a 340B-contract Pharmacy to a client, regardless of the number of prescriptions per order, on the same date of service. Additional shipping fees will be paid for new prescriptions as well as prescription refills within the medication synchronization process.

If the pharmacy does not successfully request a shipping fee as outlined in this section, no shipping fee will be paid. A shipping fee will only be paid if it is indicated in the adjudication system prior to the actual shipping of the prescription.

To receive the shipping fee, pharmacy providers must submit with the following three fields:

- Other Amount Claimed Submitted Count (NCPDP field 478-H7) = 1
- Other Amount Claim Submitted Qualifier (NCPDP field 479-HH) 02 – Shipping Cost
- Other Amount Claimed Submitted (NCPDP field 480-H9) – Shipping Amount Should Be Submitted. Up to $15.00 will be reimbursed.

Specialty mail order pharmacy shipping requirements

Specialty mail-order Pharmacies should be able to ship to any client location. At a minimum, specialty mail order Pharmacies should perform the following:

- Ensure that all eligible clients receive mail order prescriptions within five business days from the time the prescription is submitted by the health care practitioner on behalf of the eligible client to the 340B contracted Pharmacy.
- Verify delivery address and delivery date prior to each shipment of medication to each eligible client.
- Coordinate special shipping needs of persons experiencing homelessness and transient ADAP-eligible clients by ensuring prescriptions are shipped to eligible client's preferred address within the limitations of Florida law.
- Verify any changes in prescribed medications since last delivery.
- If unable to contact the eligible client, notify the prescribing health care practitioner prior to the date the eligible client is expected to be out of medications.
- If unable to contact the eligible client through the prescribing health care practitioner, notify provider to notify the Department.
- Have a documented process for dispensing controlled substances, which outlines receipt of prescriptions and shipping of dispensed medications.
- For each dispense shipped by a mail-order Pharmacy, provide the shipment date and tracking number electronically to the Department through the PBM system.
- Dispense a partial fill as needed to synchronize the future refills of all ADAP formulary medications for each eligible client.

Upon request of the eligible client or prescribing health care practitioner, provide adherence packaging as well as packaging and labeling options for eligible clients with limited English proficiency or are visually impaired.

Appendix A-6: Florida Department of Health Drug Assistance (FL ADAP) 340B Program (continued)

Dispense fee

Dispensing fee of $20.00 for each adjudicated claim received from a 340B contract Pharmacy owned by a 340B covered entity.

Dispensing fee of $30.00 for each adjudicated claim received from a specialty or mail-order 340B contract Pharmacy.

Dispensing fee of $15.50 for each adjudicated claim received from a 340B contract Pharmacy that is not owned by a 340B covered entity and not a specialty or mail-order Pharmacy.

Vaccine administration

Vaccine administration fee of $15.00 for each adjudicated claim received from 340B contract Pharmacy for flu vaccine.

Vaccine administration fee of $40.00 for each adjudicated claim received from a 340B contract Pharmacy for COVID-19 vaccine, if included on formulary.

Vaccine administration fee of $20.00 for each adjudicated claim received from a 340B contract Pharmacy for other ADAP formulary vaccines.

Appendix B: Regulatory addendums

B-1 Alabama Regulatory Addendum to Pharmacy Participation Agreement

This Alabama Addendum applies to the extent that Pharmacy provides covered drugs to covered persons of health maintenance organizations, managed care organizations, insurers or carriers under Alabama law (collectively and/or individually, plan sponsor).

In the event of a direct conflict between this Addendum and the Agreement, the applicable provisions of this Addendum shall control if required. This Addendum may be modified from time to time pursuant to the Agreement.

Without limiting the generality of the foregoing, and notwithstanding anything in the Agreement to the contrary, Pharmacy agrees as follows:

To the extent Pharmacy provides covered drugs to covered persons of a health maintenance organization under Alabama law, Pharmacy agrees:

That in no event, including, but not limited to, nonpayment, PBM's or plan sponsor's insolvency, or breach of the Agreement, shall Pharmacy bill, charge, collect a deposit from, seek compensation, remuneration or reimbursement from, or have any recourse against covered persons, or persons other than PBM or plan sponsor acting on behalf of covered persons for services provided pursuant to this agreement.

This provision shall not prohibit collection of copays, deductibles and coinsurances on PBM's or plan sponsor's behalf made in accordance with the terms of the benefit plan between plan sponsor and covered persons. Ala. Stat. § 27-21A-3(b)(4); Ala. Admin. Code r. 482-1-080-.05(2)(c); 420-5-6.10(2)(q)(1)..

Pharmacy further agrees that (a) this provision shall survive the termination of this agreement regardless of the cause giving rise to termination and shall be construed to be for the benefit of the covered person, and that (b) this provision supersedes any oral or written contrary agreement now existing or hereafter entered into between Pharmacy and covered persons, or persons on their behalf. Ala. Admin. Code r. 420-5-6.10(2)(q)(1).

Pharmacy may not change, amend or waive any provision of this agreement without prior written consent of PBM. Any attempts to change, amend or waive the Agreement are void. Ala. Admin. Code r. 420-5- 6.10(2)(q)(1).

This Agreement shall not establish reimbursement rates or procedures that result in reimbursement rates for services rendered to covered persons covered by plan sponsor which are less than the usual and customary rates paid by consumers not covered by a third-party plan for the same or similar services. Ala. Stat. § 34-23-115.

Pharmacy shall be compensated at the rate and frequency set forth in the Agreement and any related attachments. Ala. Stat. § 34-23-112.

Pharmacy agrees to resolve all disputes, controversies and claims in the manner set forth in the Agreement and any related attachments. Ala. Stat. § 34-23-112.

Pharmacy agrees to participate in plan sponsor's enrollee grievance procedures. Ala. Admin. Code r. 420-5-6-.10(2)(j).

Pharmacy shall provide PBM and the Alabama Department of Insurance with written verification that Pharmacy is registered with the Alabama State Board of Pharmacy in accordance with Ala. Code § 27-45-20.

IF A PROVIDER REQUESTS PAYMENT UNDER A HEALTH INSURANCE PLAN FROM A HEALTH INSURER OR ITS CONTRACTED VENDOR OR A REGIONAL CARE ORGANIZATION BE MADE USING ACH ELECTRONIC FUNDS TRANSFER, THAT REQUEST MUST BE HONORED. FURTHERMORE, SUCH A REQUEST MAY NOT BE USED TO DELAY OR REJECT A TRANSACTION, OR ATTEMPT TO ADVERSELY AFFECT THE PROVIDER. Ala. Stat. § 27-1-17.1

Pharmacy audit requirements (Ala. Stat. § 34-23-184 through Ala. Stat. § 34-23-187):

(a) PBM shall follow these procedures:

(1) The Pharmacy contract shall identify and describe in detail the audit procedures.

(2) PBM conducting the on-site audit shall give the Pharmacy written notice at least two weeks before conducting the initial on-site audit for each audit cycle. If PBM does not include their auditing guidelines within their Provider Manual, then the notice must include a documented checklist of all items being audited and the Manual, including the name, date and edition or volume, applicable to the audit and auditing guidelines. For on-site audits, Prime shall also provide a list of material that is copied or removed during the course of an audit to the Pharmacy. PBM may document this material on either a checklist or on an audit acknowledgement form. The Pharmacy shall produce any items during the course of the audit or within 30 days of the on-site audit.

(3) PBM may not interfere with the delivery of pharmacist services to a patient and shall utilize every effort to minimize inconvenience and disruption to pharmacy operations during the audit process.

(4) An audit that involves clinical or professional judgment shall be conducted by or in consultation with a licensed pharmacist.

(5) The audit shall not consider as fraud any clerical or recordkeeping error, such as a typographical error, scrivener's error or computer error regarding a required document or record; however, such errors may be subject to recoupment, provided that a Pharmacy shall not be subject to a chargeback or recoupment for a clerical or recordkeeping error in a required document or record, including a typographical or computer error, unless the error resulted in overpayment to the Pharmacy. The Pharmacy shall have the right to submit amended claims through an online submission to correct clerical or recordkeeping errors in lieu of recoupment of a claim where no actual financial harm to the patient or plan has occurred, provided that the prescription was dispensed according to prescription documentation requirements set forth by the Alabama Pharmacy Act and within the plan limits.The Pharmacy shall not be subject to recoupment of funds by PBM unless PBM can provide proof of intent to commit fraud or such error results in actual financial harm to PBM, a health insurance plan managed by PBM or a consumer. A person shall not be subject to criminal penalties for errors provided for in this subsection without proof of intent to commit fraud, waste or abuse.

(a) Any amount to be charged back or recouped due to overpayment shall not exceed the amount the Pharmacy was overpaid.

(b) PBM shall not include the dispensing fee in the calculation of an overpayment unless a prescription is considered a misfill. As used in this paragraph, misfill means a prescription that was not dispensed, a prescription in which the prescriber denied the authorization request, a prescription in which an additional dispensing fee was charged or a prescription error.

(6) PBM shall not require any documentation that is not required by state and federal law. The information shall be considered to be valid if documented on the prescription, computerized treatment notes, Pharmacy system or other acceptable medical records.

(7) Unless superseded by state or federal law, auditors shall only have access to previous audit reports on a particular pharmacy conducted by the auditing entity for the same pharmacy benefit manager, health plan or insurer. An auditing vendor contracting with multiple pharmacy benefit managers or health insurance plans shall not use audit reports or other information gained from an audit on a particular Pharmacy to conduct another audit for a different pharmacy benefit manager or health insurance plan.

(8) Audit results shall be disclosed to the health benefit plan in a manner pursuant to contract terms.

(9) A Pharmacy may use the records of a hospital, physician or other authorized practitioner of the healing arts for drugs or medicinal supplies written or transmitted by any means of communication for the purposes of validating the pharmacy record with respect to orders or refills of a legend or narcotic drug.

(10) PBM or its representative conducts an audit, the sample size shall not be greater than 150 prescriptions, provided that a refill does not constitute a separate prescription for the purposes of this subdivision.

(11) Reasonable costs associated with the audit shall be the responsibility of PBM if the claims sample exceeds 100 unique prescription hard copies.

(12) A finding of an overpayment or an underpayment may be a projection based on the number of patients served having a similar diagnosis or on the number of similar orders or refills for similar drugs, except that recoupment shall be based on the actual overpayment or underpayment of actual claims.

(13) A finding of an overpayment may not include the cost of the drugs that were dispensed in accordance with the prescriber's orders, provided the prescription was dispensed according to prescription documentation requirements set forth by the Alabama Pharmacy Act and within the plan limits. A finding of an overpayment may not include the dispensing fee amount unless any of the following apply:

a. A prescription was not actually dispensed.

b. The prescriber denied authorization.

c. The prescription dispensed was a medication error by the Pharmacy.

d. The identified overpayment is solely based on an extra dispensing fee.

(14) Each Pharmacy shall be audited under the same standards and parameters as other similarly situated Pharmacies audited by PBM and must be audited under rules applicable to the contractor and time period of the prescription.

(15) Where not superseded by state or federal law, the period covered by an audit may not exceed two years from the date the claim was submitted to or adjudicated by a managed care company, nonprofit hospital or medical service organization, health benefit plan, third-party payer, pharmacy benefit manager, a health program administered by a department of the state or any entity that represents those companies, groups or department. An audit may not be conducted six months past the date the pharmacy benefit management plan terminated its contract to adjudicate claims with a pharmacy benefit manager, health plan administrator or any other entity representing those companies.

(16) An audit may not be initiated or scheduled during the first five calendar days of any month.

(b) PBM shall provide the Pharmacy with a written report of the audit and comply with all the following requirements:

(1) The preliminary audit report shall be delivered to the Pharmacy within 90 days after the conclusion of the audit, with a reasonable extension to be granted upon request.

(2) A Pharmacy shall be allowed at least 30 days following receipt of the preliminary audit report in which to produce documentation to address any discrepancy found during the audit, with a reasonable extension to be granted upon request.

(3) A final audit report shall be delivered to the Pharmacy within 180 days after receipt of the preliminary audit report or final appeal, as provided for in Section 34-23-185, whichever is later.

(4) The audit documents shall be signed by the auditors assigned to the audit. The acknowledgment or receipt shall be signed by the auditor and the audit report shall contain clear contact information of the representative of the auditing organization.

(5) Recoupments of any disputed funds, or repayment of funds to PBM by the Pharmacy if permitted pursuant to contractual agreement, shall occur after final internal disposition of the audit, including the appeals process as provided for in Section 34-23-185. If the identified discrepancy for an individual audit exceeds $25,000, future payments in excess of that amount to the Pharmacy may be withheld pending finalization of the audit.

(6) Interest shall not accrue during the audit period.

(7) PBM shall provide a copy of the final audit report, after completion of any review process, to the plan sponsor in a manner pursuant to a contract.

Audit appeals:

(a) PBM shall not use extrapolation to calculate penalties or amounts to be charged back or recouped unless otherwise required by federal requirements or federal plans.

(b) PBM shall not compensate an employee or contractor with which PBM contracts to conduct a pharmacy audit based on the amount claimed or the actual amount recouped by the Pharmacy being audited.

Fraud, willful misrepresentation or waste abuse:

These audit procedures do not apply to any audit, review or investigation that involves alleged fraud, willful misrepresentation or waste abuse.

B-2 Alaska Regulatory Addendum to Participating Pharmacy Agreement

This Alaska Addendum applies to the extent that Pharmacy provides covered drugs to covered persons of medical service corporations, managed care insurance plans, health maintenance organizations and insurers under Alaska law (collectively and/or individually, plan sponsor).

In the event of a direct conflict between this Addendum and the Agreement, the applicable provisions of this Addendum shall control if required. This Addendum may be modified from time to time pursuant to the Agreement.

Without limiting the generality of the foregoing, and notwithstanding anything in the Agreement to the contrary, Pharmacy agrees as follows:

To the extent Pharmacy provides covered drugs to covered persons of a health care insurer, Pharmacy agrees:

That Pharmacy shall be responsible for providing covered drugs as communicated via the POS system or otherwise, as set forth in the Agreement. Alaska Stat. § 21.07.010(a)(1).

That Pharmacy shall be compensated at the rate set forth in the Agreement and any related attachments. Alaska Stat. § 21.07.010(a)(2).

That the Agreement may be terminated as set forth in the Agreement and any related attachments. Notwithstanding anything to the contrary in the Agreement, a provision that allows for discretionary termination by either party shall apply equally to both Pharmacy and PBM. Alaska Stat. § 21.07.010(a)(3).

In the event of a dispute between Pharmacy and PBM, a fair, prompt and mutual dispute resolution process shall be used consisting of the following:

i. The parties shall hold an initial meeting at which all parties are present or represented by individuals with authority regarding the manners in dispute. The meeting shall be held within 10 working days after PBM receives written notice of the dispute or gives written notice to Pharmacy, unless the parties otherwise agree in writing to a different schedule;

ii. If, within 30 days following the initial meeting, the parties have not resolved the dispute, the dispute shall be submitted to mediation directed by a mediator who is mutually agreeable to the parties and who is not regularly under contract to or employed by either of the parties. Each party shall bear its proportionate share of the cost of mediation, including the mediator's fees;

iii. The parties shall negotiate in good faith in the initial meeting and in mediation;

iv. If, after a period of 60 days following commencement of mediation, the parties are unable to resolve the dispute, either party may seek other relief allowed by law. Alaska Stat. § 21.07.010(a)(4).

Pharmacy shall not be penalized or Pharmacy's contract terminated by PBM because Pharmacy acts as an advocate for a covered person in seeking appropriate, medically necessary health care services. Alaska Stat. § 21.07.010(a)(5).

Pharmacy shall be free to communicate openly with a covered person about all appropriate diagnostic testing and treatment options. Alaska Stat. § 21.07.010(a)(6).

Terms used in the Agreement and this Addendum shall have the meaning set forth in the Glossary of Terms attached to the Agreement. Alaska Stat. § 21.07.010(a)(7).

Notwithstanding anything to the contrary in the Agreement, Pharmacy shall not be required to indemnify or hold harmless PBM or plan sponsor for PBM's or plan sponsor's own acts or conduct. Alaska Stat. § 21.07.010(c).

To the extent Pharmacy provides covered drugs to covered persons of a medical service corporation under Alaska law, Pharmacy agrees:

That Pharmacy shall provide covered drugs to covered persons and that the obligation to furnish these services shall be a direct obligation of the Pharmacy to the covered persons as well as to PBM and plan sponsor.

That Pharmacy shall be compensated for services rendered in accordance with the terms of the Agreement and any related attachments and that Pharmacy may not request or receive compensation for services that is not in accord with those terms.

That compensation for services may be prorated and settled under the circumstances and in the manner referred to in Alaska Stat. § 21.87.300.

That, if Pharmacy withdraws from the Agreement, the withdrawal may not be effective as to a covered person's contract in force on the date of the withdrawal until the termination of the covered person's contract or the next anniversary of the covered person's contract, whichever date is earlier; and Alaska Stat. § 21.87.140.

Pharmacy audit requirements (Alaska Stat. § 21.27.910)

a) When PBM conducts an audit of the records of a Pharmacy, the period covered by the audit of a claim may not exceed two years from the date that the claim was submitted to or adjudicated by PBM, whichever is earlier. Except as required under Alaska Stat. 21.36.495, a claim submitted to or adjudicated by PBM does not accrue interest during the audit period.

b) PBM conducting an on-site audit shall give the Pharmacy written notice of at least 10 business days before conducting an initial audit.

c) PBM may not conduct

(1) an audit during the first seven calendar days of any month unless agreed to by the Pharmacy;

(2) more than one on-site audit of a Pharmacy within a 12-month period; or

(3) on-site audits of more than 250 separate prescriptions at one Pharmacy within a 12-month period unless fraud by the Pharmacy or an employee of the Pharmacy is alleged.

d) If an audit involves clinical or professional judgment, the individual conducting the audit must

(1) be a pharmacist who is licensed and in good standing under Alaska Stat. 08.80; or

(2) conduct the audit in consultation with a pharmacist who is licensed and in good standing under Alaska Stat. 08.80.

e) A Pharmacy, in responding to an audit, may use

(1) verifiable statements or records, including medication administration records of a nursing home, assisted living facility, hospital, physician or other authorized practitioner to validate the pharmacy record;

(2) a legal prescription to validate claims in connection with prescriptions, refills or changes in prescriptions, including medication administration records, prescriptions transmitted by facsimile, electronic prescriptions or documented telephone calls from the prescriber or the prescriber's agent.

(f) PBM shall audit each Pharmacy under the same standards and parameters as other similarly situated Pharmacies in a network pharmacy contract in this state.

Overpayment or underpayment (Alaska Stat. § 21.27.915)

a) When PBM conducts an audit of a Pharmacy, PBM shall base a finding of overpayment or underpayment by the Pharmacy on the actual overpayment or underpayment and not on a projection based on the number of patients served having a similar diagnosis or on the number of similar orders or refills for similar drugs, except as provided in (b) of this section.

b) PBM may resolve a finding of overpayment or underpayment by entering into a settlement agreement with the Pharmacy. The settlement agreement

(1) must comply with the requirements of Alaska Stat. 21.36.125; and

(2) may be based on a statistically justifiable projection method.

c) PBM may not include the dispensing fee amount in a finding of an overpayment unless

(1) a prescription was not actually dispensed;

(2) the prescriber denied authorization;

(3) the prescription dispensed was a medication error by the Pharmacy; or

(4) the identified overpayment is solely based on an extra dispensing fee.

Recoupment (Alaska Stat. § 21.27.920)

a) When PBM conducts an audit of a Pharmacy, PBM shall base the recoupment of overpayments on the actual overpayment of the claim, except as provided in Alaska Stat. 21.27.915(b).

b) When conducting an audit of a Pharmacy, PBM may not

(1) use extrapolation in calculating recoupments or penalties for audits, unless required by state or federal contracts;

(2) assess a chargeback, recoupment or other penalty against a Pharmacy solely because a prescription is mailed or delivered at the request of a patient; or

(3) receive payment

(A) based on a percentage of the amount recovered; or

(B) for errors that have no actual financial harm to the patient or medical plan.

Pharmacy audit reports (Alaska Stat. § 21.27.925)

a) PBM shall deliver a preliminary audit report to the Pharmacy audited within 60 days after the conclusion of the audit.

b) PBM shall allow the Pharmacy at 30 days following receipt of the preliminary audit report to provide documentation to PBM to address a discrepancy found in the audit. PBM may grant a reasonable extension upon request by the Pharmacy.

c) PBM shall deliver a final audit report to the Pharmacy within 120 days after receipt of the preliminary audit report, settlement agreement or final appeal, whichever is latest.

Pharmacy audit appeal; future repayment (Alaska Stat. § 21.27.930)

a) PBM shall establish a written appeals process.

b) Recoupment of disputed funds or repayment of funds to PBM by the Pharmacy, if permitted by contract, shall occur, to the extent demonstrated or documented in the pharmacy audit findings, after final internal disposition of the audit, including the appeals process. If the identified discrepancy for an individual audit exceeds $15,000, future payments to the Pharmacy may be withheld pending finalization of the audit.

c) PBM may not assess against a Pharmacy a chargeback, recoupment or other penalty until PBM's appeals process has been exhausted and the final report or settlement agreement issued.

Fraudulent activity (Alaska Stat. § 21.27.935)

When PBM conducts an audit of a Pharmacy, PBM may not consider unintentional clerical or record-keeping errors, including typographical errors, writer's errors or computer errors regarding a required document or record, to be fraudulent activity. In this section, "fraudulent activity" means an intentional act of theft, deception, misrepresentation or concealment committed by the Pharmacy.

Pharmacy audits; restrictions (Alaska Stat. § 21.27.940)

The requirements of Alaska Stat. 21.27.901 — 21.27.955 do not apply to an audit

(1) in which suspected fraudulent activity or other intentional or willful misrepresentation is evidenced by a physical review, a review of claims data, a statement or another investigative method; or

(2) of claims paid for under the medical assistance program under Alaska Stat. 47.07.

B-3 Arizona Regulatory Addendum to Participating Pharmacy Agreement

This Arizona Addendum applies to the extent that Pharmacy provides covered drugs to covered persons of health care services organization, hospital and medical service corporation, insurers or carriers under Arizona law (collectively and/or individually, plan sponsor).

In the event of a direct conflict between this Addendum and the Agreement, the applicable provisions of this Addendum shall control if required. This Addendum may be modified from time to time pursuant to the Agreement.

Without limiting the generality of the foregoing, and notwithstanding anything in the Agreement to the contrary, Pharmacy agrees as follows:

PBM shall not restrict or prohibit Pharmacy's good faith communication with its patients concerning the patients' health care or medical needs, treatment options, health care risks or benefits. Ariz. Stat. § 20-118(A).

PBM shall not terminate the Agreement or refuse to renew the Agreement with Pharmacy solely because Pharmacy in good faith does any of the following:

Advocates in private or in public on behalf of a patient.

Assists a patient in seeking reconsideration of a decision made by PBM and/or plan sponsor to deny coverage for covered drugs.

Reports a violation of law to an appropriate authority. Ariz. Stat. § 20-118(B).

To the extent Pharmacy provides covered drugs to covered persons of a hospital, medical, dental or optometric service corporation or a health care services organization under Arizona law, PBM will not make or withhold a specific payment from Pharmacy as an inducement to deny, reduce, limit or delay medically necessary care that is covered by a covered person's benefit plan for a specific disease or condition. Ariz. Stat. §§ 20-833(D), 20-1061(B).

To the extent Pharmacy provides covered drugs to covered persons of a health care services organization under Arizona law, Pharmacy agrees:

In the event that PBM or plan sponsor fails to pay for covered services as set forth in the covered person's evidence of coverage or contract, the covered person shall not be liable to Pharmacy for any amounts owed by PBM and/or plan sponsor, and Pharmacy shall not bill or otherwise attempt to collect from the covered person any amount owed by PBM and/or plan sponsor. Ariz. Stat. § 20-1072(A).

Pharmacy, and any agent, trustee or assignee of Pharmacy shall not maintain an action at law against a covered person to collect any amounts owed by PBM and/or plan sponsor for which the covered person is not liable to Pharmacy under the preceding subparagraph. Ariz. Stat. § 20-1072(C).

Pharmacy shall not charge covered persons more than the amount contracted for under the Agreement. Ariz. Stat. § 20-1072(F).

In the event that plan sponsor is declared insolvent, Pharmacy shall provide services to covered persons at the same rates and subject to the same terms and conditions established in the Agreement for the duration of the period after plan sponsor is declared insolvent, until the earliest of the following:

i. The duration of the contract period under the covered person's benefit plan or for 60 days from the date of insolvency is declared, whichever is longer;

ii. If the covered person is confined on the date of insolvency in an inpatient facility until his or her discharge;

- A notification from the receiver pursuant to Ariz. Stat. 20-1069(F) or a determination by the court that plan sponsor cannot provide adequate assurance it will be able to pay Pharmacy's claims for covered services that were rendered after the plan sponsor is declared insolvent;

iii. A determination by the court that the insolvent plan sponsor is unable to pay Pharmacy's claims for covered services that were rendered after the plan sponsor is declared insolvent;

iv. A determination by the court that continuation of services would constitute undue hardship to Pharmacy;

v. A determination by the court that plan sponsor has satisfied its obligations to all covered persons under its benefit plans.

Ariz. Stat. § 20-1074(B).

Notwithstanding anything to the contrary in the Agreement, where the Agreement provides for a defined length of time to adjust or request adjustment of the payment of a claim, Pharmacy, PBM and plan sponsor shall each have the same length of time to adjust or request adjustment of the payment of a claim. Ariz. Stat. § 20-3102(I).

Audit procedures; interest prohibition (Arizona Stat. § 20-3322)

A. The following procedures apply to an audit conducted by Prime:

1. When conducting an in-pharmacy audit, Prime shall:

(a) Give Pharmacy at least 14-day written notice.

(b) Not conduct an audit during the first five days of the month unless Pharmacy otherwise consents.

(c) Provide Pharmacy a list of items to be audited that provides for identification of prescription number or numbers or date range that Prime is seeking to audit.

(d) When conducting an in-pharmacy or desktop audit, limit the audit to claims that may not exceed two years from the date that the claim was adjudicated by the pharmacy benefit manager.

2. An in-pharmacy audit or desktop audit that involves clinical or professional judgment shall be conducted by or in consultation with a pharmacist.

3. The Pharmacy may use the records of a hospital, physician or other authorized practitioner to validate the pharmacy records. The validated records may be obtained via electronic methods, fax, phone or written prescription orders and do not have to be the original hard copy prescription order.

4. Each Pharmacy shall be audited under the same standards and parameters as other similarly situated pharmacies in this state.

B. When conducting an in-pharmacy audit or desktop audit, Prime shall comply with the following requirements:

1. Prime shall base a finding of overpayment or underpayment on the actual overpayment or underpayment and not on a projection based on the number of patients served who have similar diagnoses or on the number of similar orders or refills for similar drugs, unless required by federal or state law.

2. Prime may not recoup monies from the Pharmacy for any clerical errors identified in an audit.

3. Any finding of an overpayment may not include the dispensing fee amount unless any of the following criteria are met:

(a) A prescription was not received by the patient or the patient's designee.

(b) The prescriber denied authorization.

(c) The prescription dispensed was a medication error by the Pharmacy.

(d) The identified overpayment is based solely on an extra dispensing fee.

C. Interest may not accrue during the audit period.

Audit reports (Arizona Stat. § 20-3323)

A. Prime must deliver a preliminary audit report to the Pharmacy within 60 days after the conclusion of the audit.

B. A Pharmacy is allowed at least 30 days after receipt of the preliminary audit to provide documentation to address any discrepancy found in the audit.

C. Prime shall establish and make available to network Pharmacies a written appeals process that shall include a process to appeal, investigate and resolve disputes regarding final audit findings. A Pharmacy shall have at least 30 days from the delivery of the final audit findings to appeal an unfavorable audit finding to Prime. This written appeals process shall be included in all contracts between Prime and a network Pharmacy or Prime and a pharmacy's contracting representative.

D. Prime shall provide a telephone number at which a network Pharmacy may contact Prime and speak to someone who is responsible for processing appeals.

E. Prime must deliver a final audit report to the Pharmacy within 90 days after receipt of the preliminary audit report or final appeal, whichever is later.

F. Chargebacks, recoupment or other penalties may not be assessed until the appeals process has been exhausted and the final audit report has been issued.

G. Unless otherwise required by state or federal law, audit information may not be shared with any entity other than the insurer on whose behalf the audit was conducted. Auditors may have access only to previous audit reports on a particular Pharmacy conducted by Prime.

Applicability (Arizona Stat. § 20-3324)

A. Notwithstanding any other law, this article applies only to audits conducted of Pharmacies located in this state.

B. This article does not apply to claims reviews that are initiated within three business days after transmission of a claim in which no chargeback or recoupment is demanded.

C. This article does not apply to an audit conducted in which a suspicion of fraudulent activity or other intentional and willful misrepresentation is evidenced by physical review, review of claims data, statements or other investigative methods. The reason for an audit specified in this subsection shall be documented and available on request.

B-4 Arkansas Regulatory Addendum to Participating Pharmacy Agreement

This Arkansas Addendum applies to the extent that Pharmacy provides covered drugs to covered persons of health maintenance organization, hospital or medical service corporation, insurers or carriers under Arkansas law (collectively and/or individually, plan sponsor).

In the event of a direct conflict between this Addendum and the Agreement, the applicable provisions of this Addendum shall control if required. This Addendum may be modified from time to time pursuant to the Agreement.

Without limiting the generality of the foregoing, and notwithstanding anything in the Agreement to the contrary, Pharmacy agrees as follows:

To the extent Pharmacy provides covered drugs to covered persons of a health maintenance organization under Arkansas law, Pharmacy agrees:

In the event PBM and/or plan sponsor fails to pay for services as set forth in the Agreement, covered persons shall not be liable to Pharmacy for any sums owed by PBM and/or plan sponsor. Pharmacy, or its agent, trustee or assignee, shall not maintain an action at law against covered persons to collect sums owed by PBM and/or plan sponsor nor make any statement, either written or oral, to any covered person that makes demand for, or would lead a reasonable person to believe that a demand is being made for, payment of any amounts owed by PBM and/or plan sponsor. Arkansas Stat. §23-76-119(c)(1), (3)(A).

To the extent Pharmacy provides covered drugs to covered persons of an insurer under a minimum basic benefit policy, Pharmacy agrees that covered persons shall have no obligation to make payment for any medical service rendered by Pharmacy that is determined not to be medically necessary. Arkansas Stat. § 23-98-109(a)(3)(C)(i).

Pharmacy shall, without restriction or penalty, be free to disclose to covered persons any health care information that Pharmacy deems appropriate regarding the nature of treatment, risks or alternatives thereto, the availability of alternate therapies, consultations or tests, the decision of utilization reviewers or similar persons to authorize or deny services, the process that is used to authorize or deny health care services or benefits, or information on financial incentives and structures used by PBM and/or plan sponsor. Arkansas Stat. § 23-99-407.

In the event the Agreement is terminated, Pharmacy agrees to continue to provide covered drugs to covered persons until a current episode of treatment for an acute condition is completed or until the end of 90 days, whichever occurs first. During this period of continuing care, Pharmacy shall be deemed to be a participating provider for purposes of reimbursement, utilization management and quality of care and shall be bound by those corresponding provisions of the Agreement. Arkansas Stat. § 23-99-408.

A pharmacy may submit an administrative appeal up to 30 business days after a claim submission. Arkansas Stat. § 17-92-507

PBM will issue, mail or otherwise transmit payment with respect to a clean claim submitted by a pharmacy or a pharmacist:

(1) Seven to 14 days after the date of the receipt of a claim for an electronic claim; or

(2) Thirty days after the date of the receipt of a claim for any other paper or manually submitted claim. Arkansas Stat. § 23-92-512

Arkansas pharmacy audit Bill of Rights (Arkansas Stat. § 17-92-1201)

(b) Notwithstanding any other law, when an audit of the records of a Pharmacy is conducted by a managed-care company, an insurance company, a third-party payor, or any entity that represents responsible parties such as companies or groups, the audit shall be conducted in accordance with the following Bill of Rights:

(1) The entity conducting the initial on-site audit shall give the Pharmacy notice at least one week before conducting the initial on-site audit for each audit cycle;

(2) Any audit that involves clinical or professional judgment shall be conducted by or in consultation with a pharmacist;

(3) (A)(i) Any clerical or recordkeeping error, such as a typographical error, scrivener's error or computer error, regarding a required document or record shall not in and of itself constitute fraud;

(ii) However, a claim arising under subdivision (b)(3)(A)(i) of this section may be subject to recoupment.

(B) A claim arising under subdivision (b)(3)(A)(i) of this section is not subject to criminal penalties without proof of intent to commit fraud;

(4) A Pharmacy may use the records of a hospital, physician or other authorized practitioner of the healing arts for drugs or medicinal supplies written or transmitted by any means of communication for purposes of validating the pharmacy record with respect to orders or refills of a legend or narcotic drug;

(5)(A) A finding of an overpayment or underpayment may be a projection based on the number of patients served having a similar diagnosis or on the number of similar orders or refills for similar drugs.

(B) However, recoupment of claims under subdivision (b)(5)(A) of this section shall be based on the actual overpayment unless the projection for overpayment or underpayment is part of a settlement by the Pharmacy;

(6)(A) Where an audit is for a specifically identified problem that has been disclosed to the Pharmacy, the audit shall be limited to claims that are identified by prescription number

(B) For an audit other than described in subdivision (b)(6)(A) of this section, an audit shall be limited to 25 prescriptions that have been randomly selected.

(C) If an audit reveals the necessity for a review of additional claims, the audit shall be conducted on site;

(D) Except for audits initiated under subdivision (b)(6)(A) of this section, an entity shall not initiate an audit of a Pharmacy more than two times in a calendar year;

(7)(A) A recoupment shall not be based on:

(i) Documentation requirements in addition to or exceeding requirements for creating or maintaining documentation prescribed by the Arkansas State Board of Pharmacy; or

(ii)(a) A requirement that a Pharmacy or pharmacist perform a professional duty in addition to or exceeding professional duties prescribed by the Arkansas State Board of Pharmacy.

(b) This subdivision (b)(7) applies only to audits of claims submitted for payment on or after Jan. 1, 2012.

(B) Subdivisions (b)(7)(A)(i) and (ii) of this section do not apply in cases of United States Food and Drug Administration regulation or drug manufacturer safety programs;

(8) Recoupment shall only occur following the correction of a claim and shall be limited to amounts paid in excess of amounts payable under the corrected claim;

(9) Except for Medicare claims, approval of drug, prescriber or patient eligibility upon adjudication of a claim shall not be reversed unless the Pharmacy or pharmacist obtained the adjudication by fraud or misrepresentation of claim elements;

(10) Each Pharmacy shall be audited under the same standards and parameters as other similarly situated Pharmacies audited by PBM;

(11) A Pharmacy shall be allowed at least 30 days following receipt of the preliminary audit report in which to produce documentation to address any discrepancy found during an audit;

(12) The period covered by an audit shall not exceed 24 months from the date the claim was submitted to or adjudicated by a managed-care company, an insurance company, a third-party payor, or any entity that represents such companies or groups;

(13) Unless otherwise consented to by the Pharmacy, an audit shall not be initiated or scheduled during the first seven calendar days of any month due to the high volume of prescriptions filled during that time;

(14)(A) The preliminary audit report shall be delivered to the Pharmacy within 120 days after conclusion of the audit.

(B) A final audit report shall be delivered to the Pharmacy within six months after receipt of the preliminary audit report or the final appeal as provided for in subsection (c) of this section, whichever is later; and

(15) Notwithstanding any other provision in this subsection, the agency conducting the audit shall not use the accounting practice of extrapolation in calculating recoupments or penalties for audits.

(c) Recoupments of any disputed funds shall only occur after final internal disposition of the audit, including the appeals process as set forth in subsection (d) of this section.

(d)(1) Prime shall establish an appeals process under which a Pharmacy may appeal an unfavorable preliminary audit report to the entity.

(2) If, following the appeal, the entity finds that an unfavorable audit report or any portion of the unfavorable audit report is unsubstantiated, the entity shall dismiss the audit report or the unsubstantiated portion of the audit report without any further proceedings.

(e) Each entity shall provide a copy of the final audit report to the plan sponsor after completion of any review process.

(f)(1) The full amount of any recoupment on an audit shall be refunded to the responsible party.

(2) Except as provided in subdivision (f)(3) of this section, a charge or assessment for an audit shall not be based, directly or indirectly, on amounts recouped.

(3) Subdivision (f)(2) of this section does not prevent the entity conducting the audit from charging or assessing the responsible party, directly or indirectly, based on amounts recouped if both the following conditions are met:

(A) The responsible party and Prime have a contract that explicitly states the percentage charge or assessment to the responsible party; and

(B) A commission or other payment to an agent or employee of the entity conducting the audit is not based, directly or indirectly on amounts recouped.

(g) This section does not apply to any audit, review or investigation that involves alleged fraud, willful misrepresentation or abuse, including without limitation:

(1) Medicaid fraud as defined in Arkansas Stat. § 5-55-111;

(2) Abuse or fraud as defined in Arkansas Stat.§ 20-77-1702; or

(3) Insurance fraud.

(h) The Insurance Commissioner shall:

(1) Administer and enforce this subchapter; and

(2) Promulgate rules to implement the purposes and requirements of this subchapter.

B-5 California Regulatory Addendum to Participating Pharmacy Agreement

This California Addendum applies to the extent that Pharmacy provides covered drugs to covered persons of health care service plans, health maintenance organizations and insurers under California law.

In the event of a direct conflict between this Addendum and the Agreement, the applicable provisions of this Addendum shall control if required. This Addendum may be modified from time to time pursuant to the Agreement.

Without limiting the generality of the foregoing, and notwithstanding anything in the Agreement to the contrary, Pharmacy agrees as follows:

PBM shall not terminate the Agreement or otherwise penalize Pharmacy principally for advocating for appropriate health care. Cal. Bus. & Prof. Code § 510; Cal. Ins. Code § 10120.5.

PBM may sell, lease, transfer or convey to plan sponsors, including workers' compensation and automobile insurers, and other contracting agents, PBM's Pharmacy Network. PBM and plan sponsors actively encourage covered persons' use of Pharmacy Network providers by, among other things, providing information to covered persons in the form of provider directories, the use of toll-free telephone numbers and/or internet web site addresses supplied directly to covered persons advising them of the existence of the Pharmacy Network. Neither PBM nor plan sponsors shall be required to actively encourage covered persons to use network providers when obtaining medical care in the case of an emergency. Pharmacy acknowledges that it has received a summary of all plan sponsors currently eligible to utilize Pharmacy's contracted rate pursuant to the Agreement and shall hereafter be entitled to a summary within 30 calendar days of PBM's receipt of Pharmacy's written request. Upon execution of the Agreement and a subsequent renewal or amendment, Pharmacy may decline to be included in a network that is sold, leased, transferred or conveyed to plan sponsors that do not actively encourage the plan sponsor's covered persons to use network providers when obtaining medical care. Pharmacy's election under this provision shall be binding on PBM and any other contracting agent that buys, leases, or otherwise obtains the network. Pharmacy shall not be excluded from a network that is sold, leased,

transferred, or conveyed to plan sponsors that actively encourage their covered persons to use network providers when obtaining medical care, based upon Pharmacy's refusal to be included in a network that is sold, leased, transferred or conveyed to plan sponsors that do not actively encourage their covered persons to use network providers when obtaining medical care. Cal. Bus. & Prof. Code § 511.1(b); Cal. Health & Safety Code § 1395.6; Cal. Ins. Code § 10178.3.

In the event PBM sells, leases, or transfers its Pharmacy Network, the rights and obligations of Pharmacy shall be governed by the Agreement between PBM and Pharmacy. Cal. Bus. And Prof. Code § 511.3; Cal. Health & Safety Code § 1375.7(d)(1).

Pharmacy acknowledges that PBM has disclosed in an electronic or paper format: (a) information regarding claims processes including directions for the electronic transmission, physical delivery and mailing of claims, all claim submission requirements, instructions for confirming PBM's receipt of claims; and a phone number for claims inquiries and filing information; and (b) information regarding provider dispute processes, including the identity of the office responsible for receipt and resolution of disputes, directions for the electronic transmission, physical delivery, and mailing of disputes, all claim dispute requirements, the timeframe for acknowledgment of receipt of a dispute, the phone number for dispute inquiries and filing information and directions for filing substantially similar multiple claim disputes and other disputes.

Pharmacy acknowledges it has received in electronic form: (a) information as to the amount of payment Pharmacy shall receive for each service provided under the Agreement, including any fee schedules or other factors or units used in determining the fees for each service and (b) detailed payment policies and rules and nonstandard coding methodologies, if applicable, used to adjudicate claims. Pharmacy shall hereafter be provided information regarding fee schedules and reimbursement information annually on or before the Agreement's anniversary date and upon written request.

PBM shall provide at least 45 days prior written notice before instituting any changes, amendments or modifications in the disclosures made pursuant to this provision. Cal. Bus. & Prof. Code § 511.4; Cal. Ins. Code § 10133.66; 28 Cal. Code Reg. § 1300.71(l)-(o).

To the extent required by law, PBM or plan sponsor, as applicable, will disclose to Pharmacy the processes that PBM or plan sponsor, as applicable, uses in providing utilization review or utilization management functions to authorize, modify or deny health services under benefit plans provided by plan sponsors. Cal. Health & Safety Code §§ 1363.5, 1367.01(b).

To the extent PBM or a plan sponsor conducts economic profiling with respect to Pharmacy, to the extent required by law, PBM shall provide Pharmacy with economic profiling information related to Pharmacy upon Pharmacy's written request. To the extent required by law, PBM or plan sponsor, as applicable, shall honor such requests until 60 days after termination of the Agreement. Cal. Health & Safety Code § 1367.02(c); Cal. Ins. Code § 10123.36.

Notwithstanding anything to the contrary in the Agreement, including the Pharmacy Manual, Pharmacy shall have 90 days from the date of service to submit all claims for prescription drug benefits provided to eligible persons to PBM, except as required by any state or federal law or regulation. Cal. Ins. Code § 10133.66(a); 28 Cal. Code Reg. §1300.71(b)(1).

Nothing in the Agreement shall be construed to prohibit, restrict, or limit Pharmacy from advertising. PBM may, however, require that each advertisement contain a disclaimer that Pharmacy's services may be covered for some, but not all, benefit plans or plan sponsors utilizing PBM's services, and that benefit plans and plan sponsors may cover some, but not all of Pharmacy's services. This provision shall not prohibit or limit provisions in the Agreement intended to protect service marks, trademarks, trade secrets or other confidential information or property. Cal. Bus. & Prof. Code § 512; Cal. Health & Safety Code § 1395.5; Cal. Ins. Code § 10127.4.

Neither PBM nor plan sponsor shall make payment to Pharmacy directly, in any type or form, as an inducement to deny, reduce, limit or delay specific, medically necessary and appropriate services provided with respect to a covered person or groups of covered persons with similar medical conditions. Cal. Health & Safety Code § 1348.6; Cal. Ins. Code § 10175.5.

PBM values its relationships with contracted Pharmacies and strives to address and resolve pharmacy concerns efficiently, fairly and cost-effectively. Whenever possible, PBM resolves issues raised by Pharmacy at the time of the initial contact. However, if the issue cannot be resolved informally, PBM offers a process for Pharmacy to use to resolve its grievances. A description of PBM's pharmacy grievance process is set forth in the Provider Manual. Cal. Health & Safety Code § 1367(h)(1); Cal. Ins. Code § 10123.137. The pharmacy grievance process shall allow for a submission deadline of at least 365 days to the extent required by 28 Cal. Code Reg. § 1300.71.38(d).

If PBM and Pharmacy agree that Pharmacy shall accept, as payment under the Agreement, the lowest payment rate charged by Pharmacy to any patient or third party, that provision shall not be deemed to apply to, or take into consideration, any cash payments made to Pharmacy by individual patients who do not have any private or public form of health care coverage for the service rendered by Pharmacy. Cal. Health & Safety Code § 1371.22; Cal. Ins. Code § 10126.5.

Pharmacy shall adhere to regulations adopted by the California Department of Managed Health Care to assure covered persons have access to health services in a timely manner. Pharmacy agrees to provide reporting as directed by PBM to ensure compliance with timely access standards. Cal. Health & Safety Code § 1367.03(f)(1).

PBM shall neither request reimbursement for overpayment nor reduce the level of payment to Pharmacy based solely on the allegation that Pharmacy has entered into a contract with a licensed health care service plan for participation in a benefit plan approved by the California Department of Managed Health Care. Cal. Health & Safety Code §1371.2

Notwithstanding anything in the Agreement to the contrary, PBM, plan sponsor, and Pharmacy are each responsible for their own acts or omissions and are not liable for the acts or omissions of, or the costs of defending, each other. Nothing in this provision shall preclude a finding of liability based on the doctrines of equitable indemnity, comparative negligence, contribution or other statutory or common law bases for liability. Cal. Health & Safety Code § 1371.25.

If PBM terminates the Agreement for reasons other than medical disciplinary cause, fraud or criminal activity, Pharmacy agrees, upon request, to continue to provide covered drug services to covered persons who at the time of the Agreement's termination were receiving services from Pharmacy for the following conditions: (a) an acute condition; (b) a serious chronic condition; (c) a pregnancy; (d) a terminal illness; (e) the care of a newborn child between birth and 36 months; or (f) performance of a procedure that is authorized by plan sponsor to occur within 180 days of the Agreement's termination.

For purposes of this provision, an acute condition is a medical condition that involves a sudden onset of symptoms due to an illness, injury or other medical problem that requires prompt medical attention and that has a limited duration. Pharmacy shall continue to provide covered drugs for the duration of the acute condition.

A serious chronic condition is a medical condition due to a disease, illness or other medical problem or medical disorder that is serious in nature and that persists without full cure or worsens over an extended period of time or requires ongoing treatment to maintain remission or prevent deterioration. Pharmacy shall continue to provide covered drugs to a covered person with a serious chronic condition for the period of time necessary to complete a course of treatment and to arrange for the safe transfer to another provider, as determined by PBM and plan sponsor in consultation with the covered person and Pharmacy, and consistent with good professional practice. Continued services for a serious chronic condition shall not exceed 12 months from the date the Agreement was terminated or 12 months from the effective date of coverage for a newly covered individual.

A pregnancy refers to the three trimesters of pregnancy and the immediate postpartum period. Pharmacy shall continue to provide covered drugs for the duration of a covered person's pregnancy.

A terminal illness means an incurable or irreversible condition that has a high probability of causing death within one year or less. Pharmacy shall continue to provide covered drugs for the duration of a covered person's terminal illness, which may exceed 12 months from termination of the Agreement.

Pharmacy shall continue to provide covered drugs for the care of a newborn child between birth and 36 months for a period not to exceed 12 months from the Agreement's termination.

Pharmacy shall complete a procedure that is authorized by PBM or plan sponsor as part of a documented course of treatment and has been recommended and documented by Pharmacy to occur with 180 days of the Agreement's termination.

Pharmacy agrees that in rendering covered drugs during the continuation periods outlined above, Pharmacy shall be subject to the same contractual terms and conditions that were imposed upon Pharmacy prior to termination of the Agreement, including reimbursement rates.
Cal. Health & Safety Code § 1373.96; Cal. Ins. Code § 10133.56

Upon termination of the Agreement, plan sponsor shall be liable under the same contractual terms and conditions in effect prior to termination for covered drugs rendered by Pharmacy to a covered person who retains eligibility under the benefit plan or by operation of law under the care of Pharmacy at the time of termination until the services being rendered to the covered person by Pharmacy are completed, unless PBM or plan sponsor makes reasonable and medically appropriate provision for the assumption of such services by a participating provider. 10 Cal. Code Reg. § 2240.2(d); 28 Cal. Code Reg. § 1300.67.4(10); 1300.67.8(e).

Pharmacy acknowledges that covered persons' copays, when based upon a percentage of the fee for services rendered, shall be calculated exclusively from the negotiated rate under the Agreement. Pharmacy shall not charge or collect copay amounts greater than those calculated in accordance with this provision. Cal. Health & Safety Code § 1373.18; Cal. Ins. Code §§ 10133.2, 10133.3.

PBM shall not require that in-person contact occur between Pharmacy and covered persons before payment is made for covered drugs appropriately provided through telehealth as that term is defined in subdivision (a) of Section 2290.5 of the California Business and Professions Code and provided all other terms and conditions imposed by the Agreement and by plan sponsor are met. Cal. Health & Safety Code § 1374.13; Cal. Ins. Code § 10123.85.

Except for applicable copays and deductibles, Pharmacy shall not invoice or balance bill a covered person for the difference between Pharmacy's billed or customary charges and the reimbursement paid by plan sponsor or PBM for any covered drug. Pharmacy agrees that in the event PBM or plan sponsor fails to pay for covered drugs, the covered person shall not be liable to Pharmacy for any sums owed by PBM or plan sponsor. Neither Pharmacy nor its agent, trustee or assignee may maintain any action at law against a covered person to collect sums owed by PBM or plan sponsor. Cal. Health & Safety Code §§1358.10(e)(1)(E); 1379; 28 Cal. Code Reg. § 1300.67.8(e), 1300.71(g)(4).

Pharmacy shall report to PBM all surcharge and copay moneys paid by covered persons directly to Pharmacy. Cal. Health & Safety Code § 1385.

In the event of the insolvency of PBM or plan sponsor, Pharmacy agrees to continue to provide covered drugs to covered persons until the effective date of a covered person's coverage in a successor plan pursuant to either open enrollment or the allocation process but in no event longer than 45 days in the event of allocation or 30 days in the case of open enrollment, whichever is greater. Cal. Health & Safety Code §§1394.7(e), 1394.8(e).

Nothing in the Agreement shall be construed to require Pharmacy to accept additional patients if, in Pharmacy's reasonable professional judgment, accepting additional patients would endanger patients' access to, or continuity of, care. Cal. Health & Safety Code § 1375.7(b)(2); Cal. Ins. Code § 10133.65(b)(1).

Pharmacy shall be required to comply with any quality improvement or utilization management programs or procedures of PBM or plan sponsor provided that such programs and procedures were disclosed to Pharmacy at least 15 days prior to Pharmacy's execution of the Agreement. PBM and plan sponsor may, however, make a change to the quality improvement or utilization management programs or procedures at any time if the change is necessary to comply with state or federal law or regulations or any accreditation requirements of a private sector accreditation organization, subject to the provisions of the paragraph immediately below. Cal. Health & Safety Code § 1375.7(b)(3); Cal. Ins. Code § 10133.65(b)(2).

PBM may make material changes to the Agreement upon at least 45 business days' prior notice of the change to Pharmacy. Pharmacy shall have the right to terminate the Agreement prior to implementation of the change. Cal Health & Safety Code § 1375.7(b); Cal. Ins. Code § 10133.65(c). Notwithstanding the foregoing, if the Agreement provides benefits to enrollees or subscribers covered under the Medi-Cal or Healthy Families Program, PBM may make a material change to the Agreement if: (i) Pharmacy is given a minimum of 90 business days' notice of the change; (ii) Pharmacy has the right to negotiate and agree to the change within 30 business days of the notice; (iii) Pharmacy may terminate the Agreement within 90 business days from receipt of the notice; and (iv) The material change becomes effective 90 business days from the date of the notice if Pharmacy does not exercise its right to negotiate the change or to terminate the Agreement. Cal. Health & Safety Code § 1375.7(b)(1)(C).

Pharmacy shall maintain and retain for at least two years such records and provide such information to PBM and plan sponsor and to the director of the California Department of Managed Health Care as may be necessary to demonstrate compliance by plan sponsor with California law. This provision survives termination of the Agreement, whether by rescission or otherwise. 28 Cal. Code Reg. § 1300.67.8(b).

Appendix B: Regulatory addendums (continued)

The respective directors of the California Department of Managed Health Care and Department of Insurance may request information from Pharmacy required under Article 6.2, Chapter 2.2, Division 2 of the Health and Safety Code, under Article 4.5, Chapter 1, Part 2, Division 2 of the California Insurance Code, or under the Patient Protection and Affordable Care Act. Cal. Health & Safety Code § 1385.05; Cal. Ins. Code § 10181.5.

Upon demand, Pharmacy shall grant PBM and plan sponsor access at reasonable times to the books, records and papers of Pharmacy relating to the services provided to covered persons, to the cost thereof, and to payments received by Pharmacy from covered persons (or from others on their behalf). 28 Cal. Code Reg. § 1300.67.8(c).

Nothing in the Agreement shall be construed to require Pharmacy to permit access to patient information in violation of federal or state laws concerning patient information. Cal. Health & Safety Code § 1375.7(b)(5).

Nothing in the Agreement shall be construed to require Pharmacy to waive any provision of Division 2, Chapter 2.2 of the California Health & Safety Code, or sections 1300.71, 1300.71.38, 1300.71.4, and 1300.77.4 of Title 28 of the California Code of Regulations relating to claims processing and payment. Cal. Health & Safety Code § 1375.7(b)(4); 28 Cal. Code Reg. § 1300.71(p).

Pharmacy agrees that nothing in the Agreement as presented to Pharmacy required or permitted Pharmacy to assume financial risk for the following items: (a) injectable chemotherapeutic medications and injectable adjunct pharmaceutical therapies for side effects; (b) injectable medications or blood products used for hemophilia; (c) injectable medications related to transplant services; (d) adult vaccines; (e) self- injectable medications; or (f) injectable medication or medication in an implantable dosage form costing more than $250 per dose. To assume financial risk for the above listed items, Pharmacy must request to do so in writing at the time of negotiating or renewing the Agreement. Cal. Health & Safety Code § 1375.8.

Pharmacy shall not collect surcharges for covered drugs. If PBM or plan sponsor receives notice of any such surcharge, it shall take appropriate action as provided under the Agreement. 28 Cal. Code Reg. § 1300.67.8(d).

To the extent required by law, Pharmacy shall display in a prominent place in each patient reception and waiting area a notice informing covered persons how to contact plan sponsor, file a complaint with plan sponsor, obtain assistance from the Department of Managed Health Care, and seek an independent medical review. The notice shall be in the form and displayed in the manner required by law.

Informational notices explaining how enrollees may contact their plan, file a complaint with their plan, obtain assistance from the Department, and seek an independent medical review are available in non-English languages through the Department of Insurance's website. The notice and translations can be obtained online at **HMOHelp.CA.gov** for downloading and printing. In addition, hard copies may be requested by submitting a written request to: Department of Managed Health Care, Attention: HMO Help Notices, 980 9th Street, Suite 500, Sacramento, California 95814. 28 Cal. Code Reg. § 1300.67.04 (c)(2)(D)(ii).

Pharmacy shall comply with each plan's language assistance program standards, as communicated to Pharmacy in writing from time to time and shall cooperate with PBM and plan sponsor by providing any information necessary to assess compliance. Cal. Health & Safety Code § 1367.04(f);10 Cal. Code Reg. § 2538.3(d); 28 Cal. Code Reg. §§ 1300.67.04(c)(2)(E) and 1300.67.04(e)(4).

Pharmacy agrees that if its retail price for a prescription drug is less than a covered person's copay, Pharmacy shall charge covered person no more than the retail price. 28 Cal. Code Reg. § 1300.67.24(c)(1).

Pharmacy shall not make any additional charges for rendering services provided pursuant to the Agreement except as provided for in the covered person's agreement with the plan sponsor. Cal. Admin. Code tit. 10, § 2240.4(b).

Pharmacy's primary consideration shall be the quality of services rendered to covered persons. Cal. Admin. Code tit. 10, § 2240.4(b).

Pharmacy shall not discriminate against any covered person on the basis of sex, marital status, sexual orientation, race, color, religion, ancestry, national origin, disability, health status, health insurance coverage, utilization of medical or mental health services or supplies, or other unlawful basis including without limitation, the filing by such covered person of any complaint, grievance or legal action against Pharmacy. Cal. Admin. Code tit. 10, § 2240.4(b).

To the extent Pharmacy is expressly authorized under this agreement to provide mail order pharmacy services, Pharmacy shall provide such services in compliance with the requirements of the Knox-Keene Act and applicable California and federal laws regarding pharmacists and pharmacy services. Such pharmacy's processes shall conform effectively and efficiently with PBM and/or a plan sponsor's processes, as applicable, for prior authorization for coverage of medically necessary drugs as required by the Knox-Keene Act. Such Pharmacy shall timely deliver such services via mail order to the covered person and shall promptly inform PBM in writing if and when it fails to meet timely delivery standards. 28 Cal. Code Reg. § 1300.67.24(b)(4).

Pharmacy shall comply with all state and federal recordkeeping and reporting requirements, including providing documentation to the patient's primary care provider and entering information in the appropriate immunization registry designated by the immunization branch of the State Department of Public Health. If the Agreement provides benefits to enrollees or subscribers covered under the Medi-Cal Program, Pharmacy will ensure that recipient-specific immunization information is periodically reported to the California Immunization Registry (CAIR) for both children and adults. Reports shall be made following the recipient's initial health assessment and all other health care visits which result in an immunization being provided. Cal. Bus. & Prof. Code § 4052.8.

Pharmacy has the right to submit complaints to the California Department of Managed Health Care regarding practices pursuant to this agreement. Cal. Health & Safety Code § 1371.39.

Audits exempt from chapter provisions (Cal. Bus. & Prof. Code § 4431 - Division 2 Healing Arts, Chapter 9.5 Audits of Pharmacy Benefits)

a) Nothing in this chapter shall apply to an audit conducted because PBM, a carrier, health benefit plan sponsor or other third-party payer has indications that support a reasonable suspicion that criminal wrongdoing, willful misrepresentation, fraud or abuse has occurred.

b) Nothing in this chapter shall apply to an audit conducted by, or at the direction of, the California State Board of Pharmacy, the State Department of Health Care Services, the State Department of Public Health or the Medicare program.

Payment or compensation not to be tied to amounts claimed or recovered; clerical errors (Cal. Bus. & Prof. Code § 4433)

(a) An entity conducting a pharmacy audit shall not receive payment or any other consideration on any basis that is tied to the amount claimed or actual amount recovered from the pharmacy that is the subject of the audit. Nothing in this subdivision shall be construed to prevent PBM or health benefit plan from charging or assessing the plan sponsor, directly or indirectly, based on amounts recouped if both of the following conditions are met:

(1) The plan sponsor and PBM or health benefit plan have a contract that explicitly states the percentage charge or assessment to the plan sponsor.

(2) No commission or financial incentive is paid to an agent or employee of the entity conducting the pharmacy audit based, directly or indirectly, on amounts recouped.

(b) A Pharmacy shall not be subject to recoupment of funds for a clerical or recordkeeping error, unless the error resulted in actual financial harm to PBM, the carrier, or the beneficiary of a health benefit plan.

Confidentiality of information collected; entities conducting audits on behalf of carriers or managers; notice; list of records reviewed (Cal. Bus. & Prof. Code § 4434)

a) Except as otherwise prohibited by state or federal law, an entity conducting a pharmacy audit shall keep confidential any information collected during the course of the audit and shall not share any information with any person other than the carrier, PBM or third-party payer for which the audit is being performed. An entity conducting a pharmacy audit shall have access only to previous audit reports relating to a particular Pharmacy conducted by or on behalf of the same entity. Nothing in this subdivision shall be construed to authorize access to information that is otherwise prohibited by law. Nothing in this subdivision shall be construed to prohibit any employer, trust fund, government agency or any other entity for which the audit is being performed from disclosing its general opinions or conclusions regarding the business practices of the Pharmacy based on the audit.

b) An entity that is not a carrier or PBM and that is conducting a pharmacy audit on behalf of a carrier or PBM shall, prior to conducting the audit, notify the Pharmacy in writing that the entity and the carrier or PBM have executed a business associate agreement or other agreement as required under state and federal privacy laws.

c) An entity conducting a pharmacy audit shall, prior to leaving a Pharmacy at the end of an onsite portion of the audit, provide the Pharmacist-in-Charge with a complete list of records reviewed to allow the Pharmacy to account for disclosures as required by state and federal privacy laws.

Audit scheduling; notice of initial audit (Cal. Bus, & Prof. Code § 4435)

a) An entity conducting an onsite pharmacy audit shall not initiate or schedule a pharmacy audit during the first five business days of any calendar month, unless it is expressly agreed to by the Pharmacy being audited.

b) An entity conducting an onsite pharmacy audit shall provide the Pharmacy at least two weeks' prior written notice before conducting an initial audit.

Pharmacists to conduct audits; determinations regarding prescription validity; signature logs (Cal. Bus. & Prof. Code § 4436)

a) A pharmacy audit that involves clinical judgment shall be conducted by, or in consultation with, a licensed pharmacist.

b) An entity conducting a pharmacy audit shall make all determinations regarding the legal validity of a prescription or other record consistent with determinations made pursuant to Article 4 (commencing with Section 4070) of Chapter 9.

c) Nothing in this section shall be construed to prohibit PBM from denying a claim, either in whole or in part, for failure to comply with federal Food and Drug Administration or manufacturer requirements, the prescription drug formulary, prior authorization requirements, days' supply requirements, or other coverage or plan design requirement, or for failure to include a National Provider Identification number.

d) An entity conducting a pharmacy audit shall accept paper or electronic signature logs that document the delivery of pharmacy services to a health plan beneficiary or his or her agent.

Time periods covered by audits (Cal. Bus. & Prof. Code § 4437)

The time period covered by a pharmacy audit shall not exceed 24 months from the date that the claim was submitted to, or adjudicated by, PBM, unless a longer period is required under state or federal law or unless the originating prescription is required.

Preliminary audit reports; opportunity to respond; evidence; final audit reports; appeal; further relief; chargebacks or recoupment; no interest accrual; dismissal of unsubstantiated reports (Cal. Bus. & Prof. Code § 4438)

(a)(1) An entity conducting a pharmacy audit shall deliver a preliminary audit report to the Pharmacy before issuing a final audit report. This preliminary report shall be issued no later than 60 days after conclusion of the audit.

(2) A Pharmacy shall be provided a time period of at least 30 days following receipt of the preliminary audit report under paragraph (1) to respond to the findings in the report, including addressing any alleged mistakes or discrepancies and producing documentation to that effect.

(3) To validate the pharmacy record and delivery, the Pharmacy may use authentic and verifiable statements or records, including medication administration records of a nursing home, assisted living facility, hospital, physician and surgeon, or other authorized prescriber, or additional documentation parameters located in the Provider Manual.

(4) Any legal prescription may be used to validate claims in connection with prescriptions, refills or changes in prescriptions, including medication administration records, facsimiles, electronic prescriptions, electronically stored images of prescriptions, electronically created annotations, or documented telephone calls from the prescriber or the prescriber's agent. Unless specifically addressed in the audit policies and procedures contained in the contract or Manual, documentation of an oral prescription order that has been verified by the prescriber shall meet the requirements of this subdivision.

(5) If an entity conducting a pharmacy audit uses extrapolation to calculate penalties or amounts to be recouped, the Pharmacy may present evidence to validate orders for dangerous drugs or devices that are subject to invalidation due to extrapolation.

(6) Prior to issuing a final audit report, an entity conducting a pharmacy audit shall take into consideration any response by the Pharmacy to the preliminary audit report provided within the timeframes allowed under this section, unless otherwise agreed to by the entity conducting the audit.

(b)(1) An entity conducting a pharmacy audit shall deliver a final audit report to the Pharmacy no later than 120 days after receipt of a Pharmacy's response to the preliminary audit report.

(2) An entity conducting a pharmacy audit shall establish, in the contract between the Pharmacy and the contracting entity, a process for appealing the findings in a final audit report that complies with the following requirements:

A) A Pharmacy shall be provided a time period of at least 30 days following receipt of the final audit report to file an appeal with the entity identified in the appeal process.

B) An entity conducting a pharmacy audit shall provide the Pharmacy with a written determination of appeal issued by the entity identified in the appeal process, which shall be appended to the final audit report, and a copy of the determination shall be sent to the carrier, health benefit plan sponsor or other third-party payer.

C) If, following the appeal, either party is not satisfied with the appeal, the party may seek relief under the terms of the contract.

- An entity conducting a pharmacy audit a carrier, a health benefit plan sponsor, or other third-party payer, or any person acting on behalf of those entities, shall not attempt to make chargebacks or seek recoupment from a Pharmacy, or assess or collect penalties from a Pharmacy, until the time period for filing an appeal to a final audit report has passed, or until the appeal process has been exhausted, whichever is later. Should the identified discrepancy for a single audit exceed $30,000, future payments to the Pharmacy in excess of $30,000 may be withheld pending adjudication of an appeal.

Appendix B: Regulatory addendums (continued)

d) Interest shall not accrue during the audit period for either party, beginning with the notice of the audit and ending with the conclusion of the appeal process.

e) If, following final disposition of a pharmacy audit pursuant to this section, an entity conducting a pharmacy audit — a carrier, a health benefit plan sponsor, or other third-party payer, or any person acting on behalf of those entities — finds that an audit report or any portion thereof is unsubstantiated, the entity shall dismiss the audit report or the unsubstantiated portion thereof without the necessity of any further proceedings.

B-6 Colorado Regulatory Addendum to Pharmacy Participation Agreement

This Colorado Addendum applies to the extent that Pharmacy provides covered drugs to covered persons of insurers, carriers, health maintenance organizations and managed care plans under Colorado law (collectively and/or individually, "plan sponsor").

In the event of a direct conflict between this Addendum and the Agreement, the applicable provisions of this Addendum shall control if required. This Addendum may be modified from time to time pursuant to the Agreement.

Without limiting the generality of the foregoing, and notwithstanding anything in the Agreement to the contrary, Pharmacy agrees as follows:

Neither Pharmacy, plan sponsor, nor PBM shall be prohibited from protesting or expressing disagreement with a medical decision, medical policy or medical practice of the other. Colo. Stat. § 10-16-121(1)(a); 3 CCR 702-4:4-2-15(A)(1).

Neither plan sponsor nor PBM shall terminate the Agreement with Pharmacy because Pharmacy expresses disagreement with a decision by plan sponsor or PBM to deny or limit benefits to a covered person or because Pharmacy assists a covered person to seek reconsideration of the decision or because Pharmacy discusses with a current, former or prospective patient any aspect of the patient's medical condition, any proposed treatments or treatment alternatives, whether covered by a benefit plan or not, policy provisions of a benefit plan, or Pharmacy's recommendation regarding selection of a benefit plan based on Pharmacy's knowledge of the health needs of such patients. Colo. Stat. § 10-16-121(1)(b)(I); 3 CCR 702-4:4-2-15(A)(3).

Pharmacy shall not be subject to financial disincentives based on the number of referrals made to participating providers in the benefit plan for covered benefits so long as Pharmacy adheres to the utilization review policies and procedures of plan sponsor and PBM. Colo. Stat. § 10-16-121(d).

Pharmacy shall hold covered persons harmless for money owed to Pharmacy by plan sponsor or PBM. In no circumstance shall covered persons be liable to Pharmacy for money owed to Pharmacy by plan sponsor or PBM. In no event, including, but not limited to, nonpayment by plan sponsor or PBM, insolvency of plan sponsor or PBM, or breach of the Agreement, shall Pharmacy bill, charge, collect a deposit from, seek compensation, remuneration or reimbursement from, or have any recourse against covered persons or persons (other than plan sponsor or PBM) acting on their behalf for services provided pursuant to the Agreement. This provision does not prohibit Pharmacy from collecting coinsurance, deductibles, copays or fees for noncovered services delivered on a fee-for-service basis to covered persons. Pharmacy agrees that this provision shall survive termination of the Agreement, for covered drugs rendered prior to termination of the Agreement, regardless of the cause giving rise to termination and shall be construed to be for the benefit of covered persons. This provision is not intended to apply to services provided after the Agreement has terminated. Pharmacy agrees that this provision supersedes any oral or written contrary agreement now existing or hereafter entered into between Pharmacy and covered persons or persons acting on their behalf insofar as such contrary agreement relates to liability for payment of services provided under the terms and conditions of the Agreement. Any modification, addition, or deletion to this provision shall become effective on a date no earlier than 30 days after the Colorado Commissioner of Insurance has received written notification of proposed changes.
Colo. Stat. § 10-16-705(3); 3 CCR 702-4:4-7-1 § 12.

Adjustments to claims by Pharmacy, PBM or plan sponsor shall be made as set out in the Agreement provided, however, that to the extent required by law, Pharmacy shall be afforded the same time period as PBM and plan sponsor for making adjustments to claims and provided further that the time period for adjustments to claims shall not exceed 12 months after the date of the original explanation of benefits except as otherwise required or permitted by law. Colo. Stat. § 10-16-704(4.5)(b).

If the Agreement provides for a duration of less than two years, Pharmacy and PBM shall provide 90 days' advance written notice to each other before terminating the Agreement without cause. If the Agreement provides for a duration of greater than two years, Pharmacy and PBM shall provide 60 days' advance written notice to each other before terminating the Agreement without cause. Within 15 working days of receipt from or issuance to Pharmacy of a notice of termination, PBM shall make a good faith effort to give written notice of the termination to all covered persons that are seen regularly by Pharmacy. Within five working days after Pharmacy either gives or receives notice of termination, Pharmacy shall provide PBM with a list of Pharmacy's patients that are covered persons under plan sponsors' benefit plans. Colo. Stat. §§ 10-16-705(7), 25-37-111(2).

Pharmacy shall not assign or delegate rights and responsibilities under the Agreement without prior written consent. Colo. Stat. § 10-16-705(8).

Pharmacy shall not discriminate, with respect to the provision of medically necessary covered drugs, against covered persons that are participants in a publicly financed program. Colo. Stat. § 10-16-705(9).

Pharmacy agrees that the sole responsibility for obtaining any necessary preauthorization rests with Pharmacy or the participating provider that recommends or orders particular services, treatments or procedures and not with covered persons. Colo. Stat. § 10-16-705(14).

To the extent any definitions or provisions of the Agreement conflict with definitions or provisions contained in benefit plans or contained in Colorado Revised Statute, Title 10, Article 16, Part 7, the definitions, or provisions of the Agreement shall not control. Colo. Stat. § 10-16-705(15).

Pharmacy agrees that plan sponsor shall have the right to approve or disapprove Pharmacy's participation status in plan sponsor's network. Colo. Stat. § 10-16-706(4).

Pharmacy agrees that in the event of PBM's insolvency, plan sponsor shall have the right to require the assignment to plan sponsor of the provisions of the Agreement addressing Pharmacy's obligation to furnish covered drugs. Colo. Stat. § 10-16-706(9).

In the event PBM makes a material change to the Agreement, as defined by Colorado Revised Statute, section 25-37-102, PBM shall provide Pharmacy a written notice of the proposed change conspicuously entitled "Notice of Material Change to Contract" at least 90 days before the effective date of the change. If Pharmacy objects to the change, Pharmacy must notify PBM in writing of the objection within 15 days of the date of the notice. If PBM and Pharmacy are unable to resolve the objection, either party may terminate the Agreement upon written notice of termination provided to the other not later than 60 days before the effective date of the material change. If Pharmacy does not object to the material change as provided herein, the change shall be effective as specified in the notice. Colo. Stat. § 25-37-104.

In the event Pharmacy timely objects in writing to a notice of material change to the Agreement that seeks to add a new category of coverage, as defined by Colorado Revised Statute, section 25-37-102, the addition of the category of coverage shall not be effective as to Pharmacy, and PBM shall not terminate the Agreement based on Pharmacy's objection to the addition of the category of coverage. Colo. Stat. § 25-37-104(4).

PBM may make an administrative change to the Agreement, as defined by Colorado Revised Statute section 25-37-102, and such change shall be effective upon at least 15 days' notice to Pharmacy. Colo. Stat. § 25-37-102(9)(c).

The agreement may be modified by operation of law as required by any applicable state or federal law or regulation and PBM may disclose this change by any reasonable means. Colo. Stat. § 25-37-105.

Appendix B: Regulatory addendums (continued)

Pharmacy acknowledges and agrees that PBM may assign, allow access to, sell, rent or give its rights to Pharmacy's services to (1) plan sponsors providing coverage for covered drugs to their employees or members when such plan sponsors have contracted with PBM for the administration or processing of claims for payment or service provided pursuant to the Agreement and (2) affiliates, subsidiaries, or entities under common ownership or control of PBM or third parties providing or receiving administrative services from PBM or its affiliates, subsidiaries or entities under common ownership or control with PBM. Pharmacy acknowledges and agrees that the Agreement applies to network rental arrangements and that it is for the purpose of assigning, allowing access to, selling, renting or giving PBM's rights to Pharmacy's services. Colo. Stat. § 25-37-108.

Nothing in the Agreement shall be construed or shall operate to require that Pharmacy waive or forego any right or benefit to which Pharmacy may be entitled under state or federal law or regulation that provides legal protections to a person solely based on the person's status as a health care provider providing services in Colorado. Colo. Stat. § 25-37-109.

Upon 60 days' written notice to PBM that states the reasons therefore, Pharmacy may decline to provide services under the Agreement to covered persons that are "new patients." For purposes of this paragraph, "new patients" means those patients who have not received services from Pharmacy in the immediately preceding three years. A patient shall not become a new patient solely by changing coverage from one plan sponsor or benefit plan to another plan sponsor or benefit plan. Colo. Stat. § 25- 37-110.

The agreement shall terminate automatically in the event the federal Drug Enforcement Administration (DEA) or other federal law enforcement agency ceases the operations of the Pharmacy or its pharmacist due to alleged or actual criminal activity. Colo. Stat. § 25-37-111(3).

Nothing in the Agreement shall be construed to preclude use or disclosure of the Agreement to a third-party for the purpose of enforcing the provisions of Title 25, Article 37 of Colorado Revised Statutes or other state or federal law provided the third-party shall be bound by the confidentiality requirements set forth in the Agreement and required by law. Colo. Stat. § 25-37-112.

Consistent with all state and federal statutes and regulations, Pharmacy agrees to share medical record information with other participating providers who have treated the same enrollee to facilitate the continuity of health care services. 3 CCR 702-4:4-7-03, Section 6(F).

To the extent provisions in the Agreement concerning provider disputes directly conflict with the provider-carrier dispute resolution process set forth in Colorado Insurance Regulation 4-2-23, the provisions in Regulation 4-2-23 shall control. 3 CCR 702-4:4-2-23.

The following shall apply with respect to PBM's maximum allowable cost (MAC) lists:

Information regarding PBM MAC list are available to pharmacy locations in Colorado subject to such MAC lists. Pharmacy locations in Colorado can contact **MACAppeals@PrimeTherapeutics.com** for information on PBM's MAC lists.

Pharmacy locations in Colorado subject to PBM's MAC lists may appeal reimbursement for a drug subject to maximum allowable cost pricing. Pharmacy locations in Colorado can initiate an appeal within 21 calendar days of the Pharmacy submitting the claim for which the appeal is being requested by submitting an email to **MACAppeals@PrimeTherapeutics.com** detailing the challenge to the PBM maximum allowable cost, along with supporting information and/or documentation. Pharmacy may call **612.777.2532** to speak to an individual who is responsible for processing appeals. PBM will investigate and respond to any such appeal within 21 days.

If the appeal is denied, PBM will provide the challenging Pharmacy with the reason for the denial and the National Drug Code of a drug that may be purchased by the Pharmacy at a price that is equal to or less than the maximum allowable cost.

If the appeal is upheld, PBM will make the change in the maximum allowable cost within one day after the date of determination, and Pharmacy can then reverse and rebill the claim in question.

This Section 25: (i) applies only with respect to MAC lists owned and/or controlled by PBM; and (ii) does not apply to MAC lists utilized by the state medical assistance program.

Colo. Stat. § 10-16-122.6.

After the date PBM receives a clean claim submitted by Pharmacy, PBM shall not retroactively reduce payment on the claim after the point of sale (POS) except as the result of an audit (although PBM may retroactively increase a payment to Pharmacy pursuant to a written agreement between PBM and Pharmacy, as well as make adjustments to claims in the case of a clerical error). Colo. Stat. 10-16-122.3(2)(a)-(b). A "clean claim" means a claim that has no defect or impropriety, including any lack of required substantiating documentation or particular circumstance requiring special treatment that prevents timely payment from being made on the claim (it does not include a claim based on fraud, waste, or abuse). Colo. Stat. 10-16-122.3(6)(b).

Pharmacy benefit manager — Audit of Pharmacies — Time limits on on-site audits (Colorado Stat. § 10-16-122.5)

1) A PBM, a carrier or an entity acting on behalf of a PBM, or a carrier that audits a pharmacy shall:

a) Give the Pharmacy at least seven days' written notice prior to commencing an audit;

b) Conduct the audit by or in consultation with a licensed pharmacist to the extent the audit requires the application of clinical or professional judgment

c) Not use extrapolation or other statistical expansion techniques in calculating the amount of a recoupment or penalty resulting from an audit of a Pharmacy;

d) Allow the Pharmacy to produce additional claims documentation using any commercially reasonable method, including facsimile, mail or electronic claims submission, if an audit results in the dispute or denial of a claim;

e) Establish a written appeals process that includes procedures to allow a Pharmacy to appeal to PBM or the carrier the preliminary reports resulting from the audit and any resulting recoupment or penalty; and

f) Not subject a Pharmacy to the recoupment of funds when an audit results in the identification of a clerical error in a required document or record unless the error results in actual financial harm to PBM, a health benefit plan providing prescription drug benefits that are managed by PBM, or a consumer.

2) A Pharmacy may use verifiable statements or records, including medication administration records of a nursing home, assisted living facility, hospital, physician or other authorized practitioner, to validate the pharmacy record and delivery.

3) Any legal prescription may be used to validate claims in connection with prescriptions, refills or changes in prescriptions, including medication administration records, faxes, electronic prescriptions or documented telephone calls from the prescriber or the prescriber's agent.

4) The time period covered by an audit may not exceed 24 months from the date that the prescription was submitted to or adjudicated by the entity, unless a longer period is required by state or federal law.

5) The time periods specified are waived for audits of pharmacy records when fraud or other intentional or willful misrepresentation is indicated through review of claims data, statements, physical review or other investigative methods. The PBM, carrier or entity acting on behalf of the PBM or carrier shall deliver to the Pharmacy at the time of the audit a written or verbal explanation of the information that led to the conclusion that there is an indication of fraud or other intentional or willful misrepresentation. The explanation is not required if law enforcement has intervened due to the indication of fraud.

Appendix B: Regulatory addendums (continued)

5.5) Except under circumstances specified in subsection (5) of this section, on or after July 6, 2021, a PBM, a carrier, or an entity acting on behalf of a PBM or a carrier shall not conduct an on-site audit of a Pharmacy for which the PBM, carrier or entity acting on behalf of a PBM or a carrier has conducted an on-site audit within the immediately preceding 12 months.

6) As used in this section, "Pharmacy" includes any entity authorized under article 280 of title 12 to dispense prescription drugs.

B-7 Connecticut Regulatory Addendum to Pharmacy Participating Agreement

This Connecticut Addendum applies to the extent that Pharmacy provides covered drugs to covered persons of a health care center, health maintenance organization, managed care organization ("MCO"), insurer or carrier licensed under Connecticut law (collectively and/or individually, "plan sponsor").

In the event of a direct conflict between this Addendum and the Agreement, the applicable provisions of this Addendum shall control if required. This Addendum may be modified from time to time pursuant to the Agreement.

Without limiting the generality of the foregoing, and notwithstanding anything in the Agreement to the contrary, Pharmacy agrees as follows:

In no event, including, but not limited to, nonpayment by PBM or plan sponsor, insolvency or breach of the Agreement, shall Pharmacy bill, charge, collect a deposit from, seek compensation, remuneration, or reimbursement from, or have any recourse against covered persons or a person acting on their behalf, other than PBM or plan sponsor for covered drugs provided pursuant to the Agreement. This provision shall not prohibit collection of cost sharing amounts, or costs for noncovered services, which have not otherwise been paid by a primary or secondary carrier in accordance with regulatory standards for coordination of benefits, from covered persons in accordance with the terms of the covered person's benefit plan. C.G.S.A. §§ 38a-193(c)(1)(A), 38a-479aa(l), 38a-479bb(d)(5).

In the event of the insolvency of PBM or plan sponsor, Pharmacy shall continue providing covered drugs for covered persons for the duration of the period for which premium payment has been made to plan sponsor or until covered person's discharge from inpatient facilities, whichever time is greater. C.G.S.A. § 38a-193(c)(1)(B).

Nothing in the Agreement shall be construed to modify the rights and benefits contained in covered person's benefit plan. C.G.S.A. § 38a-193(c)(1)(C).

Pharmacy shall not bill covered person for covered drugs, except for cost sharing amounts, where plan sponsor or PBM denies payment because Pharmacy has failed to comply with the terms or conditions of the Agreement or the benefit plan. C.G.S.A. § 38a-193(c)(1)(D).

Pharmacy further agrees that paragraphs 1 through 4 above shall survive termination of the Agreement regardless of the cause giving rise to termination and shall be construed to be for the benefit of plan sponsor's covered persons, and that this provision supersedes any oral or written contrary agreement now existing or hereafter entered into between Pharmacy and covered persons or persons acting on their behalf. C.G.S.A. § 38a-193(c)(1)(E).

If Pharmacy contracts with other providers or facilities who agree to provide covered drugs to covered persons of plan sponsor with the expectation of receiving payment directly or indirectly from plan sponsor or PBM, such providers or facilities shall agree to abide by paragraphs 1 through 5 above, and Pharmacy shall ensure that such agreement is memorialized in writing. C.G.S.A. § 38a-193(c)(1)(F).

Pharmacy, or an agent, trustee or assignee of Pharmacy shall not maintain any action at law against a covered person to collect sums owed by PBM or plan sponsor or request payment from a covered person for such sums. For purposes of this section "request payment" includes, but is not limited to, submitting a bill for services not actually owed or submitting for such services an invoice or other communication detailing the cost of the services that is not clearly marked with the phrase "THIS IS NOT A BILL." Pharmacy acknowledges that pursuant section 20-7f, Connecticut General Statutes, it is an unfair trade practice in violation of chapter 735a for Pharmacy to request payment from a covered person, other than a copay or deductible, for covered drugs or to report to a credit reporting agency an enrollee's failure to pay a bill for medical services when plan sponsor has primary responsibility for payment of such services. C.G.S.A. § 38a-193(c)(3).

Pharmacy and PBM shall each provide the other at least 60 days' advance notice to terminate or withdraw from the Agreement. This paragraph shall not apply:

When lack of such notice is necessary for the health or safety of a covered person.

When Pharmacy has entered into a contract with PBM that is found to be based on fraud or material misrepresentation; or When Pharmacy engages in any fraudulent activity related to the terms of the Agreement. C.G.S.A. § 38a-193(d).

To the extent applicable and required by law, in the event Pharmacy provides covered drugs to covered persons of a managed care organization contracted with a preferred provider network, Pharmacy agrees that the Agreement shall be transferred and assigned to the managed care organization for the provision of future covered drugs by Pharmacy to covered persons, at the discretion of the managed care organization, in the event the preferred provider network (A) becomes insolvent, (B) otherwise ceases to conduct business, as determined by the Connecticut Commissioner of Insurance or (C) demonstrates a pattern of nonpayment of authorized claims, as determined by the Commissioner, for a period in excess of 90 days. C.G.S.A. § 38a-479bb(d)(10).

Pharmacy agrees that in no event, including, but not limited to, nonpayment by a plan sponsor or PBM, the insolvency of a plan sponsor or PBM, or a breach of this agreement, shall Pharmacy bill, charge, collect a deposit from, seek compensation, remuneration or reimbursement from, or have any recourse against a covered person or a person (other than the health carrier or intermediary) acting on behalf of the covered person for covered drugs provided pursuant to this agreement. This agreement does not prohibit the Pharmacy from collecting coinsurance, deductibles or copays, as specifically provided in the evidence of coverage, or fees for uncovered services delivered on a fee-for-service basis to covered persons. Nor does this agreement prohibit a Pharmacy and a covered person from agreeing to continue services solely at the expense of the covered person, as long as the Pharmacy has clearly informed the covered person that plan sponsor does not cover or continue to cover a specific service or services. Except as provided herein, this agreement does not prohibit the Pharmacy from pursuing any available legal remedy. C.G.S.A. § 38a-477g(b)(1)(A).

In the event of a plan sponsor or PBM insolvency or other cessation of operations, the Pharmacy's obligation to deliver covered drugs to covered persons without requesting payment from a covered person other than a copay for such services will continue until the earlier of (i) the termination of the covered person's coverage under the benefit plan, including any extension of coverage provided under the contract terms or applicable state or federal law for covered persons who are in an active course of treatment, as set forth in subdivision (2) of subsection (g) of section 38a-472f of the Connecticut general statutes, or are totally disabled, or (ii) the date the Agreement between PBM and the Pharmacy would have terminated if PBM or plan sponsor had remained in operation, including any extension of coverage required under applicable state or federal law for covered persons who are in an active course of treatment or are totally disabled. C.G.S.A. § 38a-477g(b)(1)(B).

Pharmacy shall make health records available to appropriate state and federal authorities involved in assessing the quality of care provided to, or investigating grievances or complaints of, covered persons, and Pharmacy shall comply with applicable state and federal laws related to the confidentiality of medical and health records and a covered person's right to view, obtain copies of, or amend such covered person's medical and health records. C.G.S.A. § 38a-477g(b)(1)(C).

PBM shall timely notify Pharmacy of any change to the Agreement, including any provisions or other documents incorporated by reference into the Agreement, that will result in a material change to such Agreement. C.G.S.A. § 38a-477g(c)(2).

Pharmacy audits (C.G.S.A. § 38a-479iii)

a) As used in this section:

(1) "Extrapolation" means the practice of inferring a frequency of dollar amount of overpayments, underpayments, nonvalid claims or other errors on any portion of claims submitted, based on the frequency or dollar amount of overpayments, underpayments, nonvalid claims or other errors actually measured in a sample of claims.

(2) "Pharmacy audit" means an audit, conducted on-site or remotely by or on behalf of a PBM or plan sponsor of any records of a Pharmacy for prescription drugs or prescription devices dispensed by such Pharmacy to beneficiaries of a health benefit plan. "Pharmacy audit" does not include

(A) a concurrent review or desk audit that occurs within three business days of the Pharmacy's transmission of a claim to a PBM or plan sponsor, or (B) a concurrent review desk audit where no chargeback or recoupment is demanded by the PBM or plan sponsor.

(3) "Plan sponsor" has the same meaning as described in C.G.S.A. § 38a-479aaa.

(b)(1) No entity other than a PBM or a plan sponsor shall conduct a pharmacy audit unless such entity and manager or sponsor, as applicable, have executed a written agreement for the conducting of pharmacy audits. Prior to conducting a pharmacy audit on behalf of a PBM or sponsor, the PBM shall notify the Pharmacy in writing that Prime or sponsor, as applicable, have executed such agreement.

(2) Except as otherwise provided by state or federal law, an entity conducting a pharmacy audit may have access to a Pharmacy's previous pharmacy audit report only if such report was prepared by such entity.

(3) Any information collected during a pharmacy audit shall be confidential by law, except that the entity conducting the pharmacy audit may share such information with the PBM and the plan sponsor, for which such pharmacy audit is being conducted.

(4) No entity conducting a pharmacy audit shall compensate, directly or indirectly, any of its employees or any contractor such entity contracts with to conduct a pharmacy audit, based on the amount claimed or the actual amount recouped from the Pharmacy being audited.

(c)(1) An entity conducting a pharmacy audit shall:

A) Provide the Pharmacy being audited at least 10 business days' prior written notice before conducting a pharmacy audit

B) Provide the Pharmacy being audited with a masked list of prescriptions to assist the Pharmacy to prepare for the pharmacy audit. A list is considered masked if the last two numbers of a prescription are marked with an "X";

C) Not initiate or schedule a pharmacy audit during the first five business days of any month for any Pharmacy that averages in excess of 600 prescriptions filled per week, without the express consent of the Pharmacy;

D) Make all determinations regarding the validity of a prescription or other record consistent with sections 20-612 to 20-623, inclusive, or as specified in federal risk management programs;

E) Accept paper or electronic signature logs that document the delivery of prescription drug and device and pharmacist services to a health plan beneficiary or such beneficiary's agent; and

F) Provide to the representative of the Pharmacy, prior to leaving the Pharmacy at the conclusion of an on-site portion of a pharmacy audit, a complete list of records reviewed.

(2) Any pharmacy audit that involves clinical judgment shall be conducted by or in consultation with a licensed pharmacist.

(3) No pharmacy audit shall cover:

(A) a period of more than 24 months after the date a claim was submitted by the Pharmacy to the PBM or plan sponsor unless a longer period is required by law, or

(B) more than 250 prescriptions.

d)(1)(A) Not later than 60 calendar days after an entity concludes a pharmacy audit and before such entity issues a final pharmacy audit report, such entity shall provide an initial pharmacy audit review to the Pharmacy. The Pharmacy may, within 30 calendar days after it receives such initial review, respond to the findings in such initial review.

(B) To validate the pharmacy record and delivery, a Pharmacy may use authentic and verifiable statements or records, including, but not limited to, medication administration records of a nursing home, assisted living facility, hospital or health care provider with prescriptive authority.

(C) To validate claims in connection with prescriptions or changes in prescriptions, or refills of prescription drugs, a Pharmacy may use any valid prescription, including, but not limited to, medication administration records, facsimiles, electronic prescriptions, electronically stored images of prescriptions, electronically created annotations or documented telephone calls from the prescribing health care provider or such provider's agent. Documentation of an oral prescription order that has been verified by the prescribing health care provider shall meet the provisions of this subparagraph for the initial audit review.

(D) No entity conducting a pharmacy audit may use extrapolation to calculate penalties or amounts to be charged back or recouped unless otherwise required by federal requirements or federal plans. No such entity shall include dispensing fees in the calculation of overpayments unless a prescription is considered a misfill. As used in this subparagraph, "misfill" means a prescription that was not dispensed, a prescription error, a prescription whereby the prescriber denied the authorization request or where an extra dispensing fee was charged.

(2)(A) Not later than 60 calendar days after any responses from the Pharmacy under subdivision (1) of this subsection are received by the entity conducting the pharmacy audit or, if no such responses are received, after the entity concludes a pharmacy audit, such entity shall issue a final pharmacy audit report that takes into consideration any responses provided to such entity by the pharmacy.

(B) A Pharmacy may appeal a final pharmacy audit report in accordance with the procedures established by the entity conducting the pharmacy audit.

(e)(1) No Pharmacy shall be subject to chargeback or recoupment for a clerical or recordkeeping error in a required document or record, including a typographical error, scrivener's error or computer error, unless such error resulted in actual financial harm to the PBM, plan sponsor or a plan beneficiary.

(2) No entity conducting a pharmacy audit or person acting on behalf of such entity shall assess a chargeback or recoupment, attempt to assess a chargeback or recoupment, or assess or collect penalties from a Pharmacy until the time period to file an appeal of a final pharmacy audit report has passed or the appeals process has been exhausted, whichever is later. If an identified discrepancy in a pharmacy audit exceeds $25,000, future payments to the Pharmacy in excess of such amount may be withheld pending adjudication of an appeal. No interest shall accrue for any party during the audit period, beginning with the notice of the pharmacy audit and ending with the conclusion of the appeals process.

(f) The provisions of this section shall not apply to an audit of pharmacy records conducted when:

(1) fraud or other intentional or willful misrepresentation is indicated by physical review or review of claims data or statements, or

(2) other investigative methods indicate a Pharmacy is or has been engaged in criminal wrongdoing, fraud or other intentional or willful misrepresentation.

B-8 Delaware Regulatory Addendum to Pharmacy Participation Agreement

This Delaware Addendum applies to the extent that Pharmacy provides covered drugs to covered persons of health service corporations, managed care organizations, health maintenance organizations and insurers under Delaware law (collectively and/or individually, "plan sponsor").

In the event of a direct conflict between this Addendum and the Agreement, the applicable provisions of this Addendum shall control if required. This Addendum may be modified from time to time pursuant to the Agreement.

Without limiting the generality of the foregoing, and notwithstanding anything in the Agreement to the contrary, Pharmacy agrees as follows:

Nothing in the Agreement shall be construed to require pharmacy accreditation standards or certification requirements inconsistent with, more stringent than, or in addition to requirements of the Delaware Board of Pharmacy. 18 Del. Code § 3372A.

Nothing in the Agreement shall be construed as prohibiting Pharmacy from giving its patients information regarding diagnoses, prognoses and treatment options. 18 Del. Code § 6414.

To the extent Pharmacy provides covered drugs to covered persons of a managed care organization under Delaware law, Pharmacy agrees that:

In no event, including, but not limited to, nonpayment by plan sponsor or PBM, insolvency of plan sponsor or PBM, or breach of this agreement, shall Pharmacy bill, charge, collect a deposit from, seek compensation, remuneration or reimbursement from, or have any recourse against covered persons or a person (other than plan sponsor or PBM) acting on behalf of covered persons for services provided pursuant to this agreement. This agreement does not prohibit Pharmacy from collecting coinsurance, deductibles or copays, as specifically provided in the evidence of coverage, or fees for uncovered services delivered on a fee-for-service basis to covered persons. 18 Code of Del. Regs. §1403 (7.1.1).

In the event of plan sponsor's or PBM's insolvency or other cessation of operations, covered drugs to covered persons will continue through the period for which a premium has been paid to plan sponsor on behalf of covered persons or until covered person's discharge from an inpatient facility, whichever time is greater. Covered drugs to covered persons confined in an inpatient facility on the date of insolvency or other cessation of operations will continue until the covered person's continued confinement in an inpatient facility is no longer medically necessary. 18 Code of Del. Regs. §1403(7.1.2).

Paragraphs (2)(a) and (b) above shall be construed in favor of the covered person, shall survive the termination of the Agreement regardless of the reason for termination, including the insolvency of plan sponsor or PBM, and shall supersede any oral or written contrary agreement between Pharmacy and a covered person or the representative of the covered person if the contrary agreement is inconsistent with paragraphs (6)(a) and (b) above. 18 Code of Del. Regs. §1403(7.2).

To the extent that any of the definitions or provision set forth in the Agreement directly conflict with the definitions or provisions of Regulation 18 1400 1403, Code of Delaware Regulations, the Agreement shall not control. 18 Code of Del. Regs. §1403(7.3).

In the event that the Agreement with Pharmacy is terminated, Pharmacy agrees to continue to provide covered drugs to covered persons at the rates set forth in the Agreement for up to 120 days after notification of termination in those cases where it is medically necessary for the covered person to continue treatment with Pharmacy. In cases of the pregnancy of a covered person, medical necessity shall be deemed to have been demonstrated and Pharmacy agrees to continue to provide covered drugs through completion of postpartum care. This paragraph shall not apply in cases where the Agreement with Pharmacy was terminated due to unsafe health care practices that compromise the health or safety of covered persons. 18 Code of Del. Regs. §1403(9.3).

[Pricing/Reimbursement] Appeals (18 Del. Code § 3324A)

(a) A pharmacy benefit manager must establish a process by which a contracted Pharmacy can appeal the provider's reimbursement for a drug subject to maximum allowable cost pricing. A contracted Pharmacy has 10 calendar days after the applicable fill date to appeal a maximum allowable cost if the reimbursement for the drug is less than the net amount that the network provider paid to the supplier of the drug. A pharmacy benefit manager must respond with notice that the appeal has been denied or granted within 10 calendar days of the contracted Pharmacy making the claim for which an appeal has been submitted.

(b) At the beginning of the term of a network provider's contract, and upon renewal, a pharmacy benefit manager must provide to network providers a telephone number and email address at which a network provider can contact the pharmacy benefit manager to process an appeal under this section.

(c) If an appeal is denied, the pharmacy benefit manager must provide the reason for the denial and the name and National Drug Code number of the national or regional wholesalers operating in this state that have the drug in stock at a price below the maximum allowable cost.

(d) If the appeal is granted, the pharmacy benefit manager shall do the following:

(1) a. Adjust the maximum allowable cost for the drug as of the date of the original claim for payment.

b. Without requiring the appealing Pharmacy to reverse and rebill the claims, provide reimbursement for the claim and any subsequent and similar claims under similarly applicable contracts with the pharmacy benefit manager as follows:

1. For the original claim, in the first remittance to the Pharmacy after the date the appeal was granted.
2. For subsequent and similar claims under similarly applicable contracts, in the second remittance to the Pharmacy after the date the appeal was granted.

(2) For a similarly situated contracted Pharmacy in this state, do all of the following:

a. Adjust the maximum allowable cost for the drug as of the date the appeal was granted.

b. Provide notice to the Pharmacy or the Pharmacy's contracted agent of all the following:

1. That an appeal was granted.
2. That without filing a separate appeal, the Pharmacy or the Pharmacy's contracted agent may reverse and rebill a similar claim.

(e) A pharmacy benefit manager shall make available on its website information about the appeal process, including all of the following:

(1) A telephone number at which the contracted Pharmacy may contact the department or office responsible for processing appeals for the pharmacy benefit manager to speak to an individual specifically or leave a message for an individual or office who is responsible for processing appeals.

(2) An email address of the department or office responsible for processing appeals to which an individual who is responsible for processing appeals has access.

(f) A pharmacy benefit manager may not charge a contracted Pharmacy a fee related to the re-adjudication of a claim resulting from a granted appeal under subsection (d) of this section or the granting of an appeal under subsection (h) of this section.

(g) A pharmacy benefit manager may not retaliate against a contracted Pharmacy for exercising its right to appeal to the pharmacy benefit manager under subsection (a) of this section or to the commissioner under subsection (h) of this section.

(h)(1) If a pharmacy benefit manager denies an appeal and a contracted Pharmacy files an appeal with the commissioner, the commissioner shall do all of the following:

a. Review the pharmacy benefit manager's compensation program to ensure that the reimbursement for pharmacy benefit management services paid to the pharmacist or a Pharmacy complies with this subchapter and the terms of the contract.

b. Based on a determination made by the commissioner under paragraph (h)(1)a. of this section, do one of the following:

1. Deny the appeal.

2. Grant the appeal and order the pharmacy benefit manager to pay the claim in accordance with the commissioner's findings.

(2) All pricing information and data collected by the commissioner during a review required by paragraph (h)(1) of this section is confidential and not subject to subpoena or the Freedom of Information Act, Chapter 100 of Title 29.

Pharmacy Provider Appeals Related to Maximum Allowable Cost Pricing (MACP) Reimbursements (18 DE ADC 1411-9.0)

9.1 A PBM shall designate the name, address, phone number, and electronic mail address of the person within the PBM organization who shall be the point of contact for responding to appeals received by the Department from a pharmacy provider or PSAO under 18 Del.C. § 3324A(h).

9.2 All filings submitted to the Department, including the notice of appeal and any subsequent responses by either party shall be made by electronic mail to the electronic mail address designated by the Department on the Department's website.

9.3 Notice and Manner of Service

9.3.1 Notice and manner of service, except service of the notice of appeal, is sufficient and complete if properly addressed, upon mailing the same with prepaid first-class U.S. Postage.

9.3.2 Service of the initial notice of appeal shall be made by the pharmacy or PSAO on the PBM by Certified U.S. Postage and return receipt requested or hand delivery to the respondent and is complete upon receipt by addressee or an employee in respondent's place of business.

9.3.3 The parties must provide a brief statement verifying the service of all filed papers with the manner, date and address of service.

9.4 When an Appeal May Be Commenced

9.4.1 An appeal may be commenced after the pharmacy provider or PSAO and a PBM have attempted to resolve the matter in accordance with the PBM's internal appeal process required by 18 Del.C. § 3324A(a).

9.4.2 A PBM's failure to communicate and process an internal appeal, as required under 18 Del.C. § 3324A, or its failure to abide by its MACP appeal processes as described to the Department in the PBM's submission under subsection 4.2.4.2.1 of this regulation, shall constitute a denial under the internal appeal process for purposes of allowing the pharmacy provider or PSAO on its behalf to file an appeal with the Department.

9.4.3 The Commissioner may dismiss the appeal without prejudice if the Commissioner finds that the parties have not exhausted the PBM's internal appeals process.

9.4.4 A PBM shall not be held responsible for failure to timely process an internal appeal in the event that a pharmacy provider or PSAO acting on its behalf has not submitted sufficient information for the PBM to process the appeal.

9.4.5 All pricing information and data collected by the Department for purposes of processing an appeal under Section 9.0 of this regulation is confidential and is not subject to subpoena or the Freedom of Information Act, 29 Del.C. Ch. 100.

9.5 Commencement of Appeal

9.5.1 A pharmacy provider or PSAO may commence an appeal by filing a notice of appeal on a form provided by the Department and as specified at subsection 9.2 of this regulation, with the supporting documents or other evidence attached thereto. The pharmacy provider or PSAO shall at the same time serve a copy of the same notice of appeal and supporting documents to the PBM or PBM's representative and a statement verifying service in accordance with subsection 9.3 of this regulation. The Department may return any non-conforming notice of appeal.

9.5.2 Within 5 business days of receipt of the notice of appeal, the responding PBM ("Respondent") shall file a response on a form provided by the Department and as specified at subsection 9.2 of this regulation, that shall include a copy of the contract between the PBM and the appealing pharmacy provider or PSAO, along with any other documentation necessary for the Department to review the PBM's compensation program to determine whether the reimbursement underlying the appeal complies with 18 Del.C. §§ 3323A-3324A and the terms of the contract. The PBM shall at the same time serve a copy of the same response to the pharmacy provider or PSAO and a statement verifying service in accordance with subsection 9.3 of this regulation. The Department may return any non-conforming response.

9.5.3 If the Respondent fails to file a response in a timely fashion, the Department, after verifying proper service and notice to the parties, may enter a summary disposition. The Department may determine the matter in the nature of a default judgment after establishing that the appeal is properly supported and was properly served on Respondent. The Department may allow the re-opening of the matter to prevent a manifest injustice. A request for re-opening must be made no later than 5 business days after notice of the default judgment.

9.6 Consideration of Appeal

9.6.1 The Department shall consider the matter based on the submissions of the parties and information otherwise requested from the parties by the Department. The Department shall not consider any matter not contained in the original or supplemental submissions of the parties which has not been provided to the opposing party with at least 5 business days' notice, except claims of a continuing nature which are set out in the filed papers.

9.6.2 The Department shall review the pharmacy benefits manager's compensation program to ensure that the reimbursement for pharmacy benefits management services paid to the pharmacist or a pharmacy complies with 18 Del.C. §§ 3323A-3324A and the terms of the contract between the PBM and the appealing pharmacy or PSAO and shall either:

9.6.2.1 Dismiss the appeal; or

9.6.2.2 Grant the appeal and order the pharmacy benefits manager to pay the claim in accordance with the Department's findings.

Procedure and process for conducting and reporting an audit (18 Del. Code § 3304A)

a) *Audit procedures* – Unless otherwise prohibited by federal requirements or regulations, when any entity is conducting a pharmacy audit, they must adhere to the following procedures:

1) A Pharmacy must be given notice 14 days before an initial on-site audit is conducted.

2) An audit that involves clinical or professional judgment must be conducted by or in consultation with a licensed pharmacist.

3) Each Pharmacy shall be audited under the same standards and parameters as other similarly situated pharmacies.

(4) A Pharmacy must be given a range of prescription numbers in advance of the audit.

b) *Audit process* – Unless otherwise prohibited by federal requirements or regulations, for any entity conducting a pharmacy audit the following audit items apply:

(1) The period covered by the audit may not exceed 24 months from the date that the claim was submitted to or adjudicated by the entity unless a longer period is required under state or federal law.

(2) If an entity uses random sampling as a method for selecting a set of claims for examination, the sample size must be appropriate for a statistically reliable sample. The auditing entity shall provide the Pharmacy a masked list that provides a prescription number or date range that the auditing entity is seeking to audit.

(3) An on-site audit may not take place during the first five business days of the month or on a federal holiday unless consented to by the Pharmacy.

(4) Auditors may not enter the pharmacy area unless escorted where patient-specific information is available and to the extent possible must be out of sight and hearing range of the pharmacy customers.

(5) Any recoupment will not be deducted against future remittances until after the appeals process and both parties have received the results of the final audit.

(6) A PBM may not require information to be written on a prescription unless the information is required to be written on the prescription by state or federal law. Recoupment may be assessed for items not written on the prescription if the required information is not readily available in print or electronic form for the auditor at the time of the audit and one or more of the following conditions applies:

A) Additional information is required in the Provider Manual.

B) The information is required by the Food and Drug Administration (FDA).

C) The information is required by the drug manufacturer's product safety program.

7) The auditing company or agent may not receive payment based on a percentage of the amount recovered. This section does not prevent the entity conducting the audit from charging or assessing the responsible party, directly or indirectly, based on amounts recouped if both of the following conditions are met:

A) The plan sponsor and PBM have a contract that explicitly states the percentage charge or assessment to the plan sponsor; and

B) A commission to an agent or employee of PBM conducting the audit is not based, directly or indirectly, on amounts recouped.

Requirements for recoupment or chargeback (18 Del. Code § 3305A)

For recoupment or chargeback, the following criteria apply:

(1) Audit parameters must consider consumer-oriented parameters based on manufacturer listings.

(2) The reimbursable cost for a compounded medication shall be reflective of the ingredients, supplies and professional time reasonably required to create the finished product.

(3) A finding of overpayment or underpayment must be based on the actual overpayment or underpayment and not a projection based on the number of patients served having a similar diagnosis or on the number of similar orders or refills for similar drugs.

(4) The entity conducting the audit shall not use extrapolation in calculating the recoupment or penalties for audits unless required by state or federal law or regulations.

(5) Calculations of overpayments must not include dispensing fees unless a prescription was not actually dispensed, the prescriber denied authorization, the prescription dispensed was a medication error by the Pharmacy or the identified overpayment is solely based on an extra dispensing fee.

(6) An entity may not consider any clerical or recordkeeping error, such as a typographical error, scrivener's error or computer error regarding a required document or record as fraud, however such errors may be subject to recoupment.

(7) In the case of errors that have no actual financial harm to the patient or plan, Prime must not assess any chargebacks. Errors that are a result of the Pharmacy failing to comply with a formal corrective action plan may be subject to recovery.

(8) Interest may not accrue during the audit period for either party, beginning with the notice of the audit and ending with the final audit report.

Documentation (18 Del. Code § 3306A)

a) To validate the pharmacy record and delivery, the Pharmacy may use authentic and verifiable statements or records including medication administration records of a nursing home, assisted living facility, hospital, physician or other authorized practitioner or additional audit documentation parameters located in the Provider Manual.

b) Any legal prescription that meets the requirements in this subchapter may be used to validate claims in connection with prescriptions, refills or changes in prescriptions, including medication administration records, faxes, ePrescriptions or documented telephone calls from the prescriber or the prescriber's agents.

[Audit] Appeals process (18 Del. Code § 3307A)

The entity conducting the audit must establish a written appeals process which must include appeals of preliminary reports and final reports.

Audit information and reports (18 Del. Code § 3308A)

a) A preliminary audit report must be delivered to the Pharmacy within 30 days after the conclusion of the audit. The preliminary audit report shall contain claim level information for any discrepancy and an estimated recovery amount.

b) A Pharmacy must be allowed at least 45 days following receipt of the preliminary audit to provide documentation to address any discrepancy found in the audit.

c) A final audit report must be delivered to the Pharmacy within 120 days after receipt of the preliminary audit report or final appeal, whichever is later.

d) An entity shall remit any money due to a Pharmacy or pharmacist as a result of an underpayment of a claim within 45 days after the appeals process has been exhausted and the final audit report has been issued.

Disclosures to plan sponsor (18 Del. Code § 3309A)

Where contractually required, an auditing entity must provide a copy to the plan sponsor of its claims that were included in the audit, and any recouped money shall be returned to the plan sponsor.

Applicability of other laws and regulations (18 Del. Code § 3310A)

This subchapter does not apply to any investigative audit that involves suspected fraud, willful misrepresentation, abuse or any audit completed by the state.

B-9 District of Columbia Regulatory Addendum to Pharmacy Participation Agreement

This District of Columbia Addendum applies to the extent that Pharmacy provides covered drugs to covered persons of health maintenance organizations and carriers under District of Columbia law (collectively and/or individually, "plan sponsor").

In the event of a direct conflict between this Addendum and the Agreement, the applicable provisions of this Addendum shall control if required. This Addendum may be modified from time to time pursuant to the Agreement.

Without limiting the generality of the foregoing, and notwithstanding anything in the Agreement to the contrary, Pharmacy agrees as follows:

Pharmacy shall be permitted and obligated to discuss medical treatment options with covered persons. D.C. Code Ann § 31-3406(h)(2); Code of D.C. Mun. Reg. 26-A3503.11.

Nothing in the Agreement shall be construed to prohibit, impede or interfere in discussions between Pharmacy and covered persons concerning medical treatment options, including financial coverage of those treatment options. D.C. Code Ann § 31-3406(h)(1); Code of D.C. Mun. Reg. 26-A3503.10.

PBM shall not terminate or refuse to contract with Pharmacy based in whole or in part on the fact that Pharmacy discussed treatment options with a covered person. D.C. Code Ann § 31-3406(h)(3); Code of D.C. Mun. Reg. 26-A3503.12

To the extent Pharmacy provides covered drugs to a covered person of a health maintenance organization, Pharmacy agrees:

In the event PBM or plan sponsor fails to pay Pharmacy as set forth in the Agreement, covered persons shall not be liable to Pharmacy for any sums owed by PBM or plan sponsor. D.C. Code Ann. § 31-3412(d)(1); Code of D.C. Mun. Reg. 26-A3506.12.

Pharmacy shall not collect or attempt to collect from covered persons sums owed by PBM or plan sponsor. D.C. Code Ann. § 31-3412(d)(2); Code of D.C. Mun. Reg. 26-A3506.13.

Neither Pharmacy nor any agent, trustee, or assignee of Pharmacy may maintain any action at law against a covered person to collect sums owed by PBM or plan sponsor. D.C. Code Ann. § 31-3412(d)(3); Code of D.C. Mun. Reg. 26-A3506.14.

In the event of the insolvency of PBM or plan sponsor, Pharmacy shall continue to provide covered drugs to covered persons for the period for which premium payment has been made or until covered persons' discharge from inpatient facilities, whichever is longer. D.C. Code Ann. § 31-3412(e)(2)(B); Code of D.C. Mun. Reg. 26-A3506.16(b).

If Pharmacy terminates the Agreement, Pharmacy shall give PBM at least 60 days' advance notice of termination. D.C. Code Ann. § 31-3412(f).

B-10 Florida Regulatory Addendum to Pharmacy Participation Agreement

This Florida Addendum applies to the extent that Pharmacy provides covered drugs to covered persons of benefits sponsor of a pharmacy benefits plan or program, including insurers, carriers, health maintenance organizations, prepaid limited health service organizations, prepaid health clinics and employer/multiple employer healthcare arrangements under Florida law (collectively and/or individually, "plan sponsor").

In the event of a direct conflict between this Addendum and the Agreement or Provider Manual, the applicable provisions of this Addendum shall control as required. This Addendum may be modified from time to time pursuant to the Agreement.

Except as provided in Paragraph 9 below, without limiting the generality of the foregoing, and notwithstanding anything in the Agreement or the Manual to the contrary, Pharmacy and PBM agree as follows:

Pharmacy shall be required to exhaust internal dispute-resolution processes set forth in the Agreement as a prerequisite to submission of a claim by Pharmacy to the statewide provider dispute resolution program pursuant to Florida Stat. § 408.7057.

The Agreement shall be canceled upon issuance of an order by the Florida Department of Insurance pursuant to Florida Stat. §§ 624.4411(3), 641.234(3), and 636.036(3).

Pharmacy shall not bill or otherwise seek reimbursement from or recourse against any covered persons, with the exception of any supplemental charges or coinsurance amounts stated in covered persons' benefit plan with plan sponsor. Fla. Stat. § 627.6472(4)(e).

To the extent Pharmacy provides covered drugs to covered persons of a health maintenance organization under Florida law, Pharmacy agrees:

Covered persons shall not be liable to Pharmacy for any services for which plan sponsor is liable, as specified in Florida Statute § 641.3154. Fla. Stat. § 641.315(1).

Pharmacy shall provide no less than 60 days' advance written notice to PBM and the Florida Department of Insurance before terminating the Agreement for any reason. Nonpayment for goods or services rendered by Pharmacy shall not be a valid reason for avoiding the 60 days' advance notice of cancellation. Fla. Stat. § 641.315(2)(a)(1), (2).

PBM shall provide 60 days' advance written notice to Pharmacy and the Florida Department of Insurance before terminating the Agreement, without cause, except where a patient's health is subject to imminent danger or Pharmacy's ability to practice is effectively impaired by an action by a governmental agency. Fla. Stat. § 641.315(2)(b).

To the extent Pharmacy provides covered drugs to covered persons of a prepaid limited health service organization under Florida law, Pharmacy agrees:

In the event PBM or plan sponsor fails to pay for covered drugs already rendered to covered persons by Pharmacy, plan sponsor is liable for such fees rather than covered persons. Fla. Stat. § 636.035(1).

Covered persons shall not be liable to Pharmacy for any services covered by covered persons' benefit plan with plan sponsor, with the exception of any deductible or copay which is not covered by covered person's benefit plan or for services not authorized by plan sponsor. Fla. Stat. § 636.035(4), (5).

Pharmacy shall provide no less than 90 days' advance written notice to PBM before canceling the Agreement for any reason. Nonpayment for goods or services rendered by Pharmacy shall not be a valid reason for avoiding the 90-day advance notice of cancellation. Fla. Stat. § 636.035(6)(a), (b).

PBM shall provide 90 days' advance written notice to Pharmacy before canceling, without cause, the Agreement, except where a covered person is subject to imminent danger or Pharmacy's ability to practice is effectively impaired by an action by a governmental agency. Fla. Stat. § 636.035(8).

If any provision of the Agreement is held to be unenforceable or otherwise contrary to any applicable laws, regulations or rules, such provision shall have no effect and shall be severable without affecting the validity or enforceability of the remaining provisions of the Agreement. Fla. Stat. § 636.035(9).

To the extent Pharmacy provides covered drugs to covered persons of a prepaid health clinic under Florida law, in the event plan sponsor fails to pay for covered drugs already rendered to a covered person by Pharmacy, plan sponsor is liable for such fees rather than covered person. Fla. Stat. § 641.43.

Notwithstanding anything to the contrary in the Agreement, to the extent Pharmacy provides covered drugs to covered persons of a discount medical plan organization under Florida law, the rates charged by the Pharmacy for services rendered to covered persons shall not be in excess of the rates set forth in the Agreement and any related attachments. Fla. Stat. § 636.214(2)(c).

Pharmacy shall post a consumer assistance notice, prominently displaying the notice in the reception area of Pharmacy so that the notice will be clearly noticeable by all patients. The consumer assistance notice must state that the addresses and toll-free telephone number of plan sponsor's grievance department shall be provided upon request. Fla. Stat. § 641.511(8).

A participation contract executed, amended, adjusted or renewed on or after July 1, 2023, that applies to pharmacist services furnished on or after Jan. 1, 2024, between PBM and Pharmacy, the following shall apply in conformity with Fla. Stat. § 626.8825 and, except to the extent not allowed by law, shall supersede any contractual terms in the Agreement, Addendum, or the Manual to the contrary:

At the time of adjudication for electronic claims or the time of reimbursement for nonelectronic claims, PBM will provide Pharmacy with a remittance, including such detailed information as is necessary for Pharmacy or pharmacist to identify the reimbursement schedule for the specific network applicable to the claim and which is the basis used by PBM to calculate the amount of reimbursement paid. This information must include, but is not limited to, the applicable network reimbursement ID or plan ID as defined in the most current version of the National Council for Prescription Drug Programs (NCPDP) Telecommunication Standard Implementation Guide, or its nationally recognized successor industry guide.

PBM will ensure that any basis of reimbursement information is communicated to Pharmacy in accordance with the NCPDP Telecommunication Standard Implementation Guide, or its nationally recognized successor industry guide, when performing reconciliation for any effective rate guarantee, and that such basis of reimbursement information communicated is accurate, corresponds with the applicable network rate and may be relied upon by Pharmacy.

PBM will not charge, withhold or recoup direct or indirect remuneration fees, dispensing fees, brand name or generic effective rate adjustments through reconciliation, or any other monetary charge, withholding or recoupments as related to discounts, multiple network reconciliation offsets, adjudication transaction fees and any other instance when a fee may be recouped from Pharmacy. This requirement does not apply to:

i. Any incentive payments provided by PBM to Pharmacy for meeting or exceeding predefined quality measures, such as healthcare effectiveness data and information set measures; recoupment due to an erroneous claim, fraud, waste or abuse; a claim adjudicated in error; a maximum allowable cost appeal pricing adjustment; or an adjustment made as part of a Pharmacy audit pursuant to Fla. Stat. § 624.491.

ii. Any recoupment that is returned to the state for programs in chapter 409 or the state group insurance program.

PBM will not unilaterally change the terms of the Agreement.

Unless otherwise prohibited by law, PBM will not prohibit Pharmacy or pharmacist from:

iii. Offering mail or delivery services on an opt-in basis at the sole discretion of the covered person.

iv. Mailing or delivering a prescription drug to a covered person upon his or her request.

v. Charging a shipping or handling fee to a covered person requesting a prescription drug be mailed or delivered if Pharmacy or pharmacist discloses to the covered person before the mailing or delivery the amount of the fee that will be charged and that the fee may not be reimbursable by the covered person's pharmacy benefits plan or program.

PBM will provide Pharmacy, upon its request, a list of pharmacy benefits plans or programs in which Pharmacy is a part of the network. Updates to the list shall be communicated to Pharmacy within seven days. PBM will not restrict Pharmacy or pharmacist from disclosing this information to the public.

PBM will ensure that the Electronic Remittance Advice contains claim level payment adjustments in accordance with the American National Standards Institute Accredited Standards Committee, X12 format, and includes or is accompanied by the appropriate level of detail for Pharmacy to reconcile any debits or credits, including, but not limited to, Pharmacy NCPDP or NPI identifier, date of service, prescription number, refill number, adjustment code, if applicable, and transaction amount.

PBM will provide a reasonable administrative appeal procedure to allow Pharmacy or pharmacist to challenge the maximum allowable cost pricing information and the reimbursement made under the maximum allowable cost as defined in Fla. Stat. § 627.64741 for a specific drug as being below the acquisition cost available to the challenging Pharmacy or pharmacist.

vi. The administrative appeal procedure will include a telephone number and email address, or a website as specified in the Manual, for the purpose of submitting the administrative appeal. The appeal may be submitted by Pharmacy or an agent of Pharmacy directly to PBM or through a pharmacy service administration organization. Pharmacy or pharmacist shall be given at least 30 business days after a maximum allowable cost update or after an adjudication for an electronic claim or reimbursement for a nonelectronic claim to file the administrative appeal.

vii. PBM will respond to the administrative appeal within 30 business days after receipt of the appeal.

viii. If the appeal is upheld, PBM will:

1. Update the maximum allowable cost pricing information to at least the acquisition cost available to Pharmacy;
2. Permit Pharmacy or pharmacist to reverse and rebill the claim in question;
3. Provide to Pharmacy or pharmacist the National Drug Code on which the increase or change is based; and
4. Make the increase or change effective for each similarly situated pharmacy or pharmacist who is subject to the applicable maximum allowable cost pricing information.

ix. If the appeal is denied, PBM will provide to Pharmacy or pharmacist the National Drug Code and the name of the national or regional pharmaceutical wholesalers operating in Florida which have the drug currently in stock at a price below the maximum allowable cost pricing information.

Every 90 days, PBM will report to the state the total number of appeals received and denied in the preceding 90-day period, with an explanation or reason for each denial, for each specific drug for which an appeal was submitted.

Pharmacy audits (Florida Stat. § 624.491)

1) A pharmacy benefits plan or program as defined in s. 626.8825 providing pharmacy benefits must comply with the requirements of this section when the pharmacy benefits plan or program or any person or entity acting on behalf of the pharmacy benefits plan or program, including, but not limited to, a pharmacy benefit manager as defined in s. 626.88, audits the records of a pharmacy licensed under chapter 465. The person or entity conducting such audit must:

a) Except as provided in subsection (3), notify the Pharmacy at least seven calendar days before the initial onsite audit for each audit cycle.

b) Not schedule an on-site audit during the first three calendar days of a month unless the pharmacist consents otherwise.

c) Limit the duration of the audit period to 24 months after the date a claim is submitted to or adjudicated by the entity.

d) In the case of an audit that requires clinical or professional judgment, conduct the audit in consultation with, or allow the audit to be conducted by, a pharmacist.

e) Allow the Pharmacy to use the written and verifiable records of a hospital, physician or other authorized practitioner, which are transmitted by any means of communication, to validate the pharmacy records in accordance with state and federal law.

f) Reimburse the Pharmacy for a claim that was retroactively denied for a clerical error, typographical error, scrivener's error or computer error if the prescription was properly and correctly dispensed, unless a pattern of such errors exists, fraudulent billing is alleged or the error results in actual financial loss to the entity.

g) Provide the Pharmacy with a copy of the preliminary audit report within 120 days after the conclusion of the audit.

h) Allow the Pharmacy to produce documentation to address a discrepancy or audit finding within 10 business days after the preliminary audit report is delivered to the Pharmacy

i) Provide the Pharmacy with a copy of the final audit report within six months after the Pharmacy's receipt of the preliminary audit report

j) Calculate any recoupment or penalties based on actual overpayments and not according to the accounting practice of extrapolation

2) This section does not apply to:

a) Audits in which suspected fraudulent activity or other intentional or willful misrepresentation is evidenced by a physical review, review of claims data or statements, or other investigative methods;

b) Audits of claims paid for by federally funded programs; or

c) Concurrent reviews or desk audits that occur within three business days after transmission of a claim and where no chargeback or recoupment is demanded.

3) An entity that audits a Pharmacy located within a Health Care Fraud Prevention and Enforcement Action Team (HEAT) task force area designated by the United States Department of Health and Human Services and the United States Department of Justice may dispense with the notice requirements of paragraph (1)(a) if such Pharmacy has been a member of a credentialed provider network for less than 12 months

4) Pursuant to s. 408.7057, and after receipt of the final audit report issued under paragraph (1)(i), a Pharmacy may appeal the findings of the final audit report as to whether a claim payment is due and as to the amount of a claim payment.

5) A pharmacy benefits plan or program that, under terms of a contract, transfers to a pharmacy benefit manager the obligation to pay a pharmacy licensed under chapter 465 for any pharmacy benefit claims arising from services provided to or for the benefit of an insured or subscriber remains responsible for a violation of this section.

Medicaid audits of Pharmacies (Florida Stat. § 465.188)

(1) Notwithstanding any other law, when an audit of the Medicaid-related records of a pharmacy licensed under chapter 465 is conducted, such audit must be conducted as provided in this section.

(a) The agency conducting the audit must give the pharmacist at least one (1) week's prior notice of the initial audit for each audit cycle.

(b) An audit must be conducted by a pharmacist licensed in this state.

(c) Any clerical or recordkeeping error, such as a typographical error, scrivener's error or computer error regarding a document or record required under the Medicaid program does not constitute a willful violation and is not subject to criminal penalties without proof of intent to commit fraud.

(d) A pharmacist may use the physician's record or other order for drugs or medicinal supplies written or transmitted by any means of communication for purposes of validating the pharmacy record with respect to orders or refills of a legend or narcotic drug.

(e) A finding of an overpayment or underpayment must be based on the actual overpayment or underpayment and may not be a projection based on the number of patients served having a similar diagnosis or on the number of similar orders or refills for similar drugs.

(f) Each Pharmacy shall be audited under the same standards and parameters.

(g) A pharmacist must be allowed at least 10 days in which to produce documentation to address any discrepancy found during an audit.

(h) The period covered by an audit may not exceed one calendar year.

(i) An audit may not be scheduled during the first five days of any month due to the high volume of prescriptions filled during that time.

(j) The audit report must be delivered to the pharmacist within 90 days after conclusion of the audit. A final audit report shall be delivered to the pharmacist within six months after receipt of the preliminary audit report or final appeal, as provided for in subsection (2), whichever is later.

(k) The audit criteria set forth in this section applies only to audits of claims submitted for payment subsequent to July 11, 2003. Notwithstanding any other provision in this section, the agency conducting the audit shall not use the accounting practice of extrapolation in calculating penalties for Medicaid audits.

(2) The Agency for Health Care Administration shall establish a process under which a pharmacist may obtain a preliminary review of an audit report and may appeal an unfavorable audit report without the necessity of obtaining legal counsel. The preliminary review and appeal may be conducted by an ad hoc peer review panel, appointed by the agency, which consists of pharmacists who maintain an active practice. If, following the preliminary review, the agency or review panel finds that an unfavorable audit report is unsubstantiated, the agency shall dismiss the audit report without the necessity of any further proceedings.

(3) This section does not apply to investigative audits conducted by the Medicaid Fraud Control Unit of the Department of Legal Affairs.

(4) This section does not apply to any investigative audit conducted by the Agency for Health Care Administration when the agency has reliable evidence that the claim that is the subject of the audit involves fraud, willful misrepresentation or abuse under the Medicaid program.

B-11 Georgia Regulatory Addendum to Pharmacy Participation Agreement

This Georgia Addendum applies to the extent that Pharmacy provides covered drugs to covered persons of an accident or health insurer, nonprofit hospital services corporation, nonprofit medical service corporation, health maintenance organization and organizations entering into preferred provider arrangements under Georgia law (collectively and/or individually, "plan sponsor").

In the event of a direct conflict between this Addendum and the Agreement, the applicable provisions of this Addendum shall control if required. This Addendum may be modified from time to time pursuant to the Agreement.

Without limiting the generality of the foregoing, and notwithstanding anything in the Agreement to the contrary, Pharmacy agrees as follows:

To the extent Pharmacy provides mail-order covered drugs to covered persons, Pharmacy shall in its initial written correspondence with each covered person include a notice stating that the covered person may obtain covered drugs, including prescription drugs, from other providers of pharmaceutical services and that the exclusive utilization of Pharmacy as a mail-order pharmaceutical distributor is not required. O.C.G.A. § 33-30-4.3(d).

To the extent that Pharmacy provides covered drugs to covered persons of a plan sponsor offering a preferred provider arrangement under Georgia law, Pharmacy agrees that a covered person shall be held harmless for provider utilization review decisions over which he has no control. Ga. Admin. Code 120-2- 44-.04(3).

To the extent that Pharmacy provides covered drugs to covered persons of a provider sponsored health care corporation under Georgia law, Pharmacy agrees:

In the event that plan sponsor or PBM fails to pay for covered drugs as set forth in the benefit plan or the Agreement, covered persons shall not be liable to Pharmacy for any sums owed by plan sponsor or PBM;

In the event of the insolvency of plan sponsor or PBM, Pharmacy shall continue to provide covered drugs as set forth in the Agreement to covered persons who are confined on the date of insolvency in an inpatient facility until the earlier of the covered person's discharge or expiration of benefits. Ga. Admin. Code 120-2-75-.06(5)-(6).

Any prospective authorization or other authorization required for covered drugs shall be conducted as set forth in the Agreement, including the pharmacy Manual. Ga. Admin. Code 120-2-80-.06(4).

The following shall apply with respect to PBM's MAC lists:

The national drug pricing compendia and/or sources used to obtain drug price data utilized by PBM in establishing maximum reimbursement amount pricing are First Databank and Medi-Span. O.C.G.A. § 33-64-9(a)(1).

Pricing on PBM's MAC list will be updated at least once every five business days (and every 14 business days for those contracts pursuant to Article 7 of Chapter 4 of Title 49 (the Georgia Medical Assistance Act of 1977)). O.C.G.A. § 33-64-9(a)(1).

Pharmacy locations in Georgia subject to PBM's MAC lists may appeal reimbursement for a drug subject to maximum allowable cost pricing by initiating an appeal within 14 calendar days of the Pharmacy submitting the claim for which the appeal is being requested. PBM will respond to the appeal within 14 calendar days of receipt. O.C.G.A. § 33-64-9(d).

This section applies only with respect to MAC list owned and/or controlled by PBM.

Pharmacy Audit Bill of Rights (O.C.G.A. § 26-4-118)

(a) This Code section shall be known and may be cited as "The Pharmacy Audit Bill of Rights."

(b) Notwithstanding any other law, when an audit of the records of a Pharmacy is conducted by a managed care company, insurance company, third-party payer, PBM, any entity licensed by the Department of Insurance, or any entity that represents such companies, groups or department, it shall be conducted in accordance with the following bill of rights:

(1) The entity conducting the audit must give the Pharmacy notice at 14 days prior to conducting the audit for each audit cycle and include in such notice a comprehensive list of claims by prescription number to be audited, although the final two digits may be omitted, and the cost of such claims shall not be used as a criterion in determining which claims to audit. The audit shall not include more than 100 prescriptions per audit and an entity shall not audit more than 200 prescriptions in any 12-month period, provided that a refill shall not constitute a separate prescription;

(2) Any audit which involves clinical or professional judgment must be conducted by or in consultation with a pharmacist;

(3) Any clerical or recordkeeping error, including, but not limited to, a typographical error, scrivener's error, computer error or omission error, regarding a prescription, front or back label, or other document or record shall not in and of itself constitute fraud. No such claim shall be subject to criminal penalties without proof of intent to commit fraud. No recoupment of the cost of drugs or medicinal supplies properly dispensed shall be allowed if such error has occurred; provided, however, that recoupment shall be allowed to the extent that such error resulted in an overpayment, though recoupment shall be limited to the amount overpaid;

(4) A Pharmacy shall be allowed at least 60 days following the receipt of the preliminary audit report in which to correct any error or to address any discrepancy found during an audit which may be subject to recoupment for overpayment as provided for in paragraph 12 of this subsection, including to secure and remit an appropriate copy of the record from a hospital, physician or other authorized practitioner of the healing arts for drugs or medicinal supplies written or transmitted by any means of communication if the lack of such a record or an error in such a record is identified in the course of an audit or noticed within the preliminary audit report;

(5) A Pharmacy may use the records of a hospital, physician or other authorized practitioner of the healing arts for drugs or medicinal supplies written or transmitted by any means of communication for purposes of validating the pharmacy record with respect to orders or refills of a legend or narcotic drug;

(6) A finding of an overpayment or underpayment may be a projection based on the number of patients served having a similar diagnosis or on the number of similar orders or refills for similar drugs; however, recoupment of claims must be based on the actual overpayment or underpayment unless the projection for overpayment or underpayment is part of a settlement as agreed to by the pharmacy;

(7) (7) Each Pharmacy shall be audited under the same standards and parameters as other similarly situated Pharmacies audited by the entity;

(8) The period covered by an audit may not exceed two years from the date the claim was submitted to or adjudicated by a managed care company, insurance company, third-party payer, PBM, any entity licensed by the Department of Insurance or any entity that represents such companies, groups or department;

(9) An audit may not be initiated or scheduled during the first seven calendar days of any month due to the high volume of prescriptions filled during that time unless otherwise consented to by the Pharmacy;

(10) The preliminary audit report must be delivered to the Pharmacy within 30 days after conclusion of the audit. A final audit report shall be delivered to the Pharmacy within 60 days after receipt of the preliminary audit report or final appeal, as provided for in subsection (c) of this Code section, whichever is later;

(11) A Pharmacy shall not be held responsible for any penalty or fee in connection with an audit and there shall be no recoupment of funds from a Pharmacy in connection with claims for which the Pharmacy has already been paid without first complying with the requirements set forth in this Code section;

(12) There shall be no recoupment from a Pharmacy except in cases of:

(A) Fraud;

(B) An error that resulted in an overpayment provided that recoupment shall be limited to the amount overpaid; or

(C) A misfill; provided, however, that when a patient receives the correct drug in the correct dosage and quantity pursuant to a prescription drug order then no misfill shall be found to have occurred; and

(13) A Pharmacy shall not be audited more than once every six months.

Notwithstanding any other provision in this subsection, the agency conducting the audit shall not use the accounting practice of extrapolation in calculating recoupments or penalties for audits.

(c) Recoupments of any disputed funds shall only occur after final internal disposition of the audit, including the appeals process as set forth in subsection (d) of this Code section.

(d) Each entity conducting an audit shall establish an internal appeals process under which a Pharmacy shall have at least 30 days from the delivery of the preliminary audit report to appeal an unfavorable preliminary audit report to the entity. If, following the appeal, the entity finds that an unfavorable audit report or any portion thereof is unsubstantiated, the entity shall dismiss the audit report or such portion without the necessity of any further proceedings.

(e) Each entity conducting an audit shall provide a copy of the final audit report, after completion of any review process, to the plan sponsor at its request or in an alternate format.

(f) This Code section shall not apply to any investigative audit commenced based upon an articulable suspicion of fraud, willful misrepresentation or abuse, including without limitation investigative audits under article 7 of chapter 4 of title 49, code section 33-1-16, or any other statutory provision which authorizes investigations relating to insurance fraud.

(g) The provisions of this Code section shall not apply to the Department of Community Health conducting audits under article 7 of chapter 4 of title 49; provided, however, that the provisions of Code section 49-4-151.1 shall apply to such audits conducted by the Department of Community Health under article 7 of chapter 4 of title 49.

(h) The entity conducting the audit may not pay the agent or employee who is conducting the audit based on a percentage of the amount recovered.

B-12 Hawaii Regulatory Addendum to Pharmacy Participation Agreement

This Hawaii Addendum applies to the extent that Pharmacy provides covered drugs to covered persons of an insurer, nonprofit health service plan, health insurance service organization, managed care plan, health maintenance organization and organizations entering into preferred provider arrangements under Hawaii law (collectively and/or individually, "plan sponsor").

In the event of a direct conflict between this Addendum and the Agreement, the applicable provisions of this Addendum shall control if required. This Addendum may be modified from time to time pursuant to the Agreement.

Without limiting the generality of the foregoing, and notwithstanding anything in the Agreement to the contrary, Pharmacy agrees as follows:

In the event that plan sponsor or PBM fails to pay for covered drugs, a covered person shall not be liable to Pharmacy for any sums owed by plan sponsor or PBM. Pharmacy shall not collect or attempt to collect from a covered person sums owed by plan sponsor or PBM. Pharmacy, or its agent, trustee or assignee shall not maintain any action at law against a covered person to collect sums owed by plan sponsor or PBM. Hawaii Stat. § 432D-8(d).

In the event of insolvency by plan sponsor or PBM, Pharmacy agrees to continue to provide services to covered persons for the duration of the period after the insolvency for which premium payment has been made and until a covered person's discharge from inpatient facilities. Hawaii Stat. § 432D-8(e)(2).

Pharmacy shall provide PBM with at least 60 days' advance written notice of termination of the Agreement. Hawaii Stat. § 432D-8(f).

Pharmacy shall comply with PBM's and plan sponsors' requests for any information necessary for plan sponsor to comply with the requirement of Hawaii Statute, title 24, Chapter 432E, regarding the measurement of quality outcomes, access, satisfaction and utilization of services. Hawaii Stat. § 432E-10(a).

B-13 Idaho Regulatory Addendum to Pharmacy Participation Agreement

This Idaho Addendum applies to the extent that Pharmacy provides covered drugs to covered persons of a health insurer, hospital services corporation, professional service corporation, managed care organization, health maintenance organization and organizations entering into preferred provider arrangements under Idaho law (collectively and/or individually, "plan sponsor").

In the event of a direct conflict between this Addendum and the Agreement, the applicable provisions of this Addendum shall control if required. This Addendum may be modified from time to time pursuant to the Agreement.

Without limiting the generality of the foregoing, and notwithstanding anything in the Agreement to the contrary, Pharmacy agrees as follows:

Neither PBM nor plan sponsor shall make a specific payment under this agreement, in any type or form, to Pharmacy as an inducement to deny, reduce, limit or delay specific, medically necessary and appropriate covered drugs provided with respect to a specific covered person or group of covered persons with similar medical conditions. Idaho Stat. §§ 41-1846(1)(f), 41-3928.

To the extent Pharmacy provides covered drugs to covered persons of a hospital or professional service corporation or managed care organization under Idaho law, Pharmacy agrees if PBM or plan sponsor proposes to terminate or not renew the Agreement based on Pharmacy's breach of the Agreement, PBM or plan sponsor shall provide Pharmacy written notice identifying the breach and providing a reasonable period of time for Pharmacy to cure the breach prior to termination or nonrenewal. If the breach has not been cured within the time period stated, PBM or plan sponsor may terminate or not renew the Agreement. Provided, however, that if the breach for which PBM or plan sponsor proposes to terminate or not renew the Agreement is a willful breach, fraud or a breach which poses an immediate danger to the public health or safety, PBM or plan sponsor may terminate or not renew the Agreement immediately. Idaho Stat. §§ 41-3408(5), 41-3927(2).

To the extent Pharmacy provides covered drugs to covered persons of a hospital or professional service corporation under Idaho law, Pharmacy agrees:

Pharmacy shall provide covered persons with covered drugs and Pharmacy's obligation to so furnish such covered drugs as provided for in the benefit plan shall be a direct obligation of Pharmacy to covered persons, PBM, and plan sponsor. Idaho Stat. § 41-3415A(1).

Pharmacy shall be compensated as set forth in the Agreement and the attachments thereto. Pharmacy shall not request or receive from PBM, plan sponsor, or covered persons any compensation for covered drugs which is not in accord with the Agreement. Idaho Stat. § 41-3415A(2)(a).

Pharmacy's compensation may be prorated and settled under the circumstances and in the manner referred to in section 41-3431, Idaho Code. Idaho Stat. § 41-3415A(2)(b).

If Pharmacy terminates the Agreement, the termination shall not be effective as to any covered person enrolled in a benefit plan in force on the date of such termination and Pharmacy shall continue to provide covered drugs pursuant to the Agreement until the termination of covered person's benefit plan or the next following anniversary of covered person's benefit plan, whichever date is earlier. Idaho Stat. § 41-3415A(2)(c).

The agreement shall not be construed to require Pharmacy to deny a covered person access to services not covered by a benefit plan if the covered person is informed that he or she will be responsible to pay for the noncovered services and he or she nonetheless desires to obtain such services. Idaho Stat. § 41- 3927(4)(a).

The agreement shall not limit Pharmacy's ability to treat a covered person even at that person's request and expense if Pharmacy had been, but is no longer, a Participating Pharmacy under the benefit plan and Pharmacy has notified the covered person that Pharmacy is no longer a Participating Pharmacy under the benefit plan. Idaho Stat. § 41-3927(4)(b).

Notwithstanding anything in the Agreement, Pharmacy shall not be required to accept the unnegotiated adjustment by PBM or plan sponsor of Pharmacy's contractual reimbursement rate to equal the lowest reimbursement rate Pharmacy has agreed to charge any other plan sponsor. Idaho Stat. §§ 41-3927(4)(c), 41-3443(1).

Notwithstanding anything in the Agreement, Pharmacy shall not be required to adjust, or enter into negotiations to adjust, its charges to PBM or plan sponsor if Pharmacy agrees to charge another plan sponsor lower rates. Idaho Stat §§ 41-3927(4)(d), 41-3443(2).

Pharmacy shall not be required to disclose its contractual reimbursement rates from other plan sponsors. Idaho Code §§ 41-3927(4)(e), 41-3443(3).

To the extent the Agreement requires Pharmacy to indemnify and hold harmless a managed care organization plan sponsor under certain circumstances, to the extent required by law, such indemnification applies so long as the managed care organization plan sponsor also agrees to indemnify and hold harmless the provider under comparable circumstances. Idaho Stat § 41-3927(6).

A participation contract executed, amended, adjusted, or renewed between a PBM and Pharmacy must include, in substantial form, to the extent allowable by law, terms that ensure compliance with § 41-349 of the Idaho Statute:

(a) The pharmacy benefit manager shall provide a reasonable administrative appeal procedure to allow a pharmacy or pharmacist to challenge the maximum allowable cost pricing information and the reimbursement made under the maximum allowable cost as defined in subsection (1)(d) of this section for a specific drug as being below the acquisition cost available to the challenging pharmacy or pharmacist.

(b) The administrative appeal procedure must include a telephone number and email address, or a website, for the purpose of submitting the administrative appeal. The appeal may be submitted by the pharmacy or an agent of the pharmacy directly to the pharmacy benefit manager or through a pharmacy service administration organization. The pharmacy or pharmacist must be given at least thirty (30) business days after a maximum allowable cost update or after an adjudication for an electronic claim or reimbursement for a nonelectronic claim to file the administrative appeal.

(c) The pharmacy benefit manager must respond to the administrative appeal within thirty (30) business days after receipt of the appeal.

(i) If the appeal is upheld, the pharmacy benefit manager must:

1. Update the maximum allowable cost pricing information to at least the acquisition cost available to the pharmacy;
2. Permit the pharmacy or pharmacist to reverse and rebill the claim in question;
3. Provide to the pharmacy or pharmacist the national drug code on which the increase or change is based; and
4. Make the increase or change effective for each similarly situated pharmacy or pharmacist who is subject to the applicable maximum allowable cost pricing information; or

(ii) If the appeal is denied, the pharmacy benefit manager must provide to the pharmacy or pharmacist the national drug code and the name of the national or regional pharmaceutical wholesalers operating in this state that have the drug currently in stock at a price below the maximum allowable cost pricing information.

Requirements and prohibitions for pharmacy audits (Idaho Stat.§41-6603)

1) Any person or entity conducting an audit of a Pharmacy shall:

a) If performing the audit pursuant to a contract, identify and specifically describe the contract provisions authorizing the audit, including provisions relating to audit appeals. No contract may require prescription claim documentation or recordkeeping requirements that exceed requirements set forth in applicable federal or state law, regulation or rule;

b) Give written notice to the Pharmacy and the Pharmacy's contracting agent at 14 days prior to conducting the on-site audit. For purposes of this subsection, the term "audit" means an audit conducted on behalf of an auditing entity of any records of a Pharmacy for drugs dispensed by a pharmacy to a covered individual. The Pharmacy shall have the opportunity to reschedule any on-site audit no more than seven days from the date designated on the original audit notification;

c) Not interfere with the delivery of pharmacist services to a patient and use every reasonable effort to minimize inconvenience and disruption to pharmacy operations during the on-site audit process;

d) Conduct any audit involving clinical or professional judgment by means of or in consultation with a licensed pharmacist;

e) Prior to leaving the Pharmacy after the on-site portion of the pharmacy audit, provide to the Pharmacy a complete list of pharmacy records reviewed;

f) Not subject a Pharmacy to a chargeback or recoupment for a clerical or recordkeeping error, such as a typographical error, scrivener's error or computer error, including, but not limited to, a miscalculated days' supply, an incorrectly billed prescription written date, or an incorrect prescription origin code, unless the error resulted in overpayment to the Pharmacy. Prior to payment of the claim, the Pharmacy shall have the right to submit amended claims electronically to correct clerical or recordkeeping errors in lieu of recoupment. A person shall not be subject to criminal penalties for errors described in this paragraph without proof of the intent required for conviction of the applicable crime;

g) Limit any fee, chargeback, recoupment or other adjustment to the actual overpayment associated with the dispensed product or portion of the dispensed product or the actual underpayment or overpayment as set forth in this subsection;

h) Permit a Pharmacy to use any valid prescription, including computerized patterned medical records or the records of a hospital, physician or other authorized health care practitioner for drugs or medicinal supplies written or transmitted by any means of communication for purposes of validating the pharmacy record with respect to orders or refills of a legend or other prescribed drug. Documentation of an oral prescription order that has been verified by the prescribing health care provider shall meet the provisions of this paragraph for the initial audit review;

i) Permit a Pharmacy to use authentic and verifiable statements or records, including, but not limited to, medication administration records of a nursing home, assisted living facility, hospital or health care provider with prescriptive authority, to validate the pharmacy record and delivery;

j) Not include the dispensing fee in the calculation of overpayment of the prescription dispensed in a finding of an audit recoupment unless a prescription was not actually dispensed or a physician denied authorization of a dispensing order;

k) Audit each Pharmacy under standards, regularity and parameters as other similarly situated Pharmacies in a Pharmacy Network contract in this state. If the person or entity conducting the audit owns or manages Pharmacies, all audits of such Pharmacies shall be conducted under standards, regularity and parameters as other similarly situated Pharmacies in a pharmacy network contract in this state;

l) Not exceed 15 months from the date the claim was submitted to or adjudicated by the person or entity conducting the audit;

m) Not schedule or initiate an audit during the first seven calendar days of any month unless otherwise consented to by the Pharmacy;

n) Disclose to any plan sponsor whose claims were included in the audit any money recouped in the audit;

o) Provide network Pharmacies information on the adjudication process for unit of use prescription products where the smallest unit either exceeds or does not maximize the benefit days' supply; and

p) Permit a Pharmacy to use a paper or electronic signature log that documents the delivery of a prescription to the possession of the patient or the patient's agent.

2) Except as otherwise provided by federal or state law, an auditing entity that audits wholesale invoices during an audit of a Pharmacy may not audit the pharmacy claims of another health benefit plan or pharmacy benefit manager.

3) Any person or entity conducting a wholesale invoice audit shall not identify or label a prescription claim as an audit discrepancy when:

a) The National Drug Code for the dispensed drug is in a quantity that is a subunit or multiple of the drug purchased by the pharmacist or Pharmacy as supported by a wholesale invoice;

b) The pharmacist or Pharmacy dispensed the correct quantity of the drug according to the prescription; and

c) The drug dispensed by the pharmacist or Pharmacy shares all but the last two digits of the National Drug Code of the drug reflected on the supplier invoice.

4) Any person or entity conducting a wholesale invoice audit shall accept as evidence, subject to validation, to support the validity of a Pharmacy claim related to a dispensed drug:

a) Supplier invoices issued before the date the drug was dispensed in the pharmacist's or Pharmacy's possession; or

b) Invoices and any supporting documents from any supplier as authorized by federal or state law to transfer ownership of the drug acquired by the pharmacist or Pharmacy.

5) Any person or entity conducting a wholesale invoice audit shall provide, no later than five business days after the date of a request by the pharmacist or Pharmacy, all supporting documents the pharmacist's or Pharmacy's purchase suppliers provided to the person or entity on whose behalf the audit is being conducted.

6) Any person or entity conducting an audit shall not audit more than 250 prescriptions, based on date of service, per calendar year. The annual limit to the number of prescription claims audited shall be inclusive of all audits, including any prescription-related documentation requests from the person or entity conducting the audit or the person or entity on whose behalf the audit is being conducted during a calendar year.

7) If paper copies of records are requested by the person or entity conducting an audit, the person or entity shall pay 25 cents per page to cover the costs incurred by the Pharmacy. The person or entity conducting the audit shall provide the Pharmacy with accurate instructions, including any required form for obtaining reimbursement for the copied records.

8) The person or entity conducting an audit shall:

a) Deliver a preliminary audit findings report to the Pharmacy and the Pharmacy's contracting agent within 60 calendar days of conducting the audit. The preliminary report shall include contact information for the auditing entity that conducted the pharmacy audit and an appropriate and accessible point of contact, including telephone number, facsimile number, electronic mail address and auditing firm name and address so that audit results, procedures and discrepancies may be reviewed. The preliminary audit report shall include, but is not limited to, claim level information for any discrepancy found and total dollar amounts of claims subject to recoupment;

b) Allow the Pharmacy at least 60 calendar days following receipt of the preliminary audit findings report in which to produce documentation to address any discrepancy found during the audit. A Pharmacy may request an extension, not to exceed an additional 30 calendar days;

c) Deliver a final audit findings report to the Pharmacy and the Pharmacy's contracting agent signed by the auditor within 30 calendar days after receipt of documentation or evidence provided by the Pharmacy, as provided for in section 41-6604, Idaho Code;

d) Allow the Pharmacy to reverse and resubmit claims electronically within 30 days of receipt of the final audit report in lieu of the auditing entity recouping discrepant claim amounts from the Pharmacy;

e) Not recoup any disputed funds until after final disposition of the audit findings, including the appeals process as provided for in section 41-6604, Idaho Code; and

f) Not accrue interest during the audit and appeal period.

9) Each person or entity conducting an audit shall provide a copy of the final audit results, and a final audit report upon request, after completion of any review process to any plan sponsor whose claims were included in the audit.

10) The full amount of any recoupment on an audit shall be refunded to the plan sponsor whose claims were included in the audit and to whom the recoupment is owing. Except as otherwise provided for in this subsection, a charge or assessment for an audit shall not be based, directly or indirectly, on amounts recouped. This subsection shall not prevent the person or entity conducting the audit from charging or assessing the responsible party, directly or indirectly, based on amounts recouped if both of the following conditions are met:

a) The plan sponsor and Prime have a contract that explicitly states the percentage charge or assessment to the plan sponsor; and

b) A commission to an agent or employee of the person or entity conducting the audit is not based, directly or indirectly, on amounts recouped.

11) Unless the provisions of this subsection are superseded by state or federal law, auditors shall have access to previous audit reports on a particular Pharmacy only when the previous audits were conducted by the auditing person or entity for the same person or entity on whose behalf the audit is being conducted. An auditing vendor contracting with multiple persons or entities shall not use audit reports or other information gained from an audit on a Pharmacy to conduct another audit for another person or entity.

Appeals process (Idaho Stat. §41-6604)

1) Each person or entity conducting an audit shall establish a written appeals process under which a Pharmacy may appeal an unfavorable preliminary audit report or final audit report to the person or entity. The Pharmacy must submit documentation or other evidence to support its appeal.

2) Following an appeal, if the person or entity finds that an unfavorable audit report is unsubstantiated, the person or entity shall dismiss the unsubstantiated portion of the audit report.

3) Any final audit report, following the final audit appeal period, with a finding of potential criminal conduct shall be referred to the prosecuting attorney having proper jurisdiction upon completion of the appeals process.

Extrapolation audit prohibited (Idaho Stat. §41-6605)

1) As used in this section, "extrapolation audit" means an audit of a sample of prescription drug benefit claims submitted by a Pharmacy to the person or entity conducting an audit that is then used to estimate audit results for a larger batch or group of claims not reviewed by the auditor.

2) No person or entity may not conduct an extrapolation audit unless otherwise required by federal law or federal plans. A person or entity conducting an audit shall not use the accounting practice of extrapolation in calculating recoupments or penalties for audits.

B-14 Illinois Regulatory Addendum to Pharmacy Participation Agreement

This Illinois Addendum applies to the extent that Pharmacy provides covered drugs to covered persons of an accident or health insurer, nonprofit hospital services corporation, nonprofit medical service corporation, health maintenance organization and organizations entering into preferred provider arrangements under Illinois law.

In the event of a direct conflict between this Addendum and the Agreement, the applicable provisions of this Addendum shall control if required. This Addendum may be modified from time to time pursuant to the Agreement.

Without limiting the generality of the foregoing, and notwithstanding anything in the Agreement to the contrary, Pharmacy agrees as follows:

Pharmacy agrees to participate in the quality assurance programs instituted by PBM and plan sponsors. 215 ILCS 125/2-8(b), 215 ILCS 130/2008(b); 50 Ill. Admin. Code §4521.50(a)(4).

Pharmacy agrees that in no event, including, but not limited to, nonpayment by PBM and/or plan sponsor of amounts due Pharmacy under the Agreement, insolvency of PBM and/or plan sponsor or any breach of the Agreement, shall Pharmacy or its assignees or subcontractors have a right to seek any type of payment from, bill, charge, collect a deposit from or have any recourse against the covered person, persons acting on the covered person's behalf (other than PBM or plan sponsor), the employer or group contract holder for services provided pursuant to the Agreement except for the payment of applicable copays for services covered by plan sponsor or fees for services not covered by plan sponsor. The requirements of this clause shall survive any termination of the Agreement for services rendered prior to such termination, regardless of the cause of such termination. Plan sponsors' covered persons shall be third-party beneficiaries of this clause. This clause supersedes any oral or written agreement now existing or hereafter entered into between Pharmacy and a covered person or persons acting on the covered person's behalf (other than PBM or plan sponsor). 215 ILCS 130/2008(a).

Nothing in the Agreement shall be construed to prohibit or discourage Pharmacy from discussing any health care services and health care providers, utilization review and quality assurance policies, terms and conditions of a benefit plan and benefit plan policy with covered persons, prospective covered persons, providers, or the public. 215 ILCS 134/30.

Nothing in the Agreement shall be construed as permitting or allowing Pharmacy to dispense a different drug in place of the drug or brand of drug ordered or prescribed without the express permission of the person ordering or prescribing the drug, except as provided under Section 3.14 of the Illinois Food, Drug and Cosmetic Act. 215 ILCS 134/30.

PBM shall not retaliate against Pharmacy based on Pharmacy advocating for appropriate health care services for patients. For purposes of this paragraph, "advocating for medically appropriate health care services" means to appeal a decision to deny payment for a health care service pursuant to the reasonable grievance or appeal procedure established by PBM and/or plan sponsor or to protest a decision, policy or practice that Pharmacy, consistent with that degree of learning and skill ordinarily possessed by other pharmacy providers practicing in the same or similar locality and under similar circumstances, reasonably believes impairs the provider's ability to provide appropriate health care services to his or her patients. 215 ILCS 134/35.

PBM shall not take future contractual action regarding Pharmacy based solely on Pharmacy's participation in health care services appeals, complaints or external independent reviews under the Illinois Health Carrier External Review Act. 215 ILCS 134/45.

Nothing in the Agreement shall be construed in a manner so as to discriminate against Pharmacy. 215 ILCS 134/72.

Notwithstanding anything to the contrary in the Agreement, liability relating to the activities, actions, or omissions of PBM, plan sponsor and/or their officer, employees, or agents shall not be transferred to Pharmacy by indemnification, hold harmless provisions, or otherwise. Nothing in this paragraph shall relieve Pharmacy from liability for its own negligence in the performance of its duties arising from treatment of a patient. 215 ILCS 134/95.

PBM shall give Pharmacy at least 60 days' notice of nonrenewal or termination of Pharmacy. The notice shall include a name and address to which Pharmacy may direct comments and concerns regarding the nonrenewal or termination. However, immediate written notice may be provided without 60 days' notice when Pharmacy's license has been disciplined by a state licensing board. 215 ILCS 134/20; 50 Ill. Admin. Code §§ 2051.290(f), 4520.50. PBM may terminate the Agreement immediately for cause. 50 Ill. Admin. Code § 2051.290(f)(2).

Pharmacy shall give PBM at least 60 days' notice for termination with cause, as defined in the Agreement, and at least ninety 90 days' notice for termination without cause. 50 Ill. Admin. Code §§ 4520.50(a), 4521.50(a)(5).

In connection with preferred provider programs (as defined under Illinois law), either party shall give the other party at least 30 days' notice for termination without cause. 50 Ill. Admin. Code §§ 2051.290(f)(1).

Pharmacy must maintain and provide evidence of adequate professional liability and malpractice coverage, through insurance, self-funding or other means satisfactory to PBM, effective as of the date of the Agreement. Pharmacy must give PBM at least 15 days' advance notice of cancellation of such coverage and must notify PBM within no less than 10 days after Pharmacy's receipt of notice of any reduction or cancellation of the required coverage. 50 Ill. Admin. Code §§ 2051.290(i), 4521.50(a)(7).

Pharmacy shall be responsible for providing covered drugs as set forth in the Agreement, including the application of discount services, copays, benefit maximums, limitations and exclusions, and discounted amounts or rates as further set forth in the Agreement, and any attachments thereto. 50 Ill. Admin. Code § 2051.290(a).

Pharmacy agrees to comply with all administrative policies and procedures of PBM and plan sponsor, including, but not limited to, credentialing or recredentialing requirements, utilization review requirements and referral procedures. 50 Ill. Admin Code § 2051.290(b).

Pharmacy shall maintain and make medical records available to PBM and/or plan sponsor for the purpose of determining, on a concurrent or retrospective basis, the medical necessity and appropriateness of care provided to covered persons, and to make such medical records available to appropriate state and federal authorities and their agents involved in assessing the accessibility and availability of care or investigating grievances or complaints and to show compliance with the applicable state and federal laws related to privacy and confidentiality of medical records. 50 Ill. Admin Code § 2051.290(c).

Pharmacy shall be licensed by the State of Illinois to provide covered drugs and shall notify PBM immediately whenever there is a change in licensure or certification status. 50 Ill. Admin. Code § 2051.290(d).

Upon the termination of the Agreement, Pharmacy shall be responsible for continuing provision of covered drugs to the extent required by law or regulation or as otherwise set forth in the Agreement. 50 Ill. Admin. Code § 2051.290(g).

Neither PBM nor Pharmacy shall sell, lease, assign or otherwise delegate the rights and responsibilities under the Agreement without the prior written and informed consent of the other party. Pharmacy's written consent must also be obtained for any assignment or assumption of the Agreement in the event that PBM is bought by another administrator or insurer. Pharmacy hereby gives its consent to such assignment or assumption of the Agreement. 50 Ill. Admin. Code § 2051.290(h).

Pharmacy shall provide covered drugs without discrimination against any covered person on the basis of participation in the benefit plan, source of payment, age, sex, ethnicity, religion, sexual preference, health status or disability. 50 Ill. Admin. Code § 2051.290(j).

Pharmacy shall collect all applicable copays, coinsurance and/or deductibles from covered persons, and shall provide notice to covered persons of their personal financial obligations for services that are not covered.

Pharmacy's rates for providing covered drugs to covered persons shall be in accordance with the Agreement. Pharmacy shall not charge covered persons more than the discounted rates provided by the Agreement for covered drugs. 50 Ill. Admin. Code § 2051.290(k).

Pharmacy shall comply with plan sponsors' requirements regarding operating hours and availability. 50 Ill. Admin. Code § 2051.290(l).

PBM's payment obligations to Pharmacy, including the method and amount of reimbursement and the frequency of payment, shall be as set forth in the Agreement, and any attachments thereto. 215 ILCS 5/512-7(a); 50 Ill. Admin. Code § 2051.290(m).

PBM's services, the types of information that will be submitted to Pharmacy, and the types of information that will be accessible to the Pharmacy shall be as set forth in the Agreement, and any attachments thereto. 50 Ill. Admin. Code § 2051.290(n).

PBM shall provide a method for Pharmacy to obtain each plan sponsor's initial information and adequate notice of change in benefits and copays. PBM shall provide Pharmacy with all of PBM's operational policies, which may be included in the attachments to the Agreement. 50 Ill. Admin. Code § 2051.290(o).

Internal appeal or arbitration procedures for settling contractual disputes or disagreements between PBM and Pharmacy shall be as set forth in the Agreement, and any attachments thereto. 50 Ill. Admin. Code § 2051.290(p).

Pharmacy audits (215 ILCS 5/513b7)

a) Notwithstanding any other law, when conducting a Pharmacy audit, PBM shall:

A) Not conduct an on-site audit of a Pharmacy at any time during the first three business days of a month or the first two weeks and final two weeks of the calendar year or during a declared state or federal public health emergency;

B) Notify the Pharmacy or its contracting agent no later than 14 business days before the date of initial on-site audit; the notification to the Pharmacy or its contracting agent shall be in writing and delivered either:

(a) By mail or common carrier, return receipt requested; or

(b) Electronically, not including facsimile, with electronic receipt confirmation and delivered during normal business hours of operation, addressed to the supervising pharmacist and Pharmacy corporate office, if applicable, at least 14 business days before the date of an initial on-site audit;

C) Limit the audit period to 24 months after the date a claim is submitted to or adjudicated by the pharmacy benefit manager;

D) Provide in writing the list of specific prescription numbers to be included in the audit 14 business days before the on-site audit that may or may not include the final two digits of the prescription numbers;

E) Use the written and verifiable records of a hospital, physician or other authorized practitioner that are transmitted by any means of communication to validate the pharmacy records in accordance with state and federal law;

Appendix B: Regulatory addendums (continued)

F) Limit the number of prescriptions audited to no more than 100 prescriptions per audit and an entity shall not audit more than 200 prescriptions in any 12-month period, except in cases of fraud or knowing and willful misrepresentation; a refill shall not constitute a separate prescription and a Pharmacy shall not be audited more than once every six months;

G) Provide the Pharmacy or its contracting agent with a copy of the preliminary audit report within 45 days after the conclusion of the audit;

H) Be allowed to conduct a follow-up audit on site if a remote or desk audit reveals the necessity for a review of additional claims;

I) Accept invoice audits as validation invoices from any wholesaler registered with the Department of Financial and Professional Regulation from which the Pharmacy has purchased prescription drugs or, in the case of durable medical equipment or sickroom supplies, invoices from an authorized distributor other than a wholesaler;

J) Provide the Pharmacy or its contracting agent with the ability to provide documentation to address a discrepancy or audit finding if the documentation is received by the pharmacy benefit manager no later than the 45th day after the preliminary audit report was provided to the Pharmacy or its contracting agent; the pharmacy benefit manager shall consider a reasonable request from the Pharmacy for an extension of time to submit documentation to address or correct any findings in the report;

K) Be required to provide the Pharmacy or its contracting agent with the final audit report no later than 90 days after the initial audit report was provided to the Pharmacy or its contracting agent;

L) Conduct the audit in consultation with a pharmacist in specific cases if the audit involves clinical or professional judgment;

M) Not chargeback, recoup, or collection of penalties from a Pharmacy until the time period to file an appeal of the final pharmacy audit report has passed or the appeals process has been exhausted, whichever is later, unless the identified discrepancy is expected to exceed $25,000, in which case the auditing entity may withhold future payments in excess of that amount until the final resolution of the audit;

N) Not compensate the employee or contractor conducting the audit based on a percentage of the amount claimed or recouped pursuant to the audit;

O) Not use extrapolation to calculate penalties or amounts to be charged back or recouped unless otherwise required by federal law or regulation; any amount to be charged back or recouped due to overpayment may not exceed the amount the Pharmacy was overpaid;

P) Not include dispensing fees in the calculation of overpayments unless a prescription is considered a misfill, the medication is not delivered to the patient, the prescription is not valid or the prescriber denies authorizing the prescription; and

Q) Conduct a pharmacy audit under the same standards and parameters as conducted for other similarly situated Pharmacies audited by the auditing entity.

b) Except as otherwise provided by state or federal law, PBM conducting a pharmacy audit may have access to a Pharmacy's previous audit report only if the report was prepared by PBM.

c) Information collected during a pharmacy audit shall be confidential by law, except that PBM may share the information with the health benefit plan for which a pharmacy audit is being conducted and with any regulatory agencies and law enforcement agencies as required by law.

d) A Pharmacy may not be subject to a chargeback or recoupment for a clerical or recordkeeping error in a required document or record, including a typographical error or computer error; PBM can provide proof of intent to commit fraud or such error results in actual financial harm to PBM, a health plan managed by PBM or a consumer.

Appendix B: Regulatory addendums (continued)

e) A Pharmacy shall have the right to file a written appeal of a preliminary and final pharmacy audit report in accordance with the procedures established by PBM.

f) No interest shall accrue for any party during the audit period, beginning with the notice of the pharmacy audit and ending with the conclusion of the appeals process.

g) PBM must provide a copy to the plan sponsor of its claims that were included in the audit, and any recouped money shall be returned to the plan sponsor, unless otherwise contractually agreed upon by the plan sponsor and PBM.

h) The parameters of an audit must comply with manufacturer listings or recommendations, unless otherwise prescribed by the treating provider, and must be covered under the individual's health plan, for the following:

A) The days' supply for eye drops must be calculated so that the consumer pays only one 30-day copay if the bottle of eye drops is intended by the manufacturer to be a 30-day supply;

B) The days' supply for insulin must be calculated so that the highest dose prescribed is used to determine the days' supply and consumer copay; and

C) The days' supply for topical product must be determined by the judgment of the pharmacist or treating provider upon the treated area.

i) These audit requirements shall not apply to:

A) Audits in which suspected fraud or knowing and willful misrepresentation is evidenced by a physical review, review of claims data or statements or other investigative methods

B) Audits of claims paid for by federally funded programs not applicable to health insurance coverage regulated by the department; or

C) Concurrent reviews or desk audits that occur within three business days after transmission of a claim and in which no chargeback or recoupment is demanded.

B-15 Indiana Regulatory Addendum to Pharmacy Participation Agreement

This Indiana Addendum applies to the extent that Pharmacy provides covered drugs to covered persons of insurers, health maintenance organizations ("HMOs"), limited-service HMOs, Medicaid managed care organizations, preferred provider organizations or other third-party payers under Indiana law (collectively and/or individually, "plan sponsor").

In the event of a direct conflict between this Addendum and the Agreement, the applicable provisions of this Addendum shall control if required. This Addendum may be modified from time to time pursuant to the Agreement.

Without limiting the generality of the foregoing, and notwithstanding anything in the Agreement to the contrary, Pharmacy and PBM agree as follows:

Contractual Requirements (Ind. Code 27-1-24.2-15)

(a) A contract between a pharmacy or pharmacist and an insurer, a PBM, or any other administrator of pharmacy benefits for the provision of pharmacy or pharmacist services under a health plan, either directly or through a pharmacy services administrative organization (PSAO) or group purchasing organization (GPO), must include provisions that do the following:

(1) Outline the terms and conditions for the provision of pharmacy or pharmacist services.

(2) Subject to subsection (b), prohibit the insurer, PBM, or other administrator from retroactively denying, reducing reimbursement for, or seeking any refunds or recoupments for a claim for pharmacy or pharmacist services, in whole or in part, from the pharmacy or pharmacist after returning a paid claim response as part of the adjudication of the claim, including claims for the cost of a medication or dispensed product and claims for pharmacy or pharmacist services that are deemed ineligible for coverage, unless:

(A) the original claim was submitted fraudulently; or

(B) the pharmacy or pharmacist received an actual overpayment.

(3) Prohibit the insurer, PBM, or other administrator from reimbursing the pharmacy or pharmacist for a prescription drug or other service at a net amount that is less than the greater of the following:

(A) The amount the insurer, PBM, or other administrator reimburses itself or a pharmacy affiliate for the same prescription drug by national drug code number or service.

(B) The following amount, as applicable:

(i) If the prescription drug or service is administered, dispensed, or provided at a pharmacy that is a licensed premises (as defined in IC 7.1-1-3-20), the actual acquisition cost for the prescription drug or service plus a fair and reasonable dispensing fee.

(ii) If the prescription drug or service is administered, dispensed, or provided at a pharmacy not described in item (i), the national average drug acquisition cost (NADAC) for the prescription drug or service, as determined by the federal Centers for Medicare and Medicaid Services at the time the prescription drug or service is administered, dispensed, or provided plus a professional dispensing fee equal to the Medicaid fee for service dispensing fee under 405 IAC 5-24-6.

(b) An insurer, PBM, or any other administrator of pharmacy benefits may not request a refund or make a recoupment of a dispensing fee paid to the pharmacy if the correct medication was dispensed to the patient.

Pharmacy benefit manager; duties; appeals (Ind. Code 27-1-24.5-22)

(a) A PBM shall do the following:

(1) Identify to the contracted:

(A) Pharmacy service administrative organizations; or

(B) Pharmacies if the PBM contracts directly with pharmacies:
Sources used by PBM to calculate the drug product reimbursement paid for covered drugs available under the pharmacy health plan administered by PBM.

(2) Establish an appeals process for contracted pharmacies, PSAOs or group purchasing organizations (GPOs) to appeal and resolve disputes concerning the maximum allowable cost pricing.

(3) Update and make available to pharmacies:

(A) At least every seven (7) days; or

(B) In a different time frame if contracted between a PBM and a pharmacy;
The PBM's maximum allowable cost list.

(4) Determine that a prescription drug:

(A) Is not obsolete;

(B) Is generally available for purchase by pharmacies in Indiana from a national or regional wholesaler licensed in Indiana; and

(C) Is not:

(i) temporarily unavailable;

(ii) listed on a drug shortage list; or

(iii) Unable to be lawfully substituted;
Before the prescription drug is placed or continued on a maximum allowable cost list.

(b) PBM's appeal process required by subsection (a)(2) must include the following:

(1) The right to appeal a claim not to exceed sixty (60) days following the initial filing of the claim;

(2) The investigation and resolution of a filed appeal by the PBM in a time frame determined by the commissioner.

(3) If an appeal is denied, a requirement that the PBM do the following:

(A) Provide the reason for the denial.

(B) Provide the appealing contracted pharmacy, pharmacy services administrative organization, or group purchasing organization with the national drug code number of the prescription drug that is available from a national or regional wholesaler operating in Indiana.

(4) If an appeal is approved, a requirement that the pharmacy benefit manager do the following:

(A) Change the maximum allowable cost of the drug for the pharmacy that filed the appeal as of the initial date of service that the appealed drug was dispensed.

(B) Adjust the maximum allowable cost of the drug for the appealing pharmacy and for all other contracted pharmacies in the same network of the PBM that filled a prescription for patients covered under the same health plan beginning on the initial date of service the appealed drug was dispensed.

(C) Notify each pharmacy in the PBM's network that the maximum allowable cost for the drug has been adjusted as a result of an approved appeal.

(D) Adjust the drug product reimbursement for contracted pharmacies that resubmit claims to reflect the adjusted maximum allowable cost, if applicable.

(E) Allow the appealing pharmacy and all other contracted pharmacies in the network that filled the prescriptions for patients covered under the same health plan to reverse and resubmit claims and receive payment based on the adjusted maximum allowable cost from the initial date of service the appealed drug was dispensed.

(F) Make retroactive price adjustments in the next payment cycle unless otherwise agreed to by the pharmacy.

(5) The establishment of procedures for auditing submitted claims by a contracted pharmacy in a manner established by administrative rules under IC 4-22-2 by the department. The auditing procedures:

(A) May not use extrapolation or any similar methodology;

(B) May not allow for recovery by a PBM of a submitted claim due to clerical or other error where the patient has received the drug for which the claim was submitted;

(C) Must allow for recovery by a contracted pharmacy for underpayments by the PBM; and

(D) May only allow for the PBM to recover overpayments on claims that are actually audited and discovered to include a recoverable error.

To the extent that Pharmacy participates in the federal 340B Drug Pricing Program as a 340B covered entity, the following shall not apply: (a) a reimbursement rate for a prescription drug that would diminish the 340B benefit to Pharmacy as a 340B covered entity; (b) a fee or adjustment that is not imposed on a Pharmacy that is not a 340B covered entity; (c) a fee or adjustment amount that exceeds the fee or adjustment amount imposed on a Pharmacy that is not a 340B covered entity; (d) any provision that prevents or interferes with an individual's choice to receive a prescription drug from Pharmacy as a 340B covered entity, including the administration of the drug; (e) any provision that excludes a 340B covered entity from PBM's networks based on the Pharmacy's participation in the federal 340B Drug Pricing

Program; and (f) any provision that discriminates against Pharmacy as a 340B covered entity. Ind. Code 27-1-24.5-19.5

Pharmacy acknowledges and agrees that PBM may lease, rent or otherwise grant access to Pharmacy's services under the Agreement to third parties that are: (a) Employers or entities providing coverage for covered drugs to their employees or members when such employers and/or entities have contracted with PBM or its affiliate for the administration or processing of claims for payment or service provided under the Agreement; and (b) Affiliates or subsidiaries of PBM or entities providing or receiving administrative services from PBM or its affiliates or subsidiaries. Any such third-party that is granted access to Pharmacy's services under the Agreement shall be obligated to comply with the applicable terms of the Agreement. Pharmacy further acknowledges and agrees that contemporaneously with the execution of the Agreement, PBM has identified to Pharmacy those third parties known at the time of contracting to which PBM will grant access to Pharmacy's services. Ind. Code §§ 27-1-37.3-7, 27-1-37.3-8.

In the event plan sponsor or PBM fails to pay for covered drugs for any reason, including insolvency or breach of the Agreement, covered persons shall not be liable to Pharmacy for any sums owed by plan sponsor or PBM. This provision does not prohibit the collection of copays or uncovered charges consented to by covered persons. This provision survives termination of the Agreement, regardless of the reason for termination. Ind. Code §§ 27-13-15-1(a)(4), 27-13-34-15(1).

Pharmacy or its trustee, agent, representative or assignee shall not bring or maintain a legal action against a covered person to collect sums owed to Pharmacy by plan sponsor or PBM. If Pharmacy brings or maintains a legal action against a covered person for an amount owed to Pharmacy by plan sponsor or PBM, Pharmacy shall be liable to the covered person for costs and attorney's fees incurred by the covered person in defending the action. This provision does not prohibit the collection of copays or uncovered charges consented to by the covered person. This provision survives termination of the Agreement, regardless of the reason for termination. Ind. Code §§ 27-13-15-3(a), 27-13-34-15(2).

Limitation on frequency of on-site audits (Ind. Code § 25-26-22-4.2; 760 IAC 5-3-2)

(a) A third-party payer may cause an on-site audit to occur at a particular pharmacy location not more than one time per calendar year.

(b) A company that conducts an audit for a third-party payer may conduct an on-site audit at a particular pharmacy location not more than one time per calendar year for each third-party payer. However, if the audit results in a finding of a particular problem at the Pharmacy, the auditor may return within the calendar year to determine ongoing compliance.

General requirements (Ind. Code § 25-26-22-5; 760 IAC 5-3-3)

An auditor conducting an audit shall comply with all of the following:

(1) The contract under which the audit is performed must provide a description of audit procedures that will be followed.

(2) For an on-site audit conducted at a Pharmacy's location, the auditor that conducts the audit shall provide written notice to the Pharmacy at least two weeks before the initial on-site audit is performed for each audit cycle.

(3) The auditor shall not interfere with the delivery of pharmacist services to a patient and shall use every effort to minimize inconvenience and disruption to pharmacy operations during the audit. This subdivision does not prohibit audits during normal business hours of the Pharmacy.

(4) If the audit requires use of clinical or professional judgment, the audit must be conducted by or in consultation with a licensed pharmacist.

(5) The auditor shall allow the use of written or otherwise transmitted hospital, physician or other health practitioner records to validate a pharmacy record with respect to a prescription for a legend drug.

(6) The auditor shall perform the audit according to the same standards and parameters that the auditor uses to audit all other similarly situated Pharmacies on behalf of the third-party payer.

(7) The period covered by the audit must not exceed 24 months after the date on which the claim that is the subject of the audit was submitted to or adjudicated by the third-party payer, and the Pharmacy must be permitted to resubmit electronically any claims disputed by the audit. This subdivision does not limit the period for audits under the Medicaid program that are conducted due to a federal requirement.

(8) The audit must not be initiated or scheduled during the first seven calendar days of any month without the voluntary consent of the Pharmacy. The consent may not be mandated by a contract or any other means.

(9) Payment to the on-site auditor for conducting the audit must not be based on a percentage of any amount recovered as a result of the audit.

(10) Within 24 hours of receiving the notice of an audit, a Pharmacy may reschedule the audit to a date not more than 14 days after the date proposed by the auditor. However, if the auditor is unable to reschedule within the 14-day period, the auditor shall select and reschedule the audit for a date after the 14-day period.

(11) This subdivision does not apply to an audit conducted by the Medicaid program. If a clerical error is identified by the auditor during the course of an audit, the auditor shall allow the Pharmacy to obtain a prescription that corrects the clerical error from the prescribing physician. However, if the clerical error results in an overpayment to the Pharmacy, the overpayment may be recouped by the third-party payer.

Audit reports (Ind. Code §25-26-22-6; 760 IAC 5-3-4)

(a) This section does not apply to an audit conducted by the Medicaid, Medicare or any other federal program.

(b) Following an audit, the auditor shall provide to the Pharmacy written audit reports as follows:

(1) The auditor shall deliver a preliminary audit report to the Pharmacy not later than 90 calendar days after the audit is concluded.

(2) The auditor shall provide with the preliminary audit report a written appeal procedure for the Pharmacy to follow if the Pharmacy desires to appeal a finding contained in the preliminary audit report. The written appeal procedure must provide for a period of at least 30 calendar days after the Pharmacy receives the preliminary audit report during which the Pharmacy may file an appeal of findings contained in the preliminary audit report.

(3) The auditor shall deliver a final audit report to the Pharmacy not later than 120 calendar days after:

(A) the preliminary audit report is received by the Pharmacy; or

(B) if an appeal is filed, a final appeal determination is made; whichever is later.

(4) Each audit report must be signed by the auditor and a pharmacist participating in the audit.

(5) The auditor shall provide a copy of the final audit report to the third-party payer.

(c) If requested by the Pharmacy, the auditor shall provide the audit report under this section to the Pharmacy by a means that allows signature confirmation, including an electronic signature (as defined by). If the audit report is sent by electronic mail, any other verification system may be used, provided that the receipt is acknowledged by the Pharmacy.

Clerical errors (Ind. Code § 25-26-22-7; 760 IAC 5-3-5)

(a) A clerical error related to or contained in a document that is necessary to the conduct of an audit does not constitute fraud without proof of intent to commit fraud. A pharmacy is allowed to obtain a prescription that corrects the clerical error from the prescriber it is identified during the course of an audit.

(b) A clerical error that results in inappropriate payment of a claim by the third-party payer may result in recoupment of any inappropriately made payment.

Overpayment or underpayment of claim (Ind. Code § 25-26-22-8; 760 IAC 5-3-6)

An audit finding of an overpayment or underpayment of a claim:

(1) Must be based on an actual overpayment or underpayment; and

(2) May not be based on a projection that is based on the number of:

A) Patients who:

(i) Have similar diagnoses; and

(ii) Are served by the Pharmacy; or

B) Prescriptions for or refills of similar legend drugs that are dispensed by the Pharmacy.

An audit finding of an overpayment or underpayment of a claim must not include dispensing fees unless a prescription was not actually dispensed, the prescriber denied authorization, the prescription dispensed was a medication error by the pharmacy, or the identified overpayment is solely based on an extra dispensing fee.

Final audit report (Ind. Code § 25-26-22-9; 760 IAC 5-3-7)

(a) This section does not apply to an audit conducted by the Medicaid, Medicare or any other federal program.

(b) Before recoupment of funds may be made based on an audit finding of overpayment or underpayment:

(1) A final audit report must be distributed; and

(2) Except when an audit finds that fraud, willful misrepresentation or alleged serious abuse has occurred, at least 30 calendar days must elapse after the date on which the final audit report is distributed before the recoupment of funds exceeding $10,000.

(c) Interest on funds described in subsection (b) does not accrue during the audit period.

A PBM must remit all monies due to a pharmacy or pharmacist as a result of an underpayment of a claim within thirty (30) calendar days after the final audit report has been delivered to the pharmacy or pharmacist.

Results of extrapolation audit (Ind. Code § 25-26-22-10; 760 IAC 5-3-8)

The results of an extrapolation audit may not be used by an auditor as a basis for calculating overpayment or underpayment recoupments or penalties.

Investigative audits (Ind. Code § 25-26-22-11)

This chapter does not apply to an investigative audit conducted for purposes of determining whether fraud, willful misrepresentation or alleged serious abuse has occurred.

Internal appeal process (760 IAC 5-3-9)

(a) An auditor must establish an internal appeal process under which a Pharmacy or pharmacist may appeal a disputed claim in a preliminary audit report.

(b) Under the internal appeals process, an auditor must allow a Pharmacy or pharmacist to request an internal appeal 30 calendar days after receipt of a preliminary audit report, with reasonable extensions allowed.

(c) An auditor must include in its preliminary audit report a written explanation of the internal appeals process, including the name, address, and telephone number of the person or entity to whom an internal appeal should be addressed.

(d) The decision of the auditor on an appeal of a disputed claim in a preliminary audit report by a Pharmacy or pharmacist must be reflected in the final audit report.

(e) An auditor must deliver a final audit report to a pharmacy or pharmacist not later than one hundred twenty (120) calendar days after a final appeal determination is made. The final report must include a final accounting of all monies to be recovered or returned by the pharmacy benefit manager

760 IAC 5-3-10 - Use of third party auditors

The acts of an independent auditor are considered to be the acts of the pharmacy benefit manager on whose behalf the independent auditor is acting.

B-16 Iowa Regulatory Addendum to Pharmacy Participation Agreement

This Iowa Addendum applies to the extent that Pharmacy provides covered drugs to covered persons of discount medical plans, health maintenance organizations, managed care organizations, health service corporations, insurers or carriers under Iowa law (collectively and/or individually, "plan sponsor").

In the event of a direct conflict between this Addendum and the Agreement, the applicable provisions of this Addendum shall control if required. This Addendum may be modified from time to time pursuant to the Agreement.

Without limiting the generality of the foregoing, and notwithstanding anything in the Agreement to the contrary, Pharmacy agrees as follows:

Notwithstanding anything to the contrary in the Agreement, the parties must provide at least 60 days prior written notice before terminating the Agreement; provided, however, in the event PBM has evidence that Pharmacy has engaged in fraudulent conduct or poses a significant risk to patient care or safety, PBM may immediately suspend Pharmacy from further performance under the Agreement upon written notice of the suspension and reasoning therefor is provided to Pharmacy, the covered entity, and the commissioner. Iowa Admin. Code § 191-59.6(510B)(1) and .6(510B)(3)(a).

To the extent Pharmacy provides covered drugs to covered persons of a health maintenance organization or a limited-service organization under Iowa law, Pharmacy agrees as follows:

Pharmacy, or its assignee or subcontractor, hereby agrees that in no event, including, but not limited to, nonpayment by plan sponsor, plan sponsor's insolvency, or breach of this agreement, shall Pharmacy, or its assignee or subcontractor, bill, charge, collect a deposit from, seek compensation, remuneration or reimbursement from, or have any recourse against covered person or persons other than plan sponsor acting on their behalf for covered drugs pursuant to this agreement. This provision shall not prohibit collection of supplemental charges or copays on plan sponsor's behalf made in accordance with the terms of the Agreement between plan sponsor and the covered person. Iowa Admin. Code §§ 191- 40.18(514B); 191-41.16(514B).

Pharmacy, or its assignee or subcontractor, further agrees that (i) this provision shall survive the termination of this agreement regardless of the cause giving rise to termination and shall be construed to be for the benefit of the covered person and that (ii) this provision supersedes any oral or written contrary agreement now existing or hereafter entered into between Pharmacy and the covered person or persons acting on their behalf. Iowa Admin. Code § 191-40.18(514B); 191-41.16(514B).

PBM shall not assess, charge, or collect from Pharmacy any claims processing fees, performance-based fees, network participation fees or accreditation fees. Iowa Code § 510B.7.

Maximum allowable cost lists (Iowa Code § 510B.8A)

(1) Prior to placement of a particular prescription drug on a maximum allowable cost list, PBM shall ensure that all of the following requirements are met:

   a. The particular prescription drug must be listed as therapeutically and pharmaceutically equivalent in the most recent edition of the publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations," published by the United States Food and Drug Administration, otherwise known as the Orange Book.

   b. The particular prescription drug must not be obsolete or temporarily unavailable.

   c. The particular prescription drug must be available for purchase, without limitations, by all Pharmacies in the state from a national or regional wholesale distributor that is licensed in the state.

(2) For each maximum allowable cost list that PBM uses in Iowa, PBM shall:

a. Provide Pharmacy reasonable access to the maximum allowable cost list to which Pharmacy is subject.

b. Update the maximum allowable cost list within seven (7) calendar days from the date of an increase of 10% or more in the pharmacy acquisition cost of a prescription drug on the list by one or more wholesale distributors doing business in Iowa.

c. Update the maximum allowable cost list within seven calendar days from the date of a change in the methodology, or a change in the value of a variable applied in the methodology, on which the maximum allowable cost list is based.

d. Provide a reasonable process for Pharmacy to receive prompt notice of all changes to the maximum allowable cost list to which Pharmacy is subject.

Appeals and Disputes (Iowa Code 510B.8E)

(1) A PBM shall provide a reasonable process to allow a pharmacy to appeal any matter.

(2) The appeals process must include all of the following:

a. A dedicated telephone number at which a pharmacy may contact the PBM and speak directly with an individual who is involved with the appeals process.

b. A dedicated electronic mail address or internet site for the purpose of submitting an appeal directly to the PBM.

c. A period of no less than thirty (30) business days after the date of a pharmacy's initial submission of a clean claim during which the pharmacy may initiate an appeal.

(3) The PBM shall respond to an appeal within seven (7) business days after the date on which the PBM receives the appeal.

a. If the PBM grants a pharmacy's appeal related to a reimbursement rate, the PBM shall do all of the following:

(1) Adjust the reimbursement rate of the prescription drug that is the subject of the appeal and provide the national drug code number that the adjustment is based on to the appealing pharmacy.

(2) Reverse and resubmit the claim that is the subject of the appeal.

(3) Make the adjustment pursuant to subparagraph (1) applicable to all of the following:

(a) Each pharmacy that is under common ownership with the pharmacy that submitted the appeal.

(b) Each pharmacy in the state that demonstrates the inability to purchase the prescription drug for less than the established reimbursement rate.

b. If the PBM denies a pharmacy's appeal, the PBM shall do all of the following:

(1) Provide the appealing pharmacy the national drug code number and the name of a wholesale distributor licensed pursuant to section 155A.17 from which the pharmacy can obtain the prescription drug at or below the reimbursement rate.

(2) If the prescription drug identified by the national drug code number provided by the PBM pursuant to subparagraph (1) is not available below the pharmacy acquisition cost from the wholesale distributor from whom the pharmacy purchases the majority of its prescription drugs for resale, the PBM shall adjust the reimbursement rate above the appealing pharmacy's pharmacy acquisition cost, and reverse and resubmit each claim affected by the pharmacy's inability to procure the prescription drug at a cost that is equal to or less than the previously appealed reimbursement rate.

Audits of Pharmacies by pharmacy benefit manager (Iowa Admin. Code 191-59.4(510B)

59.4*(1)* An audit of pharmacy records by a PBM shall be conducted in accordance with the following:

a. The PBM conducting the initial on site audit must provide the Pharmacy written notice at least ten (10) business days prior to conducting any audit;

b. Any audit which involves clinical or professional judgment must be conducted by or in consultation with a pharmacist;

c. When a PBM alleges an error in reimbursement has been made to a Pharmacy, the PBM shall provide the Pharmacy sufficient documentation to determine the specific claims included in the alleged error;

d. A Pharmacy may use the records of a hospital, physician or other authorized practitioner of the healing arts for prescription drugs or medicinal supplies, written or transmitted by any means of communication, for purposes of validating the pharmacy record with respect to orders or refills of a drug dispensed pursuant to a prescription;

e. Each Pharmacy shall be audited under the same standards and parameters as other similarly situated Pharmacies audited by the pharmacy benefit manager;

f. The period covered by an audit may not exceed two (2) years from the date on which the claim was submitted to or adjudicated by a managed care company, insurance company, third-party payer or any PBM that represents such entities;

g. Unless otherwise consented to by the Pharmacy, an audit may not be initiated or scheduled during the first seven calendar days of any month due to the high volume of prescriptions filled during that time;

h. The preliminary audit report must be delivered to the Pharmacy within 120 days after conclusion of the audit. A final written audit report shall be received by the Pharmacy within six (6) months of the preliminary audit report or final appeal, whichever is later;

i. A Pharmacy shall be allowed at least thirty (30) days following receipt of the preliminary audit report in which to produce documentation to address any discrepancy found during an audit; and

j. If it is determined by the PBM that an error in reimbursement to a pharmacy occurred, the following criteria apply:

(1) For each contract between the PBM and the Pharmacy existing on or after Jan. 1, 2015, a Pharmacy's usual and customary price for compounded medications is considered the reimbursable cost, unless the contract between the PBM and the Pharmacy specifically provides details for a pricing methodology for compounded medications.

(2) A finding of error in reimbursement must be based on the actual error in reimbursement and not be based on a projection of the number of patients served having a similar diagnosis or on a projection of the number of similar orders or refills for similar prescription drugs.

(3) Calculations of errors in reimbursement must not include dispensing fees unless prescriptions were not actually dispensed, the prescriber denied authorizations, the prescriptions dispensed were medication errors by the Pharmacy, or the amounts of the dispensing fees were incorrect.

(4) Any clerical or recordkeeping error of the Pharmacy, including, but not limited to, a typographical error, scrivener's error or computer error, regarding a required document or record shall not be considered fraud by the Pharmacy under paragraph 59.6(3)"a" or under a Pharmacy's contract with the PBM.

(5) In the case of an error that has no actual financial harm to the patient or third-party payer, the PBM shall not assess a charge against the Pharmacy.

(6) If a Pharmacy has entered into a corrective action plan with the PBM, and if the Pharmacy fails to comply with the corrective action plan in a manner that results in overpayments being made by the PBM to the Pharmacy, the PBM may recover the overpaid amounts. For purposes of this paragraph, "corrective action plan" means an agreement entered into by the PBM and a Pharmacy which is intended to promote accurate submission and payment of pharmacy claims.

(7) During the audit period, interest on any outstanding balance shall not accrue for the PBM or the Pharmacy. For purposes of this rule, the audit period begins with the notice of the audit and ends with a final determination of the audit report.

59.4*(2)* Notwithstanding Iowa Code section 510B.7 and any other provision in this rule, the entity conducting the audit shall not use the accounting practice of extrapolation in calculating the recoupment or contractual penalty for an audit unless required by state or federal laws or regulations. The entity may not use the accounting practice of extrapolation in a manner more stringent than that required by state or federal laws or regulations.

59.4*(3)* Recoupment of any disputed funds shall occur only after final disposition of the audit, including the appeals process as set forth in subrules 59.4(4) and 59.4(5).

59.4*(4)* Each PBM shall establish an appeals process under which a Pharmacy may appeal an unfavorable preliminary audit report to the PBM. The PBM shall conduct a review of the unfavorable preliminary audit report. The cost of the audit review shall be paid by the PBM. If, following the review, the PBM finds that an unfavorable audit report or any portion thereof is unsubstantiated, the PBM shall dismiss the unsubstantiated audit report or unsubstantiated portion of the audit report without the necessity of any further proceedings.

59.4*(5)* The PBM shall establish a process for an independent third-party review of final audit findings. If, following the appeal of an audit report and upon conducting an audit review, the PBM finds that an unfavorable audit report or any portion thereof is found to be substantiated, the PBM shall notify the Pharmacy in writing of its right to request an independent third-party review of the final audit findings and the process used to request such a review. If a Pharmacy requests an independent third-party review of the final audit findings and the audit report is found to be substantiated, the cost of the third-party review shall be paid by the Pharmacy. If a Pharmacy requests an independent third-party review of the final audit findings and the audit report is found to be unsubstantiated, the cost of the third-party review shall be paid by the PBM. If the reviewer finds partially in favor of both parties, the reviewer shall apportion the costs accordingly, and each party will bear a portion of the costs of the review.

59.4*(7)* The PBM shall, after completion of any review process, provide a copy of the final audit report to the third-party payer within ten (10) business days of completing the report.

Fraud, willful misrepresentation or abuse:

59.4*(8)* This rule shall not apply to any investigative audit which involves fraud, willful misrepresentation, abuse or any other statutory provision which authorizes investigations relating to but not limited to, insurance fraud.

B-17 Kansas Regulatory Addendum to Pharmacy Participation Agreement

This Kansas Addendum applies to the extent that Pharmacy provides covered drugs to covered persons of covered entities, including insurers, health maintenance organizations, nonprofit medical and hospital service corporations, or preferred provider organizations under Kansas law (collectively and/or individually, "plan sponsor").

In the event of a direct conflict between this Addendum and the Agreement, the applicable provisions of this Addendum shall control if required. This Addendum may be modified from time to time pursuant to the Agreement.

Without limiting the generality of the foregoing, and notwithstanding anything in the Agreement to the contrary, Pharmacy agrees as follows:

To the extent Pharmacy provides covered drugs to covered persons of HMOs and Medicare provider organizations:

If there is valid Medicaid coverage providing benefits for covered drugs, the Medicaid coverage shall be the source of last resort of any payment to Pharmacy. Kan. Stat. § 40-3208(b).

Nothing in the Agreement shall be construed to require covered persons to guarantee payment to Pharmacy, other than copays and deductibles, in the event of nonpayment by plan sponsor or PBM for covered drugs performed under the Agreement. If plan sponsor or PBM fails to pay for covered drugs as set forth in the Agreement, covered persons shall not be liable to Pharmacy for any amounts owed by plan sponsor or PBM. Any action by Pharmacy to collect or attempt to collect from a covered person any sum owed by plan sponsor or PBM to Pharmacy is expressly prohibited. Kan. Stat. § 40-3209(b).

In the event of the insolvency of plan sponsor or PBM, Pharmacy shall continue providing covered drugs to covered persons for the period of time for which premiums have been paid to plan sponsor by a covered person and, with respect to covered persons who are confined to an inpatient facility, until their discharge or expiration of benefits. Kan. Stat. § 40-3227(k)(2).

If Pharmacy's participation under the Agreement is terminated for any reason, Pharmacy shall continue to provide covered drugs to covered persons for a period up to 90 days in those cases where the continuation of such care is medically necessary and in accordance with the dictates of medical prudence and where the covered person has special circumstances such as, a disability, a life-threatening illness or is in the third trimester of pregnancy. Covered persons shall not be liable to Pharmacy for covered drugs during this continuation period other than for any deductibles or copay amounts specified in the certificate of coverage or other contract between covered persons and plan sponsor. Pharmacy shall be entitled to payment for covered drugs during this continuation period at the rate specified in the Agreement. Kan. Stat. § 40-3230.

Without limiting the generality of the foregoing, and notwithstanding anything in the Agreement to the contrary, and to the extent Pharmacy provides covered drugs to covered persons of covered entities, PBM agrees that, upon request of Pharmacy, PBM shall provide a dispute resolution process to Pharmacy that involves an independent fact finder for dispute involving non-MAC issues. Specifically, Pharmacy may refer the dispute to binding arbitration in accordance with the commercial arbitration rules of the American Arbitration Association (AAA). If PBM and Pharmacy cannot agree upon the arbitrator, the arbitrator shall be chosen by the applicable AAA office. Judgment upon the award rendered by the arbitrator(s) may be entered in any court having jurisdiction thereof. PBM and Pharmacy will jointly share the costs of the arbitrator. PBM and Pharmacy agree that the losing party will reimburse the prevailing party for the prevailing party's reasonable attorney's fees and related arbitration costs. Kan. Stat. Ann. § 40-3823(b)(6). Disputes involving MAC issues will be resolved according to the terms of the Agreement and Provider Manual, and consistent with the requirements of Kan. Stat. § 40-3830(f)-(j).

Pharmacy Audit Integrity Act — Same; procedural requirements (Kan. Stat. § 65-16, 123)

(a) The entity conducting the audit shall follow the following procedures:

(1) An entity conducting an on-site audit must give the Pharmacy at least seven (7) days written notice before conducting an initial audit;

(2) An audit that involves clinical or professional judgment must be conducted by or in consultation with a licensed pharmacist;

(3) The period covered by the audit may not exceed two (2) years from the date that the claim was submitted to or adjudicated by the entity;

(4) The Pharmacy may request an extension not to exceed seven (7) days from the date of an originally scheduled on-site audit;

(5) The Pharmacy may use the records of a hospital, physician or other authorized practitioner to validate the pharmacy record;

(6) Any legal prescription, in compliance with the requirements of the State Board of Pharmacy, may be used to validate claims in connection with prescriptions, refills or changes in prescriptions;

(7) Each Pharmacy shall be audited under the same standards and parameters as other similarly situated Pharmacies; and

(8) The entity must establish a written appeals process.

(b) The entity conducting the audit shall also comply with the following requirements:

(1) A finding of overpayment or underpayment must be based on the actual overpayment or underpayment and not a projection based on the number of patients served having a similar diagnosis or on the number of similar orders or refills for similar drugs;

(2) The entity conducting the audit shall not use extrapolation in calculating the recoupments or penalties for audits, unless required by state or federal contracts;

(3) The auditing company or agent may not receive payment based on a percentage of the amount recovered, unless required by contracts; and

(4) Interest may not accrue during the audit period.

Pharmacy Audit Integrity Act — Same; audit reports; recoupment and repayment of funds; access to audit information (Kan. Stat. § 65-16, 124)

(a) Any preliminary audit report must be delivered to the Pharmacy within sixty (60) days after the conclusion of the audit. Any Pharmacy shall be allowed at least thirty (30) days following receipt of the preliminary audit to provide documentation to address any discrepancy found in the audit. Any final audit report shall be delivered to the Pharmacy within 120 days after receipt of the preliminary audit report or final appeal, whichever is later.

(b) Recoupment of any disputed funds or repayment of funds to the entity by the Pharmacy, if permitted pursuant to contracts, shall occur, to the extent demonstrated or documented in the pharmacy audit findings, after final internal disposition of the audit including the appeals process. If the identified discrepancy for an individual audit exceeds $20,000, any future payments to the Pharmacy may be withheld pending finalization of the audit. Unless otherwise required by the federal or state law, any audit information may not be shared. Auditors shall only have access to previous audit reports on a particular Pharmacy conducted by the same entity.

Pharmacy Audit Integrity Act — Same; final report; availability (Kan. Stat. § 65-16, 125)

(a) Any auditing entity, upon request of the plan sponsor, shall provide a copy of the final report, including the disclosure of any money recouped in the audit. The Pharmacy may provide a copy of the report to the commissioner of insurance, provided such report shall not contain any personally identifiable health information in violation of the provisions of the Health Insurance Portability and Accountability Act of 1996 (Pub. L. No. 104-191).

Pharmacy Audit Integrity Act — Same; application of the act (Kan. Stat. § 65-16, 126)

(a) This act shall apply to contracts between an auditing entity and a pharmacy entered into, extended or renewed on or after the effective date of this act. These requirements shall not apply to any audit, review or investigation that is initiated based upon suspected or alleged fraud, willful misrepresentation or abuse.

B-18 Kentucky Regulatory Addendum to Pharmacy Participation Agreement

This Kentucky Addendum applies to the extent that Pharmacy provides covered drugs to covered persons of an accident or health insurer, nonprofit hospital services corporation, nonprofit medical service corporation, health maintenance organization and organizations entering into preferred provider arrangements under Kentucky law (collectively and/or individually, "plan sponsor").

In the event of a direct conflict between this Addendum and the Agreement, the applicable provisions of this Addendum shall control if required. This Addendum may be modified from time to time pursuant to the Agreement.

Without limiting the generality of the foregoing, and notwithstanding anything in the Agreement to the contrary, Pharmacy agrees as follows:

Pharmacy may not, under any circumstance, including nonpayment of moneys due Pharmacy by plan sponsor and/or PBM, insolvency of plan sponsor or PBM, or breach of the Agreement, bill charge, collect a deposit, seek compensation, remuneration, or reimbursement from, or have any recourse against covered persons, or any persons acting on their behalf, for services provided in accordance with the Agreement. This provision shall not prohibit collection of deductible amounts, copay amounts, coinsurance amounts and amounts for services that are not covered. This provision shall survive the termination of the Agreement. Ky. Rev. Stat. Ann. §§ 304.17A-254(2); 304.17A-527(1)(a), (c); 304.17A-310(5); 304.17C-060(1)(a), (b); 806 KAR 17:300 (Section 3).

In the event the Agreement is terminated for any reason, other than a quality-of-care issue or fraud, Pharmacy shall continue to provide services and PBM shall continue to reimburse Pharmacy in accordance with the Agreement until the covered person is discharged from an inpatient facility, or the active course of treatment is completed, whichever is greater. In the case of a pregnant woman, Pharmacy shall continue to provide services through the end of the postpartum period if the pregnant woman is in her fourth or later month of pregnancy at the time the Agreement terminates. This provision shall survive termination of the Agreement. Ky. Rev. Stat. Ann. § 304.17A-527(1)(b)-(c); 806 KAR 17:300 (Section 3).

In the event of the insolvency of plan sponsor or PBM, Pharmacy shall continue providing covered drugs to covered persons for the duration of the contract period for which premiums have been paid or until the date of discharge from an inpatient facility, whichever is longer. Ky. Rev. Stat. Ann. § 304.17A-310(6).

Upon written request, PBM shall provide or make available to Pharmacy, when contracting or renewing an existing contract with Pharmacy, the payment or fee schedules or other information sufficient to enable Pharmacy to determine the manner and amount of payments for Pharmacy's services under the Agreement prior to the final execution or renewal of the contract and shall provide Pharmacy any change in such payment or fee schedules at least 90 days prior to the effective date of the change. Ky. Rev. Stat. Ann. §§ 304.17A-254(7); 304.17A-527(1)(d); 304.17A-577; 806 KAR 17:300 (Section 3).

If Pharmacy enters into any subcontract agreement with another provider to provide covered drugs to covered persons where the subcontracted provider will bill PBM or covered persons directly for the subcontracted services, the subcontract agreement must meet all requirements of Title XXV, Chapter 304, Subtitle 17A of the Kentucky Insurance Code and be filed with the Kentucky Commissioner of Insurance. Ky. Rev. Stat. Ann. §§ 304.17A-527(1)(e); 304.17C-060(1)(c); 806 KAR 17:300 (Section 3); (Section 3).

The reimbursement rate identified in the Pharmacy agreement shall apply to all covered drug services rendered by Pharmacy to all plan sponsors' covered persons. Ky. Rev. Stat. Ann. § 304.17A-728; 806 KAR 17:300 (Section 3).

PBM and Pharmacy shall comply with Ky. Rev. Stat. Ann. §§ 304.17A-700 to 304.17A-730, 205.593, 304.14-135, and 304.99-123 regarding payment of claims. Ky. Rev. Stat. Ann. § 304.17A-726.

To the extent the Agreement requires Pharmacy to submit claims electronically, payment shall be made electronically, if requested by Pharmacy, for clean claims submitted electronically in the form required by PBM and/or plan sponsor if Pharmacy agrees to accept claims details for these payments electronically and provides accurate electronic funds transfer information to PBM and the claims comply with 45 CFR Part 142. Ky. Rev. Stat. Ann. § 304.17A-705.

Identification of sources used to calculate drug product reimbursement; process to appeal disputes over maximum allowable cost pricing; adjustment of maximum allowable cost and drug product reimbursement; duties of pharmacy benefit manager (Ky. Rev. Stat. Ann. § 304.17A-162)

(1) A PBM shall:

(a) Identify to contracted pharmacies the sources used by the PBM to calculate the drug product reimbursement paid for covered drugs available under the pharmacy health benefit plan administered by the PBM; and

(b) Establish a process for contracted pharmacies, pharmacy services administration organizations, or group purchasing organizations to appeal and resolve disputes regarding the maximum allowable cost pricing. The process shall include the following provisions:

1. The right to appeal shall be limited to sixty (60) days following the initial claim;

2 The appeal shall be investigated and resolved by the PBM within ten (10) calendar days;

3. The PBM shall respond to all appeals in a manner approved by the department;

4. If the appeal is denied, the PBM shall provide the reason for the denial and identify the national drug code of a drug product and source where it may be purchased from a licensed wholesaler by contracted pharmacies at a price at or below the maximum allowable cost; and

5. If an appeal is granted, the provisions of subsection (2) of this section shall apply.

(2) If a price update is warranted as a result of an appeal granted under subsection (1) of this section, the PBM shall:

(a) Make the change in the maximum allowable cost to the initial date of service the appealed drug was dispensed;

(b) Adjust the maximum allowable cost of the drug for the appealing pharmacy and for all other contracted pharmacies in the network of that PBM that filled a prescription for patients covered under the same health benefit plan to the initial date of service the appealed drug was dispensed;

(c) Individually notify all other contracted pharmacies in the network of that PBM that a retroactive maximum allowable cost adjustment has been made as a result of a granted appeal effective to the initial date of service the appealed drug was dispensed;

(d) Adjust the drug product reimbursement for contracted pharmacies that resubmit claims to reflect the adjusted maximum allowable cost if applicable to their contract;

(e) Allow the appealing pharmacy and all other contracted pharmacies in the network that filled prescriptions for patients covered under the same health benefit plan to reverse and resubmit claims and receive payment based on the adjusted maximum allowable cost from the initial date of service the appealed drug was dispensed; and

(f) Make retroactive price adjustments in the next payment cycle.

(3) For every drug for which the pharmacy benefit manager establishes a maximum allowable cost to determine the drug product reimbursement, the pharmacy benefit manager shall make available to all contracted pharmacies information identifying the national drug pricing compendia or sources used to obtain the drug price data in a manner established by administrative regulations promulgated by the department.

(4) For every drug for which the pharmacy benefit manager establishes a maximum allowable cost to determine the drug product reimbursement, the pharmacy benefit manager shall make available to all contracted pharmacies in a manner established by administrative regulations promulgated by the department the comprehensive list of drugs subject to maximum allowable cost and the actual maximum allowable cost for each drug.

(5) For every drug for which the pharmacy benefit manager establishes a maximum allowable cost to determine the drug product reimbursement, the pharmacy benefit manager shall make available to the department, upon request, information that is needed to resolve an appeal. If the department is unable to obtain information from the pharmacy benefit manager that is necessary to resolve the appeal, the appeal shall be granted to the appealing pharmacy.

(6) For every drug for which the pharmacy benefit manager establishes a maximum allowable cost to determine the drug product reimbursement, the pharmacy benefit manager shall review and make necessary adjustments to the maximum allowable cost for every drug at least every seven (7) calendar days and shall immediately utilize the updated maximum allowable cost in calculating the payments made to all contracted pharmacies.

(7) For every drug for which the pharmacy benefit manager establishes a maximum allowable cost to determine the drug product reimbursement, the pharmacy benefit manager shall make available to all contracted pharmacies in a manner established by administrative regulations promulgated by the department weekly updates to the list of drugs subject to maximum allowable cost and the actual maximum allowable cost for each drug.

PBM will not reduce payment for prescription drug services, directly or indirectly, under a reconciliation process to an effective rate of reimbursement. This prohibition shall include, without limitation, creating, imposing, or establishing direct or indirect remuneration fees, generic effective rates, dispensing effective rates, brand effective rates, any other effective rates, in-network fees, performance fees, point-of-sale fees, retroactive fees, pre-adjudication fees, post-adjudication fees and any other mechanism that reduces, or aggregately reduces, payment for prescription drug services.

PBM will not retroactively deny, reduce reimbursement for, or seek any refunds or recoupments for a claim for prescription drug services, in whole or in part, from Pharmacy after returning a paid claim response as part of the adjudication of the claim, including claims for the cost of a medication or dispensed product and claims for Pharmacy that are deemed ineligible for coverage, unless one or more of the following occurred:

- The original claim was submitted fraudulently; or
- The Pharmacy received an actual overpayment as defined in Ky. Stat § 304.17A-595

PBM will not reimburse Pharmacy for a prescription drug service at a net amount that is lower than the amount benefit sponsor or Prime reimburses itself or a pharmacy affiliate for the same prescription drug service by National Drug code number or service.

PBM will not collect cost sharing from Pharmacy that was provided to the Pharmacy by covered person for the provision of pharmacy services under the health plan.

PBM will not designate a prescription drug service as a specialty drug unless the drug is a limited distribution drug that requires special handling and is not commonly carried at retail Pharmacies or oncology clinics or practices. Ky. Stat § 304.17A-595

Audit of pharmacy records; conditions (Ky. Stat. § 304.17A-741)

When an audit of the records of a Pharmacy is conducted by Prime, it shall be subject to the following conditions:

(1) The auditing entity shall give at least 30 days' written notice to the Pharmacy prior to conducting the audit for each audit to be conducted;

(2) An audit performed by the auditing entity that involves clinical or professional judgment shall be conducted in consultation with a pharmacist;

(3) A Pharmacy may use the records of a hospital, physician or other practitioner as defined in Ky. Stat. § 217.015(35) or transmitted by any means of communication, for purposes of validating pharmacy records with respect to orders or refills of a drug;

(4) An auditing entity shall not require a Pharmacy to keep records for a period of time longer than two years, or as required by state or federal law or regulation;

(5) The recoupment of claims shall be based on the actual overpayment or underpayment of claims unless the Pharmacy agrees to a settlement to the contrary;

(6) A Pharmacy shall be audited under the same standards and parameters as other similarly situated pharmacies audited by the auditing entity;

(7) The period covered by the audit shall not exceed two years from the date the claim was submitted for payment except if a longer period is allowed by federal law or if there is evidence of fraud;

(8) An audit shall not be scheduled during the first seven calendar days of any month, unless consented to by the Pharmacy;

(9) A preliminary audit report shall be delivered to the Pharmacy within 120 days after the exit interview;

(10) A final audit report shall be delivered to the Pharmacy within six months after receipt of the preliminary audit report or after all appeals have been exhausted, whichever is later;

(11) The auditing entity shall allow a Pharmacy at least 30 days following receipt of the preliminary audit report to produce documentation to address any discrepancies found during an audit;

(12) The final audit report shall provide claim-level detail of the amounts and reasons for each claim recovery found due. If no amounts have been found due, the final audit report shall so state;

(13) The auditing entity shall not receive payment based on the amount recovered in an audit;

(14) The auditing entity shall conduct an exit interview at the close of the audit. The exit interview shall be conducted at a time agreed to by the audited Pharmacy. The interview shall provide the audited Pharmacy an opportunity to:

(a) Respond to questions from Prime;

(b) Review and comment on the initial findings of the auditing entity; and

(c) Provide additional documentation to clarify the initial findings of the auditing entity;

(15) If an audit results in the identification of any clerical or recordkeeping errors such as typographical errors, scrivener's errors, omissions or computer errors, the Pharmacy shall not be subject to recoupment of funds by the auditing entity unless the auditing entity can provide proof of intent to commit fraud or the error results in an actual overpayment to the Pharmacy or the wrong medication being dispensed to the patient. The Pharmacy shall have the right to submit amended claims within thirty (30) days of the discovery of an error to correct clerical or recordkeeping errors in lieu of recoupment if the prescription was dispensed according to requirements set forth in state or federal law;

(16) In the case of overpayment, the auditing entity may seek a refund or recoupment of the overpayment in accordance with Ky. Stat. § 304.17A-712. The amount refunded or recouped shall be limited to the amount paid to the Pharmacy minus the amount that should have been paid to the Pharmacy absent the overpayment and shall not include the dispensing fee if the correct medication was dispensed to the patient; and

(17) Claims shall be paid pursuant to Ky. Stat. § 304.17A-702.

Pharmacy audit appeals process (Ky. Stat. § 304.17A-743)

(1) The auditing entity conducting an audit shall establish an appeals process under which a Pharmacy may appeal a final audit report. The auditing entity shall provide to the Pharmacy, prior to or at the time of the delivery of the preliminary audit report, a written explanation of the appeals process, including the name, address and phone number of the person to whom the appeal should be addressed.

(2) Following the appeal if it is determined that an audit report or any portion thereof is unsubstantiated, the audit report or unsubstantiated portion shall be dismissed without the necessity of further proceedings.

(3) The auditing entity shall not recoup disputed funds or collect interest on disputed funds until the final internal disposition of the audit, including the appeals process set forth in subsection (1) of this section.

B-19 Louisiana Regulatory Addendum to Pharmacy Participation Agreement

This Louisiana Addendum applies to the extent that Pharmacy provides covered drugs to covered persons of a health insurer, health maintenance organization (HMO), managed care organization and preferred provider organizations under Louisiana law (collectively and/or individually, "plan sponsor").

In the event of a direct conflict between this Addendum and the Participation Agreement ("Agreement"), the applicable provisions of this Addendum shall control if required. This Addendum may be modified from time to time pursuant to the Agreement.

Without limiting the generality of the foregoing, and notwithstanding anything in the Agreement to the contrary, Pharmacy agrees as follows:

Pharmacy may communicate with patients regarding their health care, including, but not limited to, communications regarding treatment options and medical alternatives or other coverage arrangements. Pharmacy shall not, however, solicit alternative coverage arrangements for the primary purpose of securing financial gain. La. Stat. § 22:1007(B).

Neither pharmacy benefit manager (PBM) nor plan sponsor shall prohibit or restrict Pharmacy from filing a complaint, making a report or commenting to an appropriate governmental body regarding the policies or practices of the plan sponsor or PBM that may negatively impact the quality of, or access to, patient care. La. Stat. § 22:1007(E).

Neither PBM nor plan sponsor shall prohibit or restrict Pharmacy from advocating to PBM or plan sponsor on behalf of covered persons for approval of coverage of a particular course of treatment or for the provision of health care services. La. Stat. § 22:1007(F).

Pharmacy shall not be required to provide indemnification or otherwise assume liability relating to activities, actions or omissions of plan sponsor. La. Stat. § 22:1007(G).

No provision of the Agreement shall operate to provide an incentive or specific payment made directly, in any form, to Pharmacy as an inducement to deny, reduce, limit or delay specific, medically necessary and appropriate services provided with respect to a specific covered person or groups of covered persons with similar medical conditions. La. Stat. § 22:263(E); La. Admin. Code tit. 37, § XIII.5307(A)(3).

In the event an HMO plan sponsor fails to pay for covered drugs as set forth in the evidence of coverage, covered persons shall not be liable to Pharmacy for any sums owed by HMO plan sponsor to Pharmacy. Neither Pharmacy, its agents, trustee, nor assignee may maintain an action at law against a covered person of an HMO plan sponsor to collect sums owed by the HMO plan sponsor. La. Stat. § 22:263(A)(1) and (C).

The procedure for processing and resolving enrollee grievances, including the location and telephone number where grievances may be submitted, is available by contacting the benefit plan. La. Stat. § 22:263(A)(3).

The methodology by which payment will be made is set forth in the Agreement. La. Stat. § 22:263(A)(2).

Appeals; maximum allowable costs (LA Stat. §22:1865)

(A) The PBM shall provide a reasonable administrative appeal procedure to allow pharmacies to challenge maximum allowable costs for a specific NDC or NDCs as not meeting the requirements of this Subpart or being below the cost at which the pharmacy may obtain the NDC. Within fifteen (15) business days after the applicable fill date, a pharmacy may file an appeal by following the appeal process as provided for in this Subpart. The PBM shall respond to a challenge within fifteen (15) business days after receipt of the challenge.

(B) If an appeal made pursuant to this Section is granted, the PBM shall take all of the following actions:

(1) Make the change in the Maximum Allowable Cost List to the initial date of service the appealed drug was dispensed.

(2) Permit the appealing pharmacy and all other pharmacies in the network that filled prescriptions for patients covered under the same health benefit plan to reverse and resubmit claims and receive payment based on the adjusted maximum allowable cost from the initial date of service the appealed drug was dispensed.

(3) Make the change effective for each similarly situated pharmacy as defined by the payor subject to the Maximum Allowable Cost List and individually notify all pharmacies in the network of that PBM of both of the following:

(a) That a retroactive maximum allowable cost adjustment has been made as a result of a granted appeal effective to the initial date of service the appealed drug was dispensed.

(b) That the pharmacy may resubmit and receive payment based upon the adjusted maximum allowable cost price.

(4) Make retroactive price adjustments in the next payment cycle.

(C) If an appeal made pursuant to this Section is denied, the PBM shall provide the challenging pharmacy or pharmacist the NDC number of a drug product and source where it may be purchased for a price at or below the maximum allowable cost from national or regional wholesalers operating in Louisiana.

Pharmacy record audits; recoupment; appeals (La. Stat. § 22:1856.1)

A. As used in this section, "entity" means a managed care company, insurance company, third-party payer or the representative of the managed care company, including a PBM, insurance company or third-party payer.

B. Notwithstanding any other provision of law to the contrary, when an audit of the records of a Pharmacy is conducted by an entity, the audit shall be conducted in accordance with the following criteria:

1. The audit may not take place during the first five days of the month.

2. (a) No entity shall conduct an audit at a particular Pharmacy more than one time annually. However, the provisions of this paragraph shall not apply when an entity must return to a Pharmacy to complete an audit already in progress, or there is an identified history of errors, an identified activity which a reasonable man would believe to be inappropriate, or illegal activity that the entity has brought to the attention of the pharmacy owner or corporate headquarters of the Pharmacy.

   (b) Nothing in this paragraph shall prohibit review of a claim filed by a Pharmacy to determine if the claim is payable or is paid correctly. Such review may require the submission of prescription copies and other documentation related to the specific claims under review but shall not require the Pharmacy to provide any additional information not related to those specific claims.

3. (a) The entity or any vendor or subcontractor of the entity which conducts the initial audit shall give the Pharmacy notice at least two weeks before conducting the initial audit for each audit cycle.

   (b) If the audit, review or investigation is initiated based on or involves alleged fraud or willful misrepresentation, notice before the initial audit is not mandatory where it could impede the audit, review or investigation.

4. (a)(i) Any clerical or recordkeeping error, such as a typographical error, scrivener's error or computer error, regarding a required document or record shall not necessarily constitute fraud. (ii) A claim arising pursuant to the provisions of this section may be subject to recoupment.

   (b) No claim arising pursuant to the provisions of this section shall be subject to criminal penalties without proof of intent to commit fraud.

5. A Pharmacy may provide the records of a hospital, physician or other authorized practitioner of the healing arts for drugs or medicinal supplies written or transmitted by any means of communication for purposes of supporting the pharmacy record with respect to orders or refills of a legend or narcotic drug.

6. Each Pharmacy shall be audited under the same standards and parameters as other similarly situated Pharmacies audited by the entity.
7. (a) The preliminary audit report shall be delivered to the Pharmacy within 90 days after conclusion of the audit.

   (b) A Pharmacy shall be allowed at least 30 days following receipt of the preliminary audit report in which to initiate an appeal to address any discrepancy found during an audit, as provided in subsection E of this section.

   (c) A final audit report shall be delivered to the Pharmacy within 120 days after receipt of the preliminary audit report or notice of appeal, whichever is later.

   (d) Each entity conducting an audit shall make available a copy of the final audit report to the plan sponsor upon request or as otherwise required by contractual agreement.
8. Any audit which involves clinical judgment shall be conducted by or in consultation with a pharmacist licensed in Louisiana.
9. Interest on recoupment debts shall not accrue during the audit or appeal period.
10. If the audit is conducted by a vendor or subcontractor of an entity, the vendor or subcontractor shall identify to the Pharmacy the entity on whose behalf the audit is being conducted without necessity of this information being requested by the Pharmacy.
11. The audit shall be based only on information obtained by the entity conducting the audit and not based on any audit report or other information gained from an audit conducted by a different auditing entity. Nothing in this paragraph shall prohibit an auditing entity from using an earlier audit report prepared by the auditing entity for the same Pharmacy. Except as required by state or federal law, an entity conducting an audit may have access to a Pharmacy's previous audit report only if the previous report was prepared by that entity.

C. 1. Recoupment of any disputed funds, or repayment of funds to the entity by the Pharmacy if permitted pursuant to contractual agreement, shall occur after final disposition of the audit, including the appeals process. Recoupment shall not be based on documentation requirements in addition to or exceeding requirements for creating or maintaining documentation prescribed by the Louisiana Board of Pharmacy; or on a requirement that a Pharmacy or pharmacist perform a professional duty in addition to or exceeding professional duties prescribed by the Louisiana Board of Pharmacy.

   2. The provisions of this section shall not apply in cases of United States Food and Drug Administration regulation or manufacturer safety programs.

   3. (a) The full amount of any recoupment on an audit shall be refunded to the responsible party.

      (b) Except as provided in this subsection, a charge or assessment for an audit shall not be based, directly or indirectly, on amounts recouped.

      (c) Nothing in this subsection shall be construed to prevent the entity conducting the audit from charging or assessing the responsible party, directly or indirectly, based on amounts recouped if both of the following conditions are met:

         (i) The responsible party and the entity have a contract that explicitly states the percentage charge or assessment to the responsible party.

         (ii) A commission or other payment to an agent or employee of the entity conducting the audit is not based, directly or indirectly, on amounts recouped.

   4. Before recoupment of funds may be made based on an audit finding overpayment or underpayment, a final audit report shall be distributed.

D. 1. No Pharmacy shall be subject to recoupment of any portion of the reimbursement for the dispensed product of a prescription unless one or more of the following has occurred at the point of adjudication:

(a) The Pharmacy has engaged in fraudulent activity or other intentional and willful misrepresentation, as evidenced by a review of claims data or statements, physical review or any other investigative method.

(b) The Pharmacy has engaged in dispensing in excess of the benefit design, as established by the plan sponsor.

(c) The Pharmacy has not filled prescriptions in accordance with the prescriber's order.

(d) The Pharmacy has received an actual overpayment.

2. Recoupment of claims shall be based on the actual financial harm to the entity, or on the actual overpayment or underpayment, at the point of adjudication. A finding of an overpayment that is the result of dispensing in excess of the benefit design, as established by the plan sponsor, shall be calculated as the difference between what was dispensed in accordance with the prescriber's orders and the dispensing requirements as set forth by the benefit design. Calculations of overpayments shall not include dispensing fees unless one or more of the following conditions has been satisfied:

(a) A prescription was not actually dispensed.

(b) The prescriber denied authorization.

(c) The prescription dispensed was a medication error by the Pharmacy.

(d) The identified overpayment is based solely on an extra dispensing fee.

(e) The Pharmacy was noncompliant with program guidelines.

(f) There was insufficient documentation.

3. If Prime determines that the processed or adjudicated claim of a Pharmacy qualifies for recoupment based upon the use of manufacturer coupon or copay card, such recoupment shall come from the beneficiary of the reduction if the product is approved by the United States Food and Drug Administration through the new drug application process or abbreviated new drug application, or is an investigational drug, which is a biological product as defined in La. Stat. § 40:1169.3.

E. 1. Each entity conducting an audit shall establish an appeal process under which a Pharmacy may appeal an unfavorable preliminary audit report to the entity.

2. If, following an appeal, the entity finds that an unfavorable audit report or any portion of an unfavorable audit report is unsubstantiated, the entity shall dismiss the audit report or the unsubstantiated portion of the audit report without any further proceedings.

3. No interest shall be charged to the entity during the appeal period.

4. Following the final audit report, and if not otherwise provided for in the provider contract, either party may seek mediation to address outstanding disagreements.

5. Notwithstanding any other provision of law to the contrary the agency conducting the audit shall not use the accounting practice of extrapolation in calculating recoupment or penalties for audits, unless otherwise agreed to by the Pharmacy or mandated by a government agency or in the case of fraud.

F. Unless otherwise provided for in the network agreement, Pharmacies or payers may seek mediation to resolve contractual disputes related to pricing or audits.

G. This section shall not apply to:

1. Any quality assurance review, as defined by the time period prior to the reimbursement by the entity to the Pharmacy.
2. An investigation that is initiated based on or that involves suspected or alleged fraud, willful misrepresentation or abuse.

B-20 Maine Regulatory Addendum to Pharmacy Participation Agreement

This Maine Addendum applies to the extent that Pharmacy provides covered drugs to covered persons of a health maintenance organization, insurer or carrier licensed under Maine law (collectively and/or individually, "plan sponsor").

In the event of a direct conflict between this Addendum and the Agreement, the applicable provisions of this Addendum shall control if required. This Addendum may be modified from time to time pursuant to the Agreement.

Without limiting the generality of the foregoing, and notwithstanding anything in the Agreement to the contrary, Pharmacy agrees as follows:

In the event that PBM or plan sponsor fails to pay for covered drugs as set forth in the Agreement, the covered person may not be held liable to Pharmacy, and its agent, trustee or assignee may not maintain any action at law against a covered person to collect sums owed by PBM or plan sponsor. If a petition to liquidate PBM or plan sponsor is filed with a court of competent jurisdiction, then after the date of filing the petition for liquidation:

Pharmacy is prohibited from collecting or attempting to collect from a covered person amounts normally payable by PBM or plan sponsor.

Pharmacy or its agent, trustee or assignee may not maintain any action at law against a covered person to collect amounts for covered drugs normally payable by PBM or plan sponsor.

Nothing in this paragraph prohibits Pharmacy from collecting or attempting to collect from a covered person any amounts for services not normally payable by PBM or plan sponsor, including applicable copays or deductibles. 24-A M.R.S. § 4204(6); 24-A M.R.S. § 4303(8-A)(B).

In the event of the insolvency of PBM or plan sponsor, Pharmacy shall continue providing covered drugs for covered persons for the duration of the period for which premium payment has been made to plan sponsor and until covered person's discharge from inpatient facilities. 24-A M.R.S. § 4204(7).

Pharmacy shall provide PBM at least 60 days' advance notice to terminate or withdraw from the Agreement. 24-A M.R.S. § 4204(8).

In the event of the insolvency of PBM, plan sponsor may require the assignment of this agreement to itself, and Pharmacy shall continue to provide services to covered persons. CMR 02-031-191 § 11.

Pharmacy shall allow appropriate access to medical records of covered persons for purposes of quality management, and quality reviews and complaint investigations conducted by PBM, plan sponsor, the state or the state's designee. CMR 10-144-109 § 1.03-2 E.3.

Pharmacy shall have policies and procedures for 1) protecting the confidentiality of covered person health information; 2) limiting access to health care information on a need-to-know basis, consistent with existing law; 3) holding all health care information confidential and not divulging it without covered person's authorization, except as consistent with existing law; and 4) allowing covered persons access to their medical records, consistent with existing law. CMR 10-144-109 § 1.03-2 E.4.

Pharmacy shall retain records of its affairs and transactions with PBM and plan sponsor for a period of at least six years. CMR 02-031-191 §10.B.

Once PBM has received payment from plan sponsors for covered drugs provided by Pharmacy under this agreement, PBM shall remit amounts due to Pharmacy within the timeframes provided in Maine Revised Statutes § 4317. 24-A M.R.S. § 4317(6).

Prescription drug pricing; maximum allowable cost (24-A M.R.S. § 4350)

Disclosure. With regard to a pharmacy with which the carrier, or the PBM under contract with a carrier, has entered into a contract, a carrier, or a PBM under contract with a carrier, shall:

A. Upon request, disclose the sources used to establish the maximum allowable costs;

B. Provide a process for a pharmacy to readily obtain the maximum allowable payment available to that pharmacy under a maximum allowable cost list; and

C. At least once every seven (7) business days, review and update maximum allowable cost list information to reflect any modification of the maximum allowable payment available to a pharmacy under a maximum allowable cost list used by the carrier or the PBM under contract with a carrier.

Appeals procedure. A carrier, or a PBM under contract with a carrier, shall provide a reasonable administrative appeal procedure, including a right to appeal that is limited to 14 days following the initial claim, to allow pharmacies with which the carrier or PBM has a contract to challenge maximum allowable costs for a specified drug.

Resolution of Appeals. A carrier, or a PBM under contract with a carrier, shall respond to, investigate and resolve an appeal under subsection 5 within fourteen (14) days after the receipt of the appeal. The carrier or PBM shall respond to an appeal as follows:

A. If the appeal is upheld, the carrier or PBM shall make the appropriate adjustment in the maximum allowable cost and permit the challenging pharmacy or pharmacist to reverse and rebill the claim in question; or

B. If the appeal is denied, the carrier or PBM shall provide the challenging pharmacy or pharmacist the national drug code from national or regional wholesalers of a comparable prescription drug that may be purchased at or below the maximum allowable cost.

Pharmacy Providers - Audits (24-A M.R.S. § 4317)

Notwithstanding any other provision of law, when an on-site audit of the records of a Pharmacy is conducted by a PBM, the audit must be conducted in accordance with the following criteria:

A. A finding of overpayment or underpayment must be based on the actual overpayment or underpayment and not a projection based on the number of patients served having a similar diagnosis or on the number of similar orders or refills for similar drugs, unless the projected overpayment or denial is a part of a settlement agreed to by the Pharmacy or pharmacist.

B. The auditor may not use extrapolation in calculating recoupments or penalties.

C. Any audit that involves clinical or professional judgment must be conducted by or in consultation with a pharmacist.

D. Each entity conducting an audit shall establish an appeals process under which a Pharmacy may appeal an unfavorable preliminary audit report to PBM.

E. This subsection does not apply to any audit, review or investigation that is initiated based on or involves suspected or alleged fraud, willful misrepresentation or abuse.

F. Prior to an audit, Prime shall give the Pharmacy ten (10) days' advance written notice of the audit and the range of prescription numbers and the range of dates included in the audit.

G. A Pharmacy has the right to request mediation by a private mediator, agreed upon by the Pharmacy and PBM, to resolve any disagreements. A request for mediation does not waive any existing rights of appeal available to a Pharmacy under this subsection or subsection 11.

H. The requirements of section 4303, subsection 10 apply to claims audited under this subsection.

Plan Requirements - Limits on Retrospective Denials (24-A M.R.S. § 4303)

A carrier offering a health plan in this state may not impose on any provider any retrospective denial of a previously paid claim or any part of that previously paid claim unless:

A. The carrier has provided the reason for the retrospective denial in writing to the provider; and

B. The time that has elapsed since the date of payment of the previously paid claim does not exceed twelve (12) months. The retrospective denial of a previously paid claim may be permitted beyond 12 months from the date of payment only for the following reasons:

(1) The claim was submitted fraudulently;

(2) The claim payment was incorrect because the provider or the insured was already paid for the health care services identified in the claim;

(3) The health care services identified in the claim were not delivered by the provider;

(4) The claim payment was for services covered by Title XVIII, Title XIX or Title XXI of the Social Security Act;

(5) The claim payment is the subject of adjustment with another insurer, administrator or payer; or

(6) The claim payment is the subject of legal action.

For purposes of this subsection, "retrospective denial of a previously paid claim" means any attempt by a carrier to retroactively collect payments already made to a provider with respect to a claim by requiring repayment of such payments, reducing other payments currently owed to the provider, withholding or setting off against future payments or reducing or affecting the future claim payments to the provider in any other manner. The provider has six months from the date of notification under this subsection to determine whether the insured has other appropriate insurance that was in effect on the date of service. Notwithstanding the terms of the provider agreement, the carrier shall allow for the submission of a claim that was previously denied by another insurer because of the insured's transfer or termination of coverage.

Pharmacy providers - Audit information and reports (24-A M.R.S. § 4317)

A preliminary audit report must be delivered to the Pharmacy within sixty (60) days after the conclusion of the audit under subsection 10. A Pharmacy must be allowed at least 30 days following receipt of the preliminary audit to provide documentation to address any discrepancy found in the audit. A final audit report must be delivered to the Pharmacy within ninety (90) days after receipt of the preliminary audit report or final appeal, whichever is later. A chargeback, recoupment or other penalty may not be assessed until the appeal process provided by PBM has been exhausted and the final report issued. Except as provided by state or federal law, audit information may not be shared. Auditors may have access only to previous audit reports on a particular Pharmacy conducted by that same entity.

B-21 Maryland Regulatory Addendum to Pharmacy Participation Agreement

This Maryland Addendum applies to the extent that Pharmacy provides covered drugs to covered persons of a health insurer, nonprofit health service plan, health maintenance organization or carrier under Maryland law (collectively and/or individually, "plan sponsor").

In the event of a direct conflict between this Addendum and the Agreement, the applicable provisions of this Addendum shall control if required. This Addendum may be modified from time to time pursuant to the Agreement.

Without limiting the generality of the foregoing, and notwithstanding anything in the Agreement to the contrary, Pharmacy agrees as follows:

Pharmacy shall not, under any circumstances, including nonpayment of moneys due Pharmacy by plan sponsor or PBM, insolvency of plan sponsor or PBM or breach of the Agreement, bill, charge, collect

a deposit, seek compensation, remuneration, or reimbursement from, or have any recourse against covered persons or any persons other than plan sponsor acting on their behalf, for covered drugs provided in accordance with the Agreement. This provision shall not operate to preclude collection from covered persons of copays or supplemental charges in accordance with the terms of the benefit plan, or charges for services not covered. Pharmacy agrees that this provision shall survive termination of this agreement regardless of the cause giving rise to termination. Md. Code Health-General § 19-710(i).

Nothing in the Agreement shall be construed to require Pharmacy to indemnify or hold plan sponsor harmless from a coverage decision or negligent act of the plan sponsor. Md. Code Health-General § 19- 710(t); Md. Code Ins. § 15-117(b).

PBM and Pharmacy shall provide written notice to the other of intent to terminate the Agreement at least 90 days prior to the termination. This provision shall not apply to PBM; however, in the event PBM terminates Pharmacy for fraud, patient abuse, incompetence or loss of Pharmacy's License. Pharmacy shall continue to provide covered drugs to covered persons from the date of Pharmacy's notice of intent to terminate until the effective date of termination. Md. Code Ins. § 15-112.2(e).

Notwithstanding anything to the contrary in the Agreement, Pharmacy shall not, as a condition of the Agreement, be required to participate in all PBM networks. Md. Code Ins. § 15-112.2(b) and (d).

To the extent required by law, nothing in the Agreement shall operate: (a) to preclude Pharmacy from providing services at a lower rate of reimbursement to members of carriers who are not contracted with PBM; (b) to require Pharmacy to accept from PBM the same reimbursement arrangement that Pharmacy has with a carrier not contracted with PBM if the reimbursement arrangement with that carrier is for a lower rate of reimbursement ; or (c) to require Pharmacy to certify that the reimbursement rates in this Agreement are not higher than the reimbursement rates being received by Pharmacy from carriers not contracted with PBM. Md. Code Ins. § 15-112(s).

PBM and plan sponsor shall not, as a condition to this Agreement, prohibit Pharmacy from discussing with or communicating to a covered person, public official or other person information that is necessary or appropriate for the delivery of health care services, including: (a) communications that relate to treatment alternatives; (b) communications that are necessary or appropriate to maintain the provider- patient relationship while the patient is under Pharmacy's care; (c) communications that relate to a covered person's right to appeal a coverage determination of a plan sponsor with which Pharmacy, or the covered person does not agree; and (d) opinions and the basis of an opinion about public policy issues. Md. Code Ins. § 15-116.

For purposes of this agreement, "experimental medical care" shall have the meaning set forth in the benefit plan documents. Md. Code Ins. § 15-123(d).

PBM shall not assign, transfer or subcontract this agreement, wholly or partly, to an insurer that offers personal injury protection under Md. Code Ins. § 19-505 without first informing Pharmacy and obtaining Pharmacy's written consent. PBM shall not terminate, limit or otherwise impair Pharmacy's rights under the Agreement based on Pharmacy's refusal to agree to an assignment, transfer or subcontract of all or part of the Agreement to an insurer that offers personal injury protection coverage under Md. Code Ins. § 15-125(b).

Pharmacy's participation under this agreement shall not be conditioned of Pharmacy's participation in a network for workers' compensation services. PBM shall not terminate, limit or otherwise impair Pharmacy's rights under this agreement based on Pharmacy's election not to participate in a network for workers' compensation services. Md. Code Ins. § 15-125(c).

Upon execution of the Agreement, and at least 30 days prior to a change, PBM shall disclose to Pharmacy: (a) applicable terms, conditions, and reimbursement rates; (b) the process and procedures for verifying covered drugs and beneficiary eligibility; (c) the process and procedures for dispute resolution and audit appeals process; and (d) the process and procedures for verifying the prescription drugs included on the benefit plan's formularies. Md. Code Ins. § 15-1628.

This agreement shall not be effective until 30 days following its submission in duplicate to the Maryland Insurance Commissioner. COMAR 31.12.02.13(C).

No amendment to the following provisions or information provided in connection with such provisions shall be effective until 30 days following its submission to the Maryland Insurance Commissioner:

(a) Section 1 of this Addendum (hold-harmless clause); (b) Section 2 of this Addendum (indemnification); (c) Section 4 of this Addendum (participation in other networks); (d) Section 8 of this Addendum (assignment to insurers offering personal injury protection; (e) any provision dealing with the administration of a coordination of benefits clause; (f) termination of this agreement; (g) any provision dealing with the applicability of Maryland law; and (h) any provision revised to comply with Maryland law. COMAR 31.12.02.13(C)(4).

Contracts between pharmacy benefits managers and pharmacies (Md. Code Ins. § 15-1628.1)

(b) In each participating pharmacy contract, the PBM shall include the sources used to determine maximum allowable cost pricing.

(c) A PBM shall:

(1) update its pricing information at least every seven (7) days;

(2) establish a reasonable process by which a contracted pharmacy has access to the current and applicable maximum allowable cost price lists in an electronic format as updated in accordance with the requirements of this section; and

(3) immediately after a pricing information update under item (1) of this subsection, use the updated pricing information in calculating the payments made to all contracted pharmacies.

(d)(1) A PBM shall maintain a procedure to eliminate products from the list of drugs subject to maximum allowable cost pricing as necessary to:

(i) remain consistent with pricing changes;

(ii) remove from the list drugs that no longer meet the requirements of subsection (e) of this section; and

(i) reflect the current availability of drugs in the marketplace.

(2) A product on the maximum allowable cost list shall be eliminated from the list by the PBM within seven (7) days after the PBM knows of a change in the availability of the product.

(e) Before placing a prescription drug on a maximum allowable cost list, a PBM shall ensure that:

(1) the drug is listed as "A" or "B" rated in the most recent version of the U.S. Food and Drug Administration's approved drug products with therapeutic equivalence evaluations, also known as the Orange Book, or has an "NR" or "NA" rating or similar rating by a nationally recognized reference;

(2)(i) if a drug is manufactured by more than one manufacturer, the drug is generally available for purchase by contracted pharmacies, including contracted retail pharmacies, in the State from a wholesale distributor with a permit in the State; or

(ii) if a drug is manufactured by only one manufacturer, the drug is generally available for purchase by contracted pharmacies, including contracted retail pharmacies, in the State from at least two wholesale distributors with a permit in the State; and

(3) the drug is not obsolete, temporarily unavailable, or listed on a drug shortage list as currently in shortage.

(f) For disputes regarding maximum allowable cost pricing, each participating pharmacy contract must include a process to appeal, investigate, and resolve disputes regarding maximum allowable cost pricing that includes:

(1) a requirement that an appeal be filed by the contract pharmacy no later than 21 days after the date of the initial adjudicated claim;

(2) a requirement that, within 21 days after the date the appeal is filed, the PBM investigate and resolve the appeal and report to the contracted pharmacy on the PBM's determination on the appeal;

(3) a requirement that a PBM make available on its website information about the appeal process, including:

(i) a telephone number at which the contracted pharmacy may directly contact the department or office responsible for processing appeals for the PBM to speak to an individual or leave a message for an individual who is responsible for processing appeals;

(ii) an e-mail address of the department or office responsible for processing appeals to which an individual who is responsible for processing appeals has access; and

(iii) a notice indicating that the individual responsible for processing appeals shall return a call or an e-mail made by a contracted pharmacy to the individual within three (3) business days or less of receiving the call or e-mail;

(4) a requirement that a PBM provide:

(i) a reason for any appeal denial;

(ii) the national drug code of a drug and the name of the wholesale distributor from which the drug was available on the date the claim was adjudicated at a price at or below the maximum allowable cost determined by the PBM; and

(iii) the mathematical calculation used to determine the maximum allowable cost; and

(5) if an appeal is upheld, a requirement that a PBM:

(i) for the appealing pharmacy:

1. adjust the maximum allowable cost for the drug as of the date of the original claim for payment; and

2. without requiring the appealing pharmacy to reverse and rebill the claims, provide reimbursement for the claim and any subsequent and similar claims under similarly applicable contracts with the PBM:

A. for the original claim, in the first remittance to the pharmacy after the date the appeal was determined; and

B. for subsequent and similar claims under similarly applicable contracts, in the second remittance to the pharmacy after the date the appeal was determined; and

(ii) for a similarly situated contracted pharmacy in the State:

1. adjust the maximum allowable cost for the drug as of the date the appeal was determined; and
2. provide notice to the pharmacy or pharmacy's contracted agent that:

A. an appeal has been upheld; and

B. without filing a separate appeal, the pharmacy or the pharmacy's contracted agent may reverse and rebill a similar claim.

Audits of Pharmacy or pharmacist (Md. Code Ins. § 15-1629).

Application of section to pharmacy benefit management services on behalf of carrier

(a) This section applies only to a PBM that provides PBM services on behalf of a carrier.

Section not applicable to audits involving fraud or willful misrepresentation

(b) This section does not apply to an audit that involves probable or potential fraud or willful misrepresentation by a Pharmacy or pharmacist.

Audit by pharmacy benefit manager

(c) (c) A PBM shall conduct an audit of a Pharmacy or pharmacist under contract with the PBM in accordance with this section.

Restrictions relating to dates of audit

(d) A PBM may not schedule an on-site audit to begin during the first five calendar days of a month unless requested by the Pharmacy or pharmacist.

Duties of pharmacy benefit manager in conducting audit

(e) When conducting an audit, a PBM shall:

(1) If the audit is onsite, provide written notice to the Pharmacy or pharmacist at least two weeks before conducting the initial onsite audit for each audit cycle;

(2) Employ the services of a pharmacist if the audit requires the clinical or professional judgment of a pharmacist;

(3) Permit its auditors to enter the prescription area of a Pharmacy only when accompanied by or authorized by a member of the pharmacy staff;

(4) Allow a pharmacist or Pharmacy to use any prescription, or authorized change to a prescription, that meets the requirements of COMAR 10.34.20.02 to validate claims submitted for reimbursement for dispensing of original and refill prescriptions;

(5) For purposes of validating the pharmacy record with respect to orders or refills of a drug, allow the Pharmacy or pharmacist to use records of a hospital or a physician or other prescriber authorized by law that are:

(i) Written; or

(ii) Transmitted electronically or by any other means of communication authorized by contract between the Pharmacy and the pharmacy benefit manager;

(6) Audit each Pharmacy and pharmacist under the same standards and parameters as other similarly situated Pharmacies or pharmacists audited by the PBM;

(7) Only audit claims submitted or adjudicated within the 2-year period immediately preceding the audit, unless a longer period is authorized under federal or state law;

(8) Deliver the preliminary audit report to the Pharmacy or pharmacist within 120 calendar days after the completion of the audit, with reasonable extensions allowed;

(9) In accordance with subsection (k) of this section, allow a Pharmacy or pharmacist to produce documentation to address any discrepancy found during the audit; and

(10) Deliver the final audit report to the Pharmacy or pharmacist:

(i) Within six (6) months after delivery of the preliminary audit report if the Pharmacy or pharmacist does not request an internal appeal under subsection (k) of this section; or

(ii) Within thirty (30) days after the conclusion of the internal appeals process under subsection (k) of this section if the Pharmacy or pharmacist requests an internal appeal.

Authorization to withdraw and resubmit claims

(f) If a contract between a Pharmacy or pharmacist and a PBM specifies a period of time in which a Pharmacy or pharmacist is allowed to withdraw and resubmit a claim and that period of time expires before the PBM delivers a preliminary audit report that identifies discrepancies, the PBM shall allow the Pharmacy or pharmacist to withdraw and resubmit a claim within thirty (30) days after:

(1) The preliminary audit report is delivered if the Pharmacy or pharmacist does not request an internal appeal under subsection (k) of this section; or

(2) The conclusion of the internal appeals process under subsection (k) of this section if the Pharmacy or pharmacist requests an internal appeal.

Services to pharmacy customers not disrupted by audit

(g) During an audit, a PBM may not disrupt the provision of services to the customers of a Pharmacy.

Restrictions relating to conduct of pharmacy benefit manager during audit process

(h)(1) A PBM may not:

(i) Use the accounting practice of extrapolation to calculate overpayments or underpayments;
(ii) Except as provided in paragraph (2) of this subsection:

1. Share information from an audit with another PBM; or
2. Use information from an audit conducted by another PBM.

(2) Paragraph (1)(ii) of this subsection does not apply to the sharing of information:

(i) Required by federal or state law;

(ii) In connection with an acquisition or merger involving the PBM; or

(iii) At the payer's request or under the terms of the Agreement between the PBM and the payer.

Recoupment of claims payment

(i) The recoupment of a claims payment from a Pharmacy or pharmacist by a PBM shall be based on an actual overpayment or denial of an audited claim unless the projected overpayment or denial is part of a settlement agreed to by the Pharmacy or pharmacist.

Overpayments by pharmacy benefit manager

(j)(1) In this subsection, "overpayment" means a payment by the PBM to a Pharmacy or pharmacist that is greater than the rate or terms specified in the contract between the Pharmacy or pharmacist and the PBM at the time that the payment is made.

(2) A clerical error, recordkeeping error, typographical error or scrivener's error in a required document or record may not constitute fraud or grounds for recoupment of a claims payment from a Pharmacy or pharmacist by a PBM if the prescription was otherwise legally dispensed and the claim was otherwise materially correct.

(3) Notwithstanding paragraph (2) of this subsection, claims remain subject to recoupment of overpayment or payment of any discovered underpayment by the PBM.

Internal appeals process

(k)(1) The PBM shall establish an internal appeals process under which a Pharmacy or pharmacist may appeal any disputed claim in a preliminary audit report.

(2) Under the internal appeals process, a PBM shall allow a Pharmacy or pharmacist to request an internal appeal within thirty (30) working days after receipt of the preliminary audit report, with reasonable extensions allowed.

(3) The PBM shall include in its preliminary audit report a written explanation of the internal appeals process, including the name, address and telephone number of the person to whom an internal appeal should be addressed.

(4) The decision of the PBM on an appeal of a disputed claim in a preliminary audit report by a Pharmacy or pharmacist shall be reflected in the final audit report.

(5) The PBM shall deliver the final audit report to the Pharmacy or pharmacist within (30) calendar days after conclusion of the internal appeals process.

Restrictions relating to recoupment by setoff

(l)(1) A PBM may not recoup by setoff any money for an overpayment or denial of a claim until:

(i) The Pharmacy or pharmacist has an opportunity to review the pharmacy benefit manager's findings; and

(ii) If the Pharmacy or pharmacist concurs with the PBM's findings of overpayment or denial, thirty (30) working days have elapsed after the date the final audit report has been delivered to the Pharmacy or pharmacist.

(2) If the Pharmacy or pharmacist does not concur with the PBM's findings of overpayment or denial, the PBM may not recoup by setoff any money pending the outcome of an appeal under subsection (k) of this section.

(3) A PBM shall remit any money due to a Pharmacy or pharmacist as a result of an underpayment of a claim within (30) working days after the final audit report has been delivered to the Pharmacy or pharmacist.

(4) Notwithstanding the provisions of paragraph (1) of this subsection, a PBM may withhold future payments before the date the final audit report has been delivered to the Pharmacy or pharmacist if the identified discrepancy for all disputed claims in a preliminary audit report for an individual audit exceeds $25,000.

Regulations relating to documentation and audit process

(m)(1) The Commissioner may adopt regulations regarding:

(i) The documentation that may be requested during an audit; and

(ii) The process the PBM may use to conduct an audit.

(2) On request of the Commissioner or the Commissioner's designee, a PBM shall provide a copy of its audit procedures or internal appeals process.

B-22 Massachusetts Regulatory Addendum to Pharmacy Participation Agreement

This Massachusetts Addendum applies to the extent that Pharmacy provides covered drugs to covered persons of a Health Maintenance Organization ("HMO"), Insurer or Carrier licensed under Massachusetts law (collectively and/or individually, "plan sponsor").

In the event of a direct conflict between this Addendum and the Agreement, the applicable provisions of this Addendum shall control if required. This Addendum may be modified from time to time pursuant to the Agreement.

Without limiting the generality of the foregoing, Pharmacy agrees as follows:

PBM shall not refuse to contract with or compensate for covered pharmacy services of an otherwise covered Pharmacy solely because Pharmacy has in good faith:

Communicated with or advocated on behalf of one of more of his/her/its prospective, current or former patients regarding the provisions, terms or requirements of PBM or plan sponsor's benefit plans as they relate to the needs of Pharmacy's patients; or

Communicated with one or more of their prospective, current or former patients with respect to the method by which Pharmacy is compensated by PBM or plan sponsor for services provided to patient. 211 CMR 52.11(1); Managed Care Checklist: Requirements for Provider Contracts, Page 11 (Rev. 121212).

Pharmacy is not required to indemnify plan sponsor for any expenses and liabilities, including, without limitation, judgments, settlements, attorneys' fees, court costs and any associated charges, incurred in connection with any claim or action brought against plan sponsor based on plan sponsor's management decisions, utilization review provisions or other policies, guidelines or actions. 211 CMR 52.11(2); Managed Care Checklist: Requirements for Provider Contracts, Page 11 (Rev. 121212).

Neither party shall terminate this agreement without cause. 211 CMR 52.11(6); Managed Care Checklist: Requirements for Provider Contracts, Page 11 (Rev. 121212).

PBM shall provide a written statement to Pharmacy of the reason or reasons for termination of this agreement. 211 CMR 52.11(7); Managed Care Checklist: Requirements for Provider Contracts, Page 11 (Rev. 121212).

PBM shall notify Pharmacy in writing of modifications in payments, modifications in covered services or modifications in PBM's procedures, documents or requirements, including those associated with utilization review, quality management and improvement, credentialing and preventive health services, that have a substantial impact on the rights or responsibilities of Pharmacy and the effective date of the modifications. The notice shall be provided 60 days before the effective date of such modification unless such other date for notice is mutually agreed upon between PBM and Pharmacy. 211 CMR 52.11(8); Managed Care Checklist: Requirements for Provider Contracts, Page 11 (Rev. 121212).

Pharmacy shall not bill covered persons for charges for covered pharmacy services other than for deductibles, copays or coinsurance. 211 CMR 52.11(9); Managed Care Checklist: Requirements for Provider Contracts, Page 11 (Rev. 121212).

Pharmacy shall not bill covered persons for nonpayment by PBM or plan sponsor of amounts owed under this agreement due to the insolvency of PBM or plan sponsor. This requirement shall survive the termination of this agreement for services rendered prior to the termination of this agreement,

regardless of the cause of the termination. 211 CMR 52.11(10); Managed Care Checklist: Requirements for Provider Contracts, Page 11 (Rev. 121212).

Pharmacy shall comply with PBM's and plan sponsor's requirements for utilization review, quality management and improvement, credentialing and the delivery of preventive health services. 211 CMR 52.11(11); Managed Care Checklist: Requirements for Provider Contracts, Page 11 (Rev. 121212).

Within 45 days after the receipt by PBM of a claim for reimbursement to Pharmacy for pharmacy services, plan sponsor through PBM shall: (1) make payment for such services provided, (2) notify Pharmacy in writing of the reason or reasons for nonpayment, or (3) notify Pharmacy in writing of what additional information or documentation is necessary to complete claims for such reimbursement. If plan sponsor fails to comply with this provision for any claims related to the provision of health care services, plan sponsor shall pay, in addition to any reimbursement for health care services provided, interest on such benefits, which shall accrue beginning 45 days after PBM's receipt of request for reimbursement at the rate of 1.5% per month, not to exceed 18% per year. This provision relating to interest payments shall not apply to a claim that PBM or plan sponsor is investigating because of suspected fraud. Mass. Gen. Laws Ann. 176G § 6; 176I § 2; Managed Care Checklist: Requirements for Provider Contracts, Page 11 (Rev. 121212).

Pharmacy agrees that in no event, including, but not limited to, nonpayment by PBM or plan sponsor of amounts due Pharmacy under this agreement, insolvency of PBM or plan sponsor or any breach of this agreement by PBM or plan sponsor, shall Pharmacy or its assignees or subcontractors have a right to seek any type of payment from, bill, charge, collect a deposit from, or have any recourse against, the covered person, persons acting on the covered person's behalf, other than PBM or plan sponsor, the employer or the group contract holder for services provided pursuant to this agreement except for the payment of applicable copay, coinsurance or deductibles for services covered by the plan sponsor. The requirements of this provision shall survive any termination of this agreement for services rendered prior to the termination, regardless of the cause of such termination. plan sponsor's covered persons, any persons acting on the covered person's behalf, other than PBM or plan sponsor, and the employer or group contract holder shall be third-party beneficiaries of this clause. This provision supersedes any oral or written agreement hereafter entered into between Pharmacy and the covered person, persons acting on the covered person's behalf, other than PBM or plan sponsor, and employer or group contract holder. Mass. Gen. Laws Ann. 176G, § 21.

Pharmacy audits; standards for the conduct of audits of records; appeals (Mass. Gen. Laws Ann. 175 § 226)

(b) A PBM shall conduct an audit of the records of a Pharmacy in accordance with paragraphs (1) to (13), inclusive.

(1) The contract between a Pharmacy and a PBM shall identify and describe the audit procedures in detail.

(2) With the exception of an investigative fraud audit, the auditor shall give the Pharmacy written notice at least two weeks prior to conducting the initial on-site audit for each audit cycle.

(3) A PBM shall not audit claims beyond two years prior to the date of audit.

(4) The auditor shall not interfere with the delivery of pharmacist services to a patient and shall make a reasonable effort to minimize the inconvenience and disruption to the pharmacy operations during the audit process.

(5) Any audit that involves clinical or professional judgment shall be conducted by, or in consultation with, a licensed pharmacist from any state.

(6) A finding of an overpayment or underpayment shall be based on the actual overpayment or underpayment. A statistically sound calculation for overpayment or underpayment may be used to determine recoupment as part of a settlement as agreed to by the Pharmacy.

(7) The auditor shall audit each Pharmacy under the same standards and parameters with which they audit other similarly situated Pharmacies.

(8) An audit shall not be initiated or scheduled during the first five (5) calendar days of any month for any Pharmacy that averages more than 600 prescriptions per week without the pharmacy's consent.

(9) A preliminary audit report shall be delivered to the Pharmacy not later than (30) days after the conclusion of the audit.

(10) The preliminary audit report shall be signed and shall include the signature of any pharmacist participating in the audit.

(11) A PBM shall not withhold payment to a Pharmacy for reimbursement claims as a means to recoup money until after the final internal disposition of an audit, including the appeals process, as provided in subsection (c), unless fraud or misrepresentation is reasonably suspected or the discrepant amount exceeds $15,000.

(12) The auditor shall provide a copy of the final audit report to the Pharmacy and plan sponsor within thirty (30) days following the Pharmacy's receipt of the signed preliminary audit report or the completion of the appeals process, as provided in subsection (c), whichever is later.

(13) No auditing company or agent shall receive payment based upon a percentage of the amount recovered or other financial incentive tied to the findings of the audit.

(c)(1) Each auditor shall establish an appeals process under which a Pharmacy may appeal findings in a preliminary audit.

(2) To appeal a finding, a Pharmacy may use the records of a hospital, physician or other authorized prescriber to validate the record with respect to orders or refills of prescription drugs or devices.

(3) A Pharmacy shall have thirty (30) days to appeal any discrepancy found during the preliminary audit.

(4) The National Council for Prescription Drug Programs or any other recognized national industry standard shall be used to evaluate claims submission and product size disputes.

(5) If an audit results in the identification of any clerical or recordkeeping errors in a required document or record, the Pharmacy shall not be subject to recoupment of funds by the PBM; provided, that the Pharmacy may provide proof that the patient received the medication billed to the plan via patient signature logs or other acceptable methods, unless there is financial harm to the plan or errors that exceed the normal course of business.

(d) This section shall not apply to any audit or investigation of a Pharmacy that involves potential fraud, willful misrepresentation or abuse, including, but not limited to, investigative audits or any other statutory or regulatory provision which authorizes investigations relating to insurance fraud.

(e) This section shall not apply to a public health care payer, as defined in section 1 of Massachusetts Statute, chapter 12C.

B-23 Michigan Regulatory Addendum to Pharmacy Participation Agreement

This Michigan Addendum applies to the extent that Pharmacy provides covered drugs to covered persons of health maintenance organizations and health care service corporations, under Michigan law (collectively and/or individually, "plan sponsor").

In the event of a direct conflict between this Addendum and the Agreement, the applicable provisions of this Addendum shall control if required. This Addendum may be modified from time to time pursuant to the Agreement.

Without limiting the generality of the foregoing, and notwithstanding anything in the Agreement to the contrary, Pharmacy agrees as follows:

Pharmacy will in no event (including, but not limited to, nonpayment by PBM or any plan sponsor, PBM or any plan sponsor's insolvency, or breach of this agreement) bill, charge, collect a deposit from, seek compensation, remuneration or reimbursement from or have any recourse against, a covered person or other persons acting on their behalf. This provision does not prohibit the collection of copays or charges for noncovered services or items. Mich. Stat. § 500.3529(3)

Pharmacy represents and warrants that it is, and will maintain, in good standing, all federal, state and local licenses and certifications as required by law. Mich. Stat. § 500.3529(4)(a)

PBM and plan sponsors shall have the access Pharmacy records and reports concerning services to covered persons, as set forth in the Agreement. Mich. Stat. § 500.3529(4)(b)

Pharmacy must comply with the quality assurance initiatives required by PBM or plan sponsor, including any special quality management requirements and programs established by PBM or plan sponsors. Mich. Stat. § 500.3529(4)(c)

In the event of a plan sponsor's insolvency, Pharmacy agrees to continue providing covered drugs to covered persons. Pharmacy acknowledges that plan sponsor is required by law to provide a mechanism for appropriate sharing of the continuation of provider services as approved by the Michigan Insurance Commissioner and in no event shall such continuation be solely the responsibility of Pharmacy. Mich. Stat. § 500.3561.

Maximum allowable cost; duties of pharmacy benefit manager; conditions; payment of benefits after adjudication of claim (MI ST 550.837)

(1) For each drug that a PBM establishes a maximum allowable cost, the pharmacy benefit manager shall do all of the following:

(a) Provide each pharmacy subject to a maximum allowable cost list with access to the maximum allowable cost list and the source used to determine the maximum allowable cost for each drug.

(b Update its maximum allowable cost list at least once every seven (7) calendar days.

(c) Provide a process for each pharmacy subject to the maximum allowable cost list to receive prompt notification of an update to the maximum allowable cost list.

(d) Establish and maintain a reasonable administrative appeals process to allow a pharmacy subject to the maximum allowable cost list or an agent of a pharmacy subject to the maximum allowable cost list to challenge the adjudication of a pharmacy's claim.

(e) Investigate and resolve an appeal under this subsection within fourteen (14) calendar days after PBM receives the appeal. An appeal under this subsection must be submitted to the PBM not later than 45 calendar days after the date the pharmacy's claim for reimbursement has been adjudicated.

(f) Respond in writing to any appealing pharmacy or an appealing pharmacy's agent not later than 30 calendar days after receipt of an appeal if the pharmacy filed the appeal more than ten (10) calendar days after the date the pharmacy's claim for reimbursement is adjudicated.

(g) If an appeal is denied, provide the appealing pharmacy or the appealing pharmacy's agent the national drug code number available for purchase in this state at or below the appealed maximum allowable cost.

(h) If an appeal is granted, permit the pharmacy to reverse and rebill the claim and all claims for the drug.

Pharmacy audit requirements (Mich. Stat. § 550.838)

Audit of Pharmacy by carrier or PBM; conduct and procedures; applicability

(1) Subject to this section, Prime may conduct an audit of a Pharmacy in this state. Prime shall do all of the following:

(a) In its pharmacy contract, identify and describe in detail the audit procedures, including the appeals process described in subdivision (m). A carrier or PBM shall update its pharmacy contract and communicate any changes to the Pharmacy as changes to the contract occur.

(b) Provide written notice to the Pharmacy at least two weeks before initiating and scheduling the initial on-site audit for each audit cycle. If the Pharmacy on average dispenses more than 600 prescriptions per week, a carrier or PBM shall not initiate or schedule an audit under this subsection during the first five business days of a month without the express consent of the Pharmacy. A carrier or PBM shall be flexible in initiating and scheduling an audit at a time that is reasonably convenient to the Pharmacy. Within three business days after the Pharmacy receives notice of an on-site audit, the Pharmacy may reschedule the audit to a date not more than ten (10) business days after the date proposed by the carrier or PBM.

(c) Utilize every effort to minimize inconvenience and disruption to pharmacy operations during the audit process. A carrier or PBM shall not interfere with the delivery of pharmacy services to a patient.

(d) Conduct an audit that involves clinical or professional judgment by or in consultation with a pharmacist.

(e) Subject to the requirements of article 15 of the public health code, 1978 PA 368, MCL 333.16101 to 333.18838, for the purpose of validating a pharmacy record with respect to orders, refills or changes in prescriptions, allow the use of either of the following:

(i) Hospital or physician records that are written or that are transmitted or stored electronically, including file annotations, document images and other supporting documentation that is date- and time-stamped.

(ii) A prescription that complies with the requirements of the Michigan Board of Pharmacy created under section 17721 of the public health code, 1978 PA 368, MCL 333.17721, and federal law.

(f) Base any finding of an overpayment or underpayment on the actual overpayment or underpayment of claims.

(g) Subject to subsection (4), base any recoupment or payment adjustments of claims on a calculation that is reasonable and proportional in relation to the type of error detected.

(h) If there is a finding of an underpayment, reimburse the Pharmacy as soon as possible after detection.

(i) Conduct its audit of the Pharmacy under the same standards and parameters that the carrier or PBM uses when auditing other similarly situated Pharmacies.

(j) Audit only claims submitted or adjudicated within the one-year period preceding the initiation of the audit unless a longer period is permitted under federal or state law.

(k) Not receive payment and not compensate the auditor based on the amount recovered.

(l) Not include the dispensing fee amount in a finding of an overpayment unless any of the following apply: (i) The prescription was not dispensed. As used in this subparagraph, "dispense" means that term as defined in section 17703 of the public health code, 1978 PA 368, MCL 333.17703.

(ii) The prescription was not delivered to the patient. As used in this subparagraph, "deliver" means that term as defined in section 17703 of the public health code, 1978 PA 368, MCL 333.17703.

(iii) The prescriber denied prior authorization.

(iv) The prescription was a medication error by the Pharmacy.

(v) The overpayment is solely based on an extra dispensing fee.

(m) Establish a written appeals process that includes a process to appeal preliminary audit reports and final audit reports prepared under this section. A Pharmacy has thirty (30) days after the Pharmacy receives the final audit report to file an appeal under this section.

(n) Not limit the days' supply for unit-of-use items, such as topicals, drops, vials and inhalants, beyond manufacturer recommendations.

(o) If the only commercially available package size exceeds the maximum days' supply, not use the dispensing of the package size as the basis for recoupment.

(p) If the only commercially available package size exceeds the maximum days' supply and the claim was affirmatively adjudicated, not recoup the claim as an early refill.

(q) In conducting an audit of wholesale invoices, all of the following:

(i) Not audit the claims of another carrier or PBM.

(ii) Within five business days after a request by the audited Pharmacy, provide supporting documentation provided to the carrier or PBM by the audited pharmacy's suppliers.

(iii) Not utilize any of the following as a basis for recoupment:

(A) The National Drug Code for the dispensed drug is in a quantity that is a subunit or multiple of the purchased drug as reflected on a supporting wholesale invoice.

(B) The correct quantity dispensed is reflected on the audited pharmacy claim.

(C) The drug dispensed by the Pharmacy on an audited pharmacy claim is identical to the labeler and product code section under the National Drug Code. A difference in the package code under the National Drug Code is not subject to recoupment.

(iv) Accept as evidence each of the following:

(A) Supplier invoices issued to the audited Pharmacy before the date of dispensing the drug underlying the audited claim.

(B) Invoices issued to the audited Pharmacy from any supplier permitted by law to transfer ownership of the drug acquired by the audited Pharmacy, subject to validation by the supplier.

(C) Copies of supplier invoices in the possession of the audited Pharmacy.

(2)(2) Upon completion of an audit of a Pharmacy, the carrier or PBM shall do all of the following:

(a) Deliver a preliminary written audit report to the Pharmacy not later than (60) days after the completion of the audit. The preliminary written audit report must include contact information for the person performing the audit and a description of the appeals process established under subsection (1)(m).

(b) Allow the Pharmacy at least thirty (30) days after its receipt of the preliminary written audit report under subdivision (a) to produce documentation to address any discrepancy found during the audit.

(c) If an appeal is not filed, deliver a final written audit report to the Pharmacy within ninety (90) days after the time described in subdivision (b) has elapsed. If an appeal is filed, deliver a final written audit report to the Pharmacy within ninety (90) days after the conclusion of the appeal.

(d) Except as otherwise provided in this section, recoup disputed money or overpayments or restore underpayments only after the final written audit report is delivered to the Pharmacy under subdivision (c).

(3) Except as required by federal law, a carrier or PBM shall not conduct an extrapolation audit in calculating recoupments, restoration or penalties for an audit under this section. For the purposes of this subsection, "extrapolation audit" means an audit of a sample of prescription drug benefit claims submitted by a Pharmacy to the carrier that is then used to estimate audit results for a larger batch or group of claims not reviewed during the audit.

(4) Any clerical or recordkeeping error, including a typographical error, a scrivener's error or a computer error, regarding a required document or record that is found during an audit does not, on its face, constitute fraud. An error does not subject the individual involved to criminal penalties without proof of intent to commit fraud. To the extent that an audit results in the identification of a clerical or recordkeeping error, including a typographical error, a scrivener's error or a computer error, in a required document or record, the Pharmacy is not subject to recoupment of money by Prime unless clerical error or recordkeeping error surpasses the statistical threshold established by the Centers for Medicare & Medicaid Services or the carrier can provide proof of intent to commit fraud or the error results in actual financial harm to the carrier, PBM, or a covered person or enrollee.

(5) The audit requirements provided above do not apply to any of the following:

(a) An audit conducted to investigate fraud, willful misrepresentation or abuse, including, but not limited to, investigative audits or audits conducted under any other statute that authorizes investigation relating to insurance fraud.

(b) An audit based on a criminal investigation.

(6) This section does not impair or supersede a provision regarding carrier pharmacy audits in the insurance code of 1956, 1956 PA 218, MCL 500.100 to 500.8302. If any provision of this section conflicts with a provision of the insurance code of 1956, 1956 PA 218, MCL 500.100 to 500.8302, with regard to carrier pharmacy audits, the provision in the insurance code of 1956, 1956 PA 218, MCL 500.100 to 500.8302, controls.

B-24 Minnesota Regulatory Addendum to Pharmacy Participation Agreement

This Minnesota Addendum applies to the extent that Pharmacy provides covered drugs to covered persons of a health plan company, health maintenance organization ("HMO"), or insurer licensed under Minnesota law (collectively and/or individually, "plan sponsor").

In the event of a direct conflict between this Addendum and the Agreement, the applicable provisions of this Addendum shall control if required. This Addendum may be modified from time to time pursuant to the Agreement.

Without limiting the generality of the foregoing, Pharmacy agrees as follows:

Pharmacy acknowledges and agrees that it has been given a complete copy of the Agreement, including all attachments and exhibits, operating manuals, guidelines and fee schedule. Minn. Stat. § 62Q.735, subdiv. 1.

In accordance with and to the extent required by Minn. Stat. § 62Q.739(a), in the event the Agreement contains only a unilateral indemnification provision for PBM, the following is added to the indemnification provision:

PBM shall indemnify and hold harmless Pharmacy and its employees, agents and representatives against loss, expense, liability or damage, including, without limitation, any and all claims, causes of action, judgments, awards, settlements, costs, fees or debts of whatever nature, including without limitation reasonable attorneys' fees and costs, arising out of or in connection with PBM's breach of this agreement.

The agreement may not be terminated or fail to be renewed by PBM without cause unless Pharmacy is given a written notice of the termination or nonrenewal 120 days before the effective date. Minn. Stat. § 62Q.739(b). If Pharmacy intends to terminate the Agreement without cause, Pharmacy must give PBM at least 120 days' advance written notice of its intent to terminate. Minn. Stat. § 62D.123, subdiv. 3.

Pharmacy agrees not to bill, charge, collect a deposit from, seek remuneration from or have any recourse against a covered person or persons acting on their behalf for services provided under the Agreement. This provision applies to but is not limited to the following events: (1) nonpayment by the plan sponsor, (2) insolvency of the plan sponsor, or (3) breach of the Agreement. This provision does not prohibit Pharmacy from collecting copays or fees for uncovered services.

This provision survives the termination of this agreement for authorized services provided before this agreement terminates, regardless of the reason for termination. This provision is for the benefit of covered persons. This provision does not apply to services provided after the Agreement terminates.

This provision supersedes any contrary oral or written agreement existing now or entered into in the future between the Pharmacy and the covered person or persons acting on their behalf regarding liability for payment for services provided under the Agreement.

Minn. Stat. § 62D.123, subdiv. 1; Minn. Stat. §. 62D.12, subdiv. 5.

Pharmacy must cooperate with and participate in the quality assurance programs, dispute resolution procedures and utilization review programs of PBM and plan sponsor. Minn. Stat. § 62D.123, subdiv. 2.

Pharmacy agrees to review claims subject to any limitations or requirements as set forth in the Agreement. Minn. Stat. § 62C.16, subdiv. 2.

If Pharmacy is subject to a tax under section Minn. Stat. § 295.52 or if Pharmacy has paid additional expense transferred under Minn. Stat. § 295.582 by a wholesale drug distributor, Pharmacy may transfer such additional expense generated by Minn. Stat. § 295.52 obligations on to plan sponsor through PBM for the purchase of health care services on behalf of an covered person, and plan sponsor (not PBM) shall be responsible for payments due to the extent agreed upon by plan sponsor and PBM and as required by law. Minn. Stat. § 295.582.

Nothing in the Agreement shall require Pharmacy to participate in a network under a category of coverage that differs from the categories of coverage to which the Agreement applies, without the affirmative consent of Pharmacy. Further, nothing in the Agreement shall be construed to require as a condition of participation, that Pharmacy participate in a new or different health plan, product, or other arrangement within a category of coverage specified in the Agreement that results in a different underlying financial reimbursement methodology without the affirmative consent of Pharmacy. For purposes of this paragraph, to the extent required by law, the procedure required for obtaining consent shall be as set forth in Minn. Stat. § 62Q.74.

Maximum Allowable Cost Pricing (Minn. Stat. § 62W.08)

(a) With respect to each contract and contract renewal between a PBM and a pharmacy, the PBM must:
   (1) provide to the pharmacy, at the beginning of each contract and contract renewal, the sources utilized to determine the maximum allowable cost pricing of the PBM;
   (2) update any maximum allowable cost price list at least every seven (7) business days, noting any price changes from the previous list, and provide a means by which network pharmacies may promptly review current prices in an electronic, print, or telephonic format within one (1) business day at no cost to the pharmacy;
   (3) maintain a procedure to eliminate products from the list of drugs subject to maximum allowable cost pricing in a timely manner in order to remain consistent with changes in the marketplace;
   (4) ensure that the maximum allowable cost prices are not set below sources utilized by the PBM; and
   (5) upon request of a network pharmacy, disclose the sources utilized for setting maximum allowable cost price rates on each maximum allowable cost price list included under the contract and identify each maximum allowable cost price list that applies to the network pharmacy. A PBM must make the list of the maximum allowable costs available to a contracted pharmacy in a format that is readily accessible and usable to the network pharmacy.

(b) A PBM must not place a prescription drug on a maximum allowable cost list unless the drug is available for purchase by pharmacies in this state from a national or regional drug wholesaler and is not obsolete.

(c) Each contract between a PBM and a pharmacy must include a process to appeal, investigate, and resolve disputes regarding maximum allowable cost pricing that includes:
   (1) a 15-business-day limit on the right to appeal following the initial claim;
   (2) a requirement that the appeal be investigated and resolved within seven (7) business days after the appeal is received; and
   (3) a requirement that a PBM provide a reason for any appeal denial and identify the national drug code of a drug that may be purchased by the pharmacy at a price at or below the maximum allowable cost price as determined by the PBM.

If an appeal is upheld, the PBM must make an adjustment to the maximum allowable cost price no later than one (1) business day after the date of determination. The PBM must make the price adjustment applicable to all similarly situated network pharmacy providers as defined by the plan sponsor.

Pharmacy audits (Minn. Stat. § 62W.09)

Subdivision 1. Procedure and process for conducting and reporting an audit.

(a) Unless otherwise prohibited by federal requirements or regulations, any entity conducting a pharmacy audit must follow the following procedures:

(1) A Pharmacy must be given notice 14 days before an initial on-site audit is conducted;

(2) An audit that involves clinical or professional judgment must be conducted by or in consultation with a licensed pharmacist; and

(3) Each Pharmacy shall be audited under the same standards and parameters as other similarly situated Pharmacies.

(b) Unless otherwise prohibited by federal requirements or regulations, for any entity conducting a Pharmacy audit the following items apply:

(1) The period covered by the audit may not exceed 24 months from the date that the claim was submitted to or adjudicated by the entity, unless a longer period is required under state or federal law;

(2) If an entity uses random sampling as a method for selecting a set of claims for examination, the sample size must be appropriate for a statistically reliable sample. Auditing entity shall provide the Pharmacy a masked list that provides a prescription number or date range that the auditing entity is seeking to audit;

(3) An on-site audit may not take place during the first five (5) business days of the month unless consented to by the Pharmacy;

(4) Auditors may not enter the Pharmacy area unless escorted where patient-specific information is available and to the extent possible must be out of sight and hearing range of the pharmacy customers;

(5) Any recoupment will not be deducted against future remittances until after the appeals process and both parties have received the results of the final audit;

(6) A PBM may not require information to be written on a prescription unless the information is required to be written on the prescription by state or federal law. Recoupment may be assessed for items not written on the prescription if:

(i) Additional information is required in the Provider Manual; or

(ii) The information is required by the Food and Drug Administration (FDA); or

(iii) The information is required by the drug manufacturer's product safety program; and

(iv) The information in item (i), (ii), or (iii) is not readily available for the auditor at the time of the audit; and

(7) The auditing company or agent may not receive payment based on a percentage of the amount recovered. This section does not prevent the entity conducting the audit from charging or assessing the responsible party, directly or indirectly, based on amounts recouped if both of the following conditions are met:

(i) The plan sponsor and the entity conducting the audit have a contract that explicitly states the percentage charge or assessment to the plan sponsor; and

(ii) A commission to an agent or employee of the entity conducting the audit is not based, directly or indirectly, on amounts recouped.

(c) An amendment to Pharmacy audit terms in a contract between a PBM and a Pharmacy must be disclosed to the Pharmacy at least sixty (60) days prior to the effective date of the proposed change.

Subd. 2. Requirement for recoupment or chargeback

For recoupment or chargeback, the following criteria apply:

(1) Audit parameters must consider consumer-oriented parameters based on manufacturer listings;

(2) A Pharmacy's usual and customary price for compounded medications is considered the reimbursable cost unless the pricing methodology is outlined in the pharmacy provider contract;

(3) A finding of overpayment or underpayment must be based on the actual overpayment or underpayment and not a projection based on the number of patients served having a similar diagnosis or on the number of similar orders or refills for similar drugs;

(4) The entity conducting the audit shall not use extrapolation in calculating the recoupment or penalties for audits unless required by state or federal law or regulations;

(5) Calculations of overpayments must not include dispensing fees unless a prescription was not actually dispensed, the prescriber denied authorization, the prescription dispensed was a medication error by the Pharmacy or the identified overpayment is solely based on an extra dispensing fee;

(6) An entity may not consider any clerical or recordkeeping error, such as a typographical error, scrivener's error or computer error regarding a required document or record as fraud; however, such errors may be subject to recoupment;

(7) In the case of errors that have no actual financial harm to the patient or plan, the PBM must not assess any chargebacks. Errors that are a result of the Pharmacy failing to comply with a formal corrective action plan may be subject to recovery; and

(8) Interest may not accrue during the audit period for either party, beginning with the notice of the audit and ending with the final audit report.

Subd. 3. Documentation

(a) To validate the pharmacy record and delivery, the Pharmacy may use authentic and verifiable statements or records including medication administration records of a nursing home, assisted living facility, hospital, physician or other authorized practitioner or additional audit documentation parameters located in the Provider Manual.

(b) Any legal prescription that meets the requirements in this chapter may be used to validate claims in connection with prescriptions, refills or changes in prescriptions, including medication administration records, faxes, ePrescriptions or documented telephone calls from the prescriber or the prescriber's agents.

Subd. 4. Appeals process

The entity conducting the audit must establish a written appeals process which must include appeals of preliminary reports and final reports.

Subd. 5. Audit information and reports

(a) A preliminary audit report must be delivered to the Pharmacy within 60 days after the conclusion of the audit.

(b) A Pharmacy must be allowed at least 45 days following receipt of the preliminary audit to provide documentation to address any discrepancy found in the audit.

(c) A final audit report must be delivered to the Pharmacy within 120 days after receipt of the preliminary audit report or final appeal, whichever is later.

(d) An entity shall remit any money due to a Pharmacy or pharmacist as a result of an underpayment of a claim within 45 days after the appeals process has been exhausted and the final audit report has been issued.

Subd. 6. Disclosure to plan sponsor

Where contractually required, an auditing entity must provide a copy to the plan sponsor of its claims that were included in the audit, and any recouped money shall be returned to the plan sponsor.

Subd. 7. Applicability of other laws and regulations

This section does not apply to any investigative audit that involves suspected fraud, willful misrepresentation, abuse or any audit completed by Minnesota health care programs.

B-25 Mississippi Regulatory Addendum to Pharmacy Participation Agreement

This Mississippi Addendum applies to the extent that Pharmacy provides covered drugs to covered persons of hospital and medical service associations, health maintenance organizations, managed care entities and insurers under Mississippi law (collectively and/or individually, "plan sponsor").

In the event of a direct conflict between this Addendum and the Agreement, the applicable provisions of this Addendum shall control if required. This Addendum may be modified from time to time pursuant to the Agreement.

Without limiting the generality of the foregoing, and notwithstanding anything in the Agreement to the contrary, Pharmacy agrees as follows:

To the extent that the timely claim payment provisions of the Agreement differ from, but are at least as stringent as, the provisions Miss. Code § 73-21-155(3), the provisions of the Agreement shall control. Miss. Code § 73-21-155(4)(d).

To the extent the Agreement allows for a no cause termination, each party shall provide the other party at least 60 days' written notice before termination without cause. Miss. Code § 83-41-325(17); 19 MS ADC Pt.3, R. 14.6(L).

Pharmacy agrees that in no event, including, but not limited to, nonpayment by the plan sponsor or PBM, insolvency of the plan sponsor or PBM or breach of this agreement, shall Pharmacy bill, charge, collect a deposit from, seek compensation, remuneration or reimbursement from or have any recourse against a covered person or a person (other than the plan sponsor or PBM) acting on behalf of the covered person for covered drugs provided pursuant to this agreement. This agreement does not prohibit Pharmacy from collecting coinsurance, deductibles, or copays, as specifically provided in the evidence of coverage, or fees for uncovered services delivered on a fee-for-service basis to covered persons. Nor does this agreement prohibit a Pharmacy (except for a health care professional who is employed full-time on the staff of a health carrier and has agreed to provide services exclusively to that health carrier's covered persons and no others) and a covered person from agreeing to continue services solely at the expense of the covered person, as long as the Pharmacy has clearly informed the covered person that the plan sponsor may not cover or continue to cover a specific service or services. Except as provided herein, this agreement does not prohibit Pharmacy from pursuing any available legal remedy. Miss. Code Ann. § 83- 41-325(13); 19 MS ADC Pt.3, R. 14.6(B).

In the event of a plan sponsor or PBM insolvency or cessation of operations, Pharmacy shall continue to provide covered drugs pursuant to the terms of the Agreement to covered persons following for the duration of the period for which premium payment has been made to plan sponsor and, for those covered persons confined on the date of insolvency, until the covered person's discharge from inpatient facilities, whichever is later. Miss. Code § 83-41-325(16); 19 MS ADC Pt.3, R. 14.6(C).

Sections 4 and 5 above shall be construed in favor of covered persons, shall survive termination of this agreement for any reason, and shall supersede any oral or written agreement to the contrary between Pharmacy and a covered person or the covered person's representative. 19 MS ADC Pt.3, R. 14.6(D)

Pharmacy shall make health records available to appropriate state and federal authorities involved in assessing the quality of care or investigating the grievances or complaints of covered persons and shall comply with applicable laws related to the confidentiality of medical or health records. 19 MS ADC Pt.3, R. 14.6(K)

The definitions and provisions contained in a Managed Care Plan as defined in Miss. Code § 83-41- 403(b) or 19 MS ADC Pt.3, R. 14.3, et. seq. control over and supersede any inconsistent definition, term or condition of this agreement. 19 MS ADC Pt.3, R. 14.6(T)

Plan sponsors have the right to approve or disapprove participation of any Pharmacy for the purpose of providing covered drugs to covered persons. 19 MS ADC Pt.3, R. 14.7(C)

In the event of PBM's insolvency, PBM may assign Pharmacy's obligations under section 5 above to plan sponsor. 19 MS ADC Pt.3, R. 14.7(H)

This agreement cannot be assigned by Pharmacy without the consent of PBM and plan sponsor. 19 MS ADC Pt.3, R. 14.6(M)

Payment and reimbursement methodologies are set forth in the Agreement (including attachments). 19 MS ADC Pt.3, R. 14.6(S)

Maximum allowable cost lists (MS ST § 73-21-156)

(3) A PBM shall:

(a) Provide access to its maximum allowable cost list to each pharmacy subject to the maximum allowable cost list;

(b) Update its maximum allowable cost list on a timely basis, but in no event longer than three (3) calendar days; and

(c) Provide a process for each pharmacy subject to the maximum allowable cost list to receive prompt notification of an update to the maximum allowable cost list.

(4) A PBM shall:

(a) Provide a reasonable administrative appeal procedure to allow pharmacies to challenge a maximum allowable cost list and reimbursements made under a maximum allowable cost list for a specific drug or drugs as:

(i) Not meeting the requirements of this section; or

(ii) Being below the pharmacy acquisition cost.

(b) The reasonable administrative appeal procedure shall include the following:

(i) A dedicated telephone number, email address and website for the purpose of submitting administrative appeals;

(ii) The ability to submit an administrative appeal directly to the PBM regarding the pharmacy benefit management plan or through a pharmacy service administrative organization; and

(iii) A period of less than thirty (30) business days to file an administrative appeal.

(c) The PBM shall respond to the challenge under paragraph (a) of this subsection (4) within thirty (30) business days after receipt of the challenge.

(d) If a challenge is made under paragraph (a) of this subsection (4), the PBM shall within thirty (30) business days after receipt of the challenge either:

(i) If the appeal is upheld:

1. Make the change in the maximum allowable cost list payment to at least the pharmacy acquisition cost;
2. Permit the challenging pharmacy or pharmacist to reverse and rebill the claim in question;
3. Provide the National Drug Code that the increase or change is based on to the pharmacy or pharmacist; and
4. Make the change under item 1 of this subparagraph (i) effective for each similarly situated pharmacy as defined by the payor subject to the maximum allowable cost list; or

(ii) If the appeal is denied, provide the challenging pharmacy or pharmacist the National Drug Code and the name of the national or regional pharmaceutical wholesalers operating in Mississippi that have the drug currently in stock at a price below the maximum allowable cost as listed on the maximum allowable cost list; or

(iii) If the National Drug Code provided by the PBM is not available below the pharmacy acquisition cost from the pharmaceutical wholesaler from whom the pharmacy or pharmacist purchases the majority of prescription drugs for resale, then the PBM shall adjust the maximum allowable cost as listed on the maximum allowable cost list above the challenging pharmacy's pharmacy acquisition cost and permit the pharmacy to reverse and rebill each claim affected by the inability to procure the drug at a cost that is equal to or less than the previously challenged maximum allowable cost.

Audit procedures; reports (Miss. Code § 73-21-183)

(1) The entity conducting an audit shall follow these procedures:

(a) The pharmacy contract must identify and describe in detail the audit procedures;

(b) The entity conducting the on-site audit must give the Pharmacy written notice at least two weeks before conducting the initial on-site audit for each audit cycle, and the Pharmacy shall have at least 14 days to respond to any desk audit requirements;

(c) The entity conducting the on-site or desk audit shall not interfere with the delivery of pharmacist services to a patient and shall utilize every effort to minimize inconvenience and disruption to pharmacy operations during the audit process;

(d) Any audit that involves clinical or professional judgment must be conducted by or in consultation with a pharmacist;

(e) Any clerical or recordkeeping error, such as a typographical error, scrivener's error or computer error, regarding a required document or record shall not constitute fraud; however, those claims may be subject to recoupment. No such claim shall be subject to criminal penalties without proof of intent to commit fraud;

(f) A Pharmacy may use the records of a hospital, physician or other authorized practitioner of the healing arts for drugs or medicinal supplies written or transmitted by any means of communication for purposes of validating the pharmacy record with respect to orders or refills of a legend or narcotic drug;

(g) A finding of an overpayment or an underpayment may be a projection based on the number of patients served having a similar diagnosis or on the number of similar orders or refills for similar drugs, except that recoupment shall be based on the actual overpayment or underpayment;

(h) A finding of an overpayment shall not include the dispensing fee amount unless a prescription was not dispensed;

(i) Each Pharmacy shall be audited under the same standards and parameters as other similarly situated Pharmacies audited by the entity;

(j) The period covered by an audit may not exceed two years from the date the claim was submitted to or adjudicated by a managed care company, nonprofit hospital or medical service organization, insurance company, third-party payer, PBM, a health program administered by a department of the state or any entity that represents those companies, groups or department;

(k) An audit may not be initiated or scheduled during the first five calendar days of any month due to the high volume of prescriptions filled in the Pharmacy during that time unless otherwise consented to by the Pharmacy;

(l) Any prescription that complies with state law and rule requirements may be used to validate claims in connection with prescriptions, refills or changes in prescriptions;

(m) An exit interview that provides a Pharmacy with an opportunity to respond to questions and comment on and clarify findings must be conducted at the end of an audit. The time of the interview must be agreed to by the Pharmacy;

(n) Unless superseded by state or federal law, auditors shall only have access to previous audit reports on a particular Pharmacy conducted by the auditing entity for the PBM, health plan or insurer. An auditing vendor contracting with multiple PBMs or health insurance plans shall not use audit reports or other information gained from an audit on a particular Pharmacy to conduct another audit for a different PBM or health insurance plan;

(o) The parameters of an audit must comply with consumer-oriented parameters based on manufacturer listings or recommendations for the following:

(i) The days' supply for eyedrops must be calculated so that the consumer pays only one 30-day copay if the bottle of eyedrops is intended by the manufacturer to be a 30-day supply;

(ii) The days' supply for insulin must be calculated so that the highest dose prescribed is used to determine the days' supply and consumer copay;

(iii) The days' supply for a topical product must be determined by the judgment of the pharmacist based upon the treated area;

(p)(i) Where an audit is for a specifically identified problem that has been disclosed to the Pharmacy, the audit shall be limited to claims that are identified by prescription number;

(ii) For an audit other than described in subparagraph (i) of this paragraph (p), an audit shall be limited to 100 individual prescriptions that have been randomly selected;

(iii) If an audit reveals the necessity for a review of additional claims, the audit shall be conducted on-site;

(iv) Except for audits initiated under paragraph (i) of this subsection, an entity shall not initiate an audit of a Pharmacy more than one time in any quarter;

(r) A recoupment shall not be based on:

(i) Documentation requirements in addition to or exceeding requirements for creating or maintaining documentation prescribed by the State Board of Pharmacy; or

(ii) A requirement that a Pharmacy or pharmacist perform a professional duty in addition to or exceeding professional duties prescribed by the State Board of Pharmacy;

(s) Except for Medicare claims, approval of drug, prescriber or patient eligibility upon adjudication of a claim shall not be reversed unless the Pharmacy or pharmacist obtained the adjudication by fraud or misrepresentation of claim elements; and

(t) A commission or other payment to an agent or employee of the entity conducting the audit is not based, directly or indirectly, on amounts recouped.

(2) Must provide the Pharmacy with a written report of the audit and comply with the following requirements:

(a) The preliminary audit report must be delivered to the Pharmacy within 120 days after conclusion of the audit, with a reasonable extension to be granted upon request;

(b) A Pharmacy shall be allowed at least 30 days following receipt of the preliminary audit report in which to produce documentation to address any discrepancy found during the audit, with a reasonable extension to be granted upon request;

(c) A final audit report shall be delivered to the Pharmacy within 180 days after receipt of the preliminary audit report or final appeal, as provided for in section 73-21-185, whichever is later;

(d) The audit report must be signed by the auditor;

(e) Recoupments of any disputed funds, or repayment of funds to the entity by the Pharmacy if permitted pursuant to contractual agreement, shall occur after final internal disposition of the audit, including the appeals process as set forth in section 73-21-185. If the identified discrepancy for an individual audit exceeds $25,000, future payments in excess of that amount to the Pharmacy may be withheld pending finalization of the audit;

(f) Interest shall not accrue during the audit period; and

(g) Each entity conducting an audit shall provide a copy of the final audit report, after completion of any review process, to the plan sponsor.

Appeal procedure; dismissal of report; mediation (Miss. Code § 73-21-185)

(1) Each entity conducting an audit shall establish a written appeals process under which a Pharmacy may appeal an unfavorable preliminary audit report to the entity.

(2) If, following the appeal, the entity finds that an unfavorable audit report or any portion thereof is unsubstantiated, the entity shall dismiss the audit report or that portion without the necessity of any further action.

(3) If, following the appeal, any of the issues raised in the appeal are not resolved to the satisfaction of either party, that party may ask for mediation of those unresolved issues. A certified mediator shall be chosen by agreement of the parties from the Court Annexed Mediators List maintained by the Mississippi Supreme Court.

Extrapolation audit; definition; prohibition (Miss. Code § 73-21-187)

Notwithstanding any other provision in sections 73-21-175 through 73-21-189, the entity conducting the audit shall not use the accounting practice of extrapolation in calculating recoupments or penalties for audits. An extrapolation audit means an audit of a sample of prescription drug benefit claims submitted by a Pharmacy to the entity conducting the audit that is then used to estimate audit results for a larger batch or group of claims not reviewed by the auditor.

Inapplicability of provisions to fraud, misrepresentation or abuse cases (Miss. Code § 73-21-189)

Sections 73-21-175 through 73-21-189 do not apply to any audit, review or investigation that involves alleged fraud, willful misrepresentation or abuse.

B-26 Missouri Regulatory Addendum to Pharmacy Participation Agreement

This Missouri Addendum applies to the extent that Pharmacy provides covered drugs to covered persons of a health maintenance organization, health plan, insurer or carrier licensed under Missouri law (collectively and/or individually, "plan sponsor").

In the event of a direct conflict between this Addendum and the Agreement, the applicable provisions of this Addendum shall control if required. This Addendum may be modified from time to time pursuant to the Agreement.

Without limiting the generality of the foregoing, Pharmacy agrees as follows:

Pharmacy is not prohibited or restricted from disclosing to any covered person any information that Pharmacy deems appropriate regarding the nature of treatment, risks or alternatives thereto, the availability of other therapy, consultation or test, the decision of any plan sponsor to authorize or deny services, or the process that the plan sponsor or any person contracting with the plan sponsor uses or proposes to use, to authorize or deny health care services or benefits. MO Stat. §§ 354.441, 354.559

Pharmacy agrees that in no event, including, but not limited to, nonpayment by plan sponsor or PBM, insolvency of plan sponsor or PBM, or breach of this agreement, shall the Pharmacy bill, charge, collect a deposit from, seek compensation, remuneration or reimbursement from, or have any recourse against a covered person or a person, other than the plan sponsor or PBM, acting on behalf of the covered person, for covered drugs provided pursuant to this agreement. This agreement shall not prohibit the Pharmacy from collecting coinsurance, deductibles or copays, as specifically provided in the evidence of coverage, or fees for services that are not covered drugs delivered on a fee-for-service basis to covered person. This agreement shall not prohibit a provider, except for a health care professional who is employed full time on the staff of plan sponsor and has agreed to provide services exclusively to plan sponsor's covered persons and no others, and a covered person from agreeing to continue services solely at the expense of the covered person, as long as the provider has clearly informed the covered person that the plan sponsor may not cover or continue to cover a specific service or services. Except as provided herein, this agreement does not prohibit the Pharmacy from pursuing any available legal remedy, including, but not limited to, collecting from any insurance carrier providing coverage to a covered person. MO Stat. § 354.606(2).

Either party can exercise right of nonrenewal at the expiration of contract period or upon 60 days' notice. Nonrenewal does not constitute termination. MO Stat. § 354.609(3)

In the event of plan sponsor's or PBM's insolvency or other cessation of operations, covered drugs to covered persons shall continue to be provided by Pharmacy through the period for which a premium has been paid to the plan sponsor on behalf of the covered person or until the covered person's discharge from an inpatient facility, whichever time is greater. MO Stat. § 354.606(3)

Paragraphs 2 and 4 above shall: (1) be construed in favor of the covered persons; (2) survive the termination of this agreement regardless of the reasons for termination, including the insolvency of plan sponsor, PBM or plan sponsor's intermediary; (3) supersede any oral or written contrary agreement between Pharmacy and covered person or the representative of covered person if the contrary agreement is inconsistent with the hold harmless and continuation of covered drug provisions required by paragraphs 2 and 4 above; and (4) be binding upon all individuals with whom a Pharmacy may subcontract to provide services to covered persons. MO Stat. § 354.606(4)

In no event shall Pharmacy collect or attempt to collect from a covered person any money owed to the Pharmacy by plan sponsor or PBM nor shall Pharmacy collect or attempt to collect from a covered person any money in excess of the coinsurance, copay or deductibles. MO Stat. § 354.606.5.(5)

Pharmacy must make health records available to appropriate state and federal authorities involved in assessing the quality of care (but shall not disclose individual identities), or investigating the grievances or complaints of covered persons, and to comply with the applicable state and federal laws related to the confidentiality of medical or health records. MO Stat. § 354.606(12). Pharmacy shall furnish records that PBM, or plan sponsor may require in order to document and/or demonstrate that Pharmacy is capable of meeting the terms of the Agreement. MO Stat. § 354.603(1)(3).

The rights and responsibilities of Pharmacy under this agreement shall not be assigned or delegated by Pharmacy without the prior written consent of PBM or plan sponsor, as applicable. MO Stat. § 354.606(13). Plan sponsor shall have the right, in the event of PBM's insolvency, to require the assignment to plan sponsor of the provisions of this agreement addressing the Pharmacy's obligation to furnish covered drugs. MO Stat. § 354.621(6).

Pharmacy must furnish covered drugs to all covered persons without regard to the covered person's enrollment in a plan as a private purchaser of the plan or as a participant in a publicly financed program of health care services. MO Stat. § 354.606(14).

Pharmacy must collect applicable coinsurance, copays or deductibles from covered persons and must notify covered persons of their personal financial obligations for services that are not covered. MO Stat. § 354.606(15).

At least 60 days written notice must be provided to the other party before terminating this agreement without cause. This written notice shall include an explanation of why the Agreement is being terminated. Within 15 working days of the date that the Pharmacy either gives or receives notice of termination, the Pharmacy shall supply PBM and plan sponsor with a list of those patients of the Pharmacy that are covered by a benefit plan of the plan sponsor. MO Stat. § 354.609(1).

To the extent required by law, PBM shall not terminate the Agreement unless it gives Pharmacy a written explanation of the reason(s) for the proposed termination and an opportunity for review or hearing, except in the case of imminent harm to patients, determination of fraud or final disciplinary action by a licensing board or other governmental agency. The notice to Pharmacy shall include (i) reasons for the proposed action, (ii) statement of the right to request a hearing or review before a panel appointed by PBM, (iii) a time limit of not less than 30 days within which to request a hearing or review, and (iv) a time limit for a hearing date which shall be held within 30 days of receipt of the request for a hearing. The hearing panel shall comply with the requirements set forth in MO Stat. § 354.609(2)(3)-(6).

Upon termination of this agreement, Pharmacy must continue care to covered persons for a period of up to 90 days where the continuation of care is medically necessary and in accordance with the dictates of medical prudence, including circumstances such as disability, pregnancy or life-threatening illness. In such circumstances, covered person shall not be liable to Pharmacy for any amounts owed for medical care other than deductibles or copay amounts specified in the certificate of coverage or other contract between the covered person and plan sponsor as set forth in paragraph 2 above. In the event the terminated Pharmacy is authorized to continue treating covered person pursuant to this paragraph, Pharmacy shall have the right to be paid at the previously contracted rate for services provided to the covered person as required by MO Stat. § 354.612(1).

Unless such other time is specified in the Agreement, Pharmacy may file claims for reimbursement for covered drugs provided in Missouri for a period of up to six months from the date of service. MO Stat. § 376.384(1)(2). In the event of a conflict between the requirements of MO Stat. § 376.383 and MO Stat. § 376.384 and the provisions of the Agreement, the requirements of MO Stat. § 376.383 and MO Stat. § 376.384 shall control. MO ST 376.383; MO Stat. § 376.384.

To the extent Pharmacy provides covered drug services to covered persons of a discount medical plan under Missouri law, Pharmacy agrees that the scope of services shall be as set forth in the Agreement, that Pharmacy will adhere to the fee schedule in the Agreement, and that Pharmacy will not charge covered persons more than the discounted rates provided for by the Agreement. MO Stat. § 376.1514.

Appendix B: Regulatory addendums (continued)

Pharmacy will be notified on an ongoing basis of specific covered drugs via the POS system. MO Stat. § 354.606(1).

PBM shall notify Pharmacy in accordance with the applicable terms and conditions set forth in the Agreement of Pharmacy's responsibilities with respect to PBM's and plan sponsors' applicable administrative policies and programs, including, but not limited to, payment terms, utilization review, quality assessment and improvement programs, credentialing, grievance procedures, data reporting requirements, confidentiality requirements and any applicable federal or state programs. MO Stat. § 354.606(8)

The parties acknowledge and agree that the Agreement does not require the use of hospitalists as a condition for Pharmacy participation under this agreement. MO Stat. § 354.606(9)

Nothing in the Agreement shall be construed to induce Pharmacy to provide less than medically necessary services to a covered person. MO Stat. § 354.606(10)

Nothing herein prohibits Pharmacy from advocating on behalf of covered persons within the utilization review or grievance processes established by PBM or the plan sponsor. MO Stat. § 354.606(11)

PBM will not penalize Pharmacy because provider reports in good faith to state or federal authorities any act or practice by PBM or plan sponsor that may jeopardize patient health or welfare. MO Stat. § 354.606(16)

Pharmacy can determine in a timely manner whether a person is covered as set forth in the Agreement (e.g., POS system). MO Stat. § 354.606(17)

Resolution of administrative, payment or other disputes between PBM and Pharmacy shall be handled in accordance with the dispute resolution provisions set forth in the Agreement (to the extent not inconsistent with the provisions of MO Stat. § 354.600-354.636). MO Stat. § 354.606(19)

To the extent that any definitions or provisions of the Agreement conflict with definitions or provisions contained in benefit plans or in sections 354.600 to 354.636 of the Revised Statutes of Missouri, the conflicting definitions and/or provisions of the Agreement shall not control. MO Stat. § 354.606(20).

PBM will not terminate the Agreement solely or in part because Pharmacy in good faith: (i) advocates on behalf of a covered person; (ii) files a complaint against PBM or plan sponsor; (iii) appeals a decision of PBM or plan sponsor; (iv) provides information or files a report with the Department of Insurance, financial institutions and professional registration; or (v) requests a hearing or review pursuant to MO Stat. § 354.609. MO Stat. § 354.609(5)

Notwithstanding anything to the contrary, to the extent required by law, Pharmacy shall have at least 30 days to review a managed care contract. MO Stat. § 354.609(6)

Notwithstanding legitimate and medically based referral patterns, neither party shall act in a manner that unreasonably restricts a covered person's access to the entire network, unless the HMO plan sponsor has a written agreement with the holder of the benefits contract (not this agreement) to a reduced network, and has requested an exception for a reduced network per 20 CSR 400-7.095 and filed an access plan for the reduced network prior to selling a new product per MO Stat. § 354.603(2). MO Stat. § 354.603(1)(4)

Nothing in this Agreement shall be construed to conflict with a covered person's right to sue someone under MO Stat. § 538.205 et al.

Nothing in this Agreement shall be construed to conflict with Missouri's Coordination of Benefits regulation or Missouri case law that prohibits subrogation from liable third parties in connection with fully insured contracts. 20 CSR 400-2.030.

PBM and Pharmacy shall comply with Missouri Statute, sections 354.600 to 354.636. MO Stat. § 354.621(1)

PBM will transmit utilization documentation and claims paid data to the HMO plan sponsor to the extent required by MO Stat. § 354.621(3).

PBM will maintain the documents hereunder to the extent required by MO ST 354.621(4) for at least five years. MO Stat. § 354.612(4). HMO and DIFP plan sponsors will have access to all documents that relate to compliance with Missouri Statute, Sections 354-600 to 354.636 in accordance with MO Stat. § 354.621(5).

Maximum allowable costs--definitions--contract requirements--reimbursement--appeals process required (MO ST 376.388)

3. A PBM shall reimburse pharmacies for drugs subject to maximum allowable cost pricing that has been updated to reflect market pricing at least every seven (7) days as set forth under subdivision (1) of subsection 2 of this section.
4. A PBM shall not place a drug on a maximum allowable cost list unless there are at least two (2) therapeutically equivalent multisource generic drugs, or at least one (1) generic drug available from at least one manufacturer, generally available for purchase by network pharmacies from national or regional wholesalers.
5. All contracts between a PBM and a contracted pharmacy or between a PBM and a pharmacy's contracting representative or agent, such as a pharmacy services administrative organization, shall include a process to internally appeal, investigate, and resolve disputes regarding maximum allowable cost pricing. The process shall include the following:

(1) The right to appeal shall be limited to fourteen (14) calendar days following the reimbursement of the initial claim; and

(2) A requirement that the PBM shall respond to an appeal described in this subsection no later than fourteen (14) calendar days after the date the appeal was received by such PBM.

6. For appeals that are denied, the PBM shall provide the reason for the denial and identify the national drug code of a drug product that may be purchased by contracted pharmacies at a price at or below the maximum allowable cost and, when applicable, may be substituted lawfully.
7. If the appeal is successful, the PBM shall:

(1) Adjust the maximum allowable cost price that is the subject of the appeal effective on the day after the date the appeal is decided;

(2) Apply the adjusted maximum allowable cost price to all similarly situated pharmacies as determined by the PBM; and

(3) Allow the pharmacy that succeeded in the appeal to reverse and rebill the pharmacy benefits claim giving rise to the appeal.

8. Appeals shall be upheld if:

(1) The pharmacy being reimbursed for the drug subject to the maximum allowable cost pricing in question was not reimbursed as required under subsection 3 of this section; or

(2) The drug subject to the maximum allowable cost pricing in question does not meet the requirements set forth under subsection 4 of this section.

Criteria for audit-appeals process to be established-report to be provided-applicability exceptions (MO Stat. § 338.600)

1. Notwithstanding any other provision of law to the contrary, when an audit of the records of a Pharmacy licensed in this state is conducted by a managed care company, insurance company, third- party payer or any entity that represents such companies or groups, such audit shall be conducted in accordance with the following:

(1) The entity conducting the initial on-site audit shall provide the Pharmacy with notice at least one week prior to conducting the initial on-site audit for each audit cycle;

(2) Any audit which involves clinical judgment shall be conducted by or in consultation with a licensed pharmacist;

(3) Any clerical error, recordkeeping error, typographical error or scrivener's error regarding a required document or record shall not constitute fraud or grounds for recoupment, so long as the prescription was otherwise legally dispensed and the claim was otherwise materially correct; except that, such claims may be otherwise subject to recoupment of overpayments or payment of any discovered underpayment. No claim arising under this subdivision shall be subject to criminal penalties without proof of intent to commit fraud;

(4) A Pharmacy may use the records of a hospital, physician or other authorized practitioner of the healing arts involving drugs or medicinal supplies written or transmitted by any means of communication for purposes of validating the pharmacy record with respect to orders or refills of a legend or narcotic drug. Electronically stored images of prescriptions, electronically created annotations and other related supporting documentation shall be considered valid prescription records. Hard copy and electronic signature logs that indicate the delivery of pharmacy services shall be considered valid proof of receipt of such services by a program enrollee;

(5) A finding of an overpayment or underpayment may be a projection based on the number of patients served and having a similar diagnosis or on the number of similar orders or refills for similar drugs; except that, recoupment of claims shall be based on the actual overpayment or underpayment unless the projection for overpayment or underpayment is part of a settlement as agreed to by the Pharmacy;

(6) Each Pharmacy shall be audited under the same standards and parameters as other Pharmacies audited by the entity;

(7) A Pharmacy shall be allowed at least 30 days following receipt of the preliminary audit report in which to produce documentation to address any discrepancy found during an audit;

(8) The period covered by the audit shall not exceed a two-year period beginning two years prior to the initial date of the on-site portion of the audit unless otherwise provided by contractual agreement or if there has been a previous finding of fraud or as otherwise provided by state or federal law;

(9) An audit shall not be initiated or scheduled during the first three business days of any month due to the high volume of prescriptions filled during such time unless otherwise consented to by the Pharmacy;

(10) The preliminary audit report shall be delivered to the Pharmacy within 120 days after conclusion of the audit, with reasonable extensions permitted. A final audit report shall be delivered to the Pharmacy within six months of receipt by the Pharmacy of the preliminary audit report or final appeal, as provided for in subsection 3 of this section, whichever is later;

(11) Notwithstanding any other provision in this subsection, the entity conducting the audit shall not use the accounting practice of extrapolation in calculating recoupments or penalties for audits, except as otherwise authorized under subdivision (5) of this subsection.

2. Recoupments of any disputed moneys shall only occur after final internal disposition of the audit, including the appeals process set forth in subsection 3 of this section. Should the identified discrepancy for an individual audit exceed $25,000, future payments to the Pharmacy in excess of $25,000 may be withheld pending finalization of the audit.

3. Each entity conducting an audit shall establish an appeals process, lasting no longer than six months, under which a licensed Pharmacy may appeal an unfavorable preliminary audit report to the entity. If, following such appeal, Prime finds that an unfavorable audit report or any portion thereof is unsubstantiated, the entity shall dismiss the audit report or such portion without the necessity of any further proceedings.

4. Each entity conducting an audit shall provide a copy of the final audit report, after completion of any appeal process, to the plan sponsor.

Appendix B: Regulatory addendums (continued)

5. This section shall not apply to any investigative audit that involves probable fraud, willful misrepresentation or abuse.
6. This section shall not apply to any audit conducted as part of any inspection or investigation conducted by any governmental entity or law enforcement agency.

B-27 Montana Regulatory Addendum to Pharmacy Participation Agreement

This Montana Addendum applies to the extent that Pharmacy provides covered drugs to covered persons of health maintenance organizations, managed care community networks, multiple employer welfare arrangements, insurers or carriers under Montana law (collectively and/or individually, "plan sponsor").

In the event of a direct conflict between this Addendum and the Agreement, the applicable provisions of this Addendum shall control if required. This Addendum may be modified from time to time pursuant to the Agreement.

Without limiting the generality of the foregoing, and notwithstanding anything in the Agreement to the contrary, Pharmacy agrees as follows:

To the extent Pharmacy provides covered drugs to covered persons of a heath carrier offering a managed care plan under Montana law, Pharmacy agrees:

That Pharmacy may not for any reason, including, but not limited to, nonpayment by plan sponsor or PBM, insolvency of plan sponsor or PBM, or breach of this agreement, bill, charge, collect a deposit, seek compensation, remuneration, or reimbursement, or have any recourse from or against a covered person or a person other than plan sponsor or PBM acting on behalf of the covered person for covered drugs provided pursuant to this agreement. This agreement does not prohibit Pharmacy from collecting coinsurance, copays, or deductibles, as specifically provided in the evidence of coverage, or fees for uncovered services delivered on a fee-for-service basis to covered persons. This agreement does not prohibit Pharmacy, except a health care professional who is employed full-time on the staff of a plan sponsor and who has agreed to provide services exclusively to that plan sponsor's covered persons and no others, and a covered person from agreeing to continue services solely at the expense of the covered person if Pharmacy has clearly informed the covered person that plan sponsor may not cover or continue to cover a specific service or services. Except as provided in this agreement, this agreement does not prohibit Pharmacy from pursuing any legal remedy available for obtaining payment for services from plan sponsor. Mont. Code § 33-36-202(1).

If PBM or plan sponsor becomes insolvent or otherwise ceases operations, covered drugs to covered persons will continue through the end of the period for which a premium has been paid to plan sponsor on behalf of the covered person, but not to exceed 30 days, or until the covered person's discharge from an acute care inpatient facility, whichever occurs last. Covered drugs to a covered person confined in an acute care inpatient facility on the date of insolvency or other cessation of operations must be continued by Pharmacy until the confinement in an inpatient facility is no longer medically necessary. Mont. Code § 33-36-202(2).

The provisions of the paragraphs above must be construed in favor of the covered person, survive the termination of this agreement regardless of the reason for termination, including the insolvency ofPBM or plan sponsor, and supersede an oral or written contrary agreement between Pharmacy and an covered person or the representative of an covered person if the contrary agreement is inconsistent with the hold harmless and continuation of covered benefits provisions required by the paragraphs above. Mont. Code § 33-36-202(3).

To the extent permitted by law, PBM and Pharmacy shall provide at least 60 days written notice to each other before terminating the Agreement without cause. Mont. Code § 33-36-204(5).

Pharmacy has responsibilities and obligations under administrative policies and programs of PBM and plan sponsor as set forth in the Agreement, including payment terms, utilization reviews, the quality assurance program, credentialing, grievance procedures, data reporting requirements, confidentiality requirements and compliance with applicable federal and state laws. Mont. Code § 33-36-204(1), (12).

Pharmacy shall make its health records available to appropriate state and federal authorities, in accordance with applicable state and federal laws related to confidentiality of medical or health records, when such authorities are involved in assessing the quality of care or investigating a grievance or complaint of a covered person. Mont. Code § 33-36-204(4).

Pharmacy shall furnish covered drugs to covered persons without regard to the covered person's enrollment in the benefit plan as a private purchaser or as a participant in a publicly financed program of health services. This paragraph does not apply to circumstances in which Pharmacy should not render services because of Pharmacy's lack of training, experience or skill or because of a restriction on Pharmacy's license. Mont. Code § 33-36-204(6).

Pharmacy shall be required to collect applicable coinsurance, copays or deductibles from covered persons as set forth in the Agreement. Mont. Code § 33-36-204(7).

To the extent any of the definitions or provisions contained in the Agreement conflict with definitions or provisions of benefit plans or with title 33, chapter 36, part 2, Mont. Code Ann., the definitions, and provisions of the Agreement shall not control. Mont. Code § 33-36-204(11).

Maximum allowable cost or reference price list — price formulation, updating, and disclosure — exceptions (MT ST 33-22-172)

(1) At the time of entering into a contract with a pharmacy or a pharmacy services administrative organization and subsequently upon request, a plan sponsor, health insurance issuer, or PBM shall provide the pharmacy or pharmacy services administrative organization with the sources used to determine the pricing for the maximum allowable cost list or the reference used for reference pricing.

(2) If using a maximum allowable cost list, a plan sponsor, health insurance issuer, or PBM shall:

(a) review and update the price information for each drug on the maximum allowable cost list at least once every ten (10) calendar days to reflect any modification of pricing, ensuring that maximum allowable cost increases are processed and updated on the same schedule as decreases;

(b) establish a process for eliminating products from the maximum allowable cost list or modifying the prices in the maximum allowable cost list in a timely manner to remain consistent with pricing changes and product availability in the marketplace; and

(c) provide a process for each pharmacy to readily access the maximum allowable cost list specific to the pharmacy in a searchable and usable format.

(3) If using reference pricing, a plan sponsor, health insurance issuer, or PBM shall:

(a) review and update not less than every ten (10) business days the price information for each drug, product, supply, or service for which reference pricing is used, updating reference pricing on the same date of the change in the referenced source; and

(b) provide a process for each pharmacy to readily access the reference pricing specific to the plan sponsor or the health insurance issuer's plan.

Maximum allowable cost appeals process (MT ST 33-22-173)

(1) In contracting with a pharmacy or a pharmacy services administrative organization, a plan sponsor or PBM shall:

(a) provide a procedure by which a pharmacy or a pharmacy services administrative organization may appeal the price of a drug or drugs on the maximum allowable cost list;

(b) provide a telephone number at which a network pharmacy may contact the PBM to discuss the status of the pharmacy's appeal; and

(c) respond to an appeal no later than 10 calendar days after the date the appeal is made.

(2) If the final determination is a denial of the pharmacy's or the pharmacy services administrative organization's appeal, the PBM shall state the reason for the denial and provide the national drug code of an equivalent drug that is available for purchase by pharmacies in this state from national or regional wholesalers at a price that is equal to or less than the maximum allowable cost for that drug.

(3) If a pharmacy's or a pharmacy services administrative organization's appeal is determined to be valid by the PBM, the PBM shall:

(a) make an adjustment in the drug price effective on the date the appeal is resolved;

(b) make the adjustment applicable to all similarly situated network pharmacy providers as determined by the plan sponsor or the PBM, as appropriate; and

(c) permit the appealing pharmacy to reverse and rebill the claim in question, using the dates of the original claim or claims.

(4) A PBM shall make price adjustments to all similarly situated pharmacies within three (3) days.

(5) A pharmacy or a pharmacy services administrative organization shall file its appeal within ten (10) calendar days from the time of denial by the PBM.

Applicability - Audits (Mont. Code § 33-2-2003)

(1) Except as provided in subsection (2), this part applies to an audit of the records of a pharmacy licensed under title 37, chapter 7.

(2) This part does not apply to an audit of pharmacy records when fraud or other intentional and willful misrepresentation is evidenced by the review of claims data, statements, physical review or other investigative methods.

Audit of pharmacy records (Mont. Code § 33-2-2004)

(1) An entity conducting an audit of pharmacy records shall audit a Pharmacy using the same standards and parameters as used by Prime in auditing other Pharmacies on behalf of the same audit client.

(2) An audit that involves clinical or professional judgment must be conducted by or in consultation with a licensed pharmacist who is employed by or working with the entity conducting the audit.

(3) If an audit is conducted onsite at a pharmacy, the entity conducting the audit:

(a) Shall give the Pharmacy ten 10 days' advance written notice of the audit, along with the range of prescription numbers or a date range that will be included in the audit; and

(b) May not audit the Pharmacy during the first five business days of the month unless the Pharmacy agrees to the timing of the audit.

(4) An entity may not audit prescription records that exceed 275 selected prescriptions. The period covered by the audit may not exceed 24 months from the date that the prescription was submitted to or adjudicated by the entity unless a longer period is required under state or federal law.

(5) Except as required by state or federal law, the entity conducting an audit may have access to a Pharmacy's previous audit report only if the previous report was prepared by Prime.

(6) To validate a pharmacy record, a Pharmacy may use documented statements of records in the Pharmacy or pharmacy system, including medication administration records of a nursing home, assisted living facility, hospital, physician, surgeon or other prescriber authorized by the laws of this state.

(7) If an audit results in the dispute or denial of a claim, the entity conducting the audit shall allow the Pharmacy to produce additional claims documentation using any commercially reasonable method, including fax, mail or email.

Prohibitions — recoupment — payment — interest (Mont. Code § 33-2-2005)

An entity conducting an audit may not:

(1) Include dispensing fees unless a prescription was not actually dispensed, the prescriber denied authorization, the prescription dispensed was a dispensing error by the Pharmacy, or the identified overpayment is based solely on an extra dispensing fee;

(2) Recoup funds for prescription clerical or recordkeeping errors, including typographical errors, scrivener's errors and computer errors, in a required document or record unless the error results in actual financial harm to the entity or to a consumer;

(3) Collect any funds, chargebacks or penalties until the audit and all appeals are final unless the entity is alleging fraud or other intentional or willful misrepresentation that is evidenced by the review of claims data, statements, physical review or other investigative methods;

(4) Use extrapolation or other statistical expansion techniques in calculating the amount of any recoupment or penalty;

(5) Pay the agent or employee who conducted the audit based on a percentage of the amount recovered; or

(6) Charge interest during the audit period.

On-site audits — preliminary and final reports — appeals (Mont. Code § 33-2-2006)

For audits conducted on-site, the following provisions apply:

(1) An entity that audits a Pharmacy shall provide the Pharmacy with a preliminary audit report, delivered to the Pharmacy or its corporate office of record within sixty (60) days after completion of the audit.

(2) A Pharmacy has thirty (30) days following receipt of the preliminary audit report to respond to questions, provide additional documentation and comment on and clarify findings of the audit. The date of receipt of the report must be determined by the postmark date or the date of the electronic transmission if transferred electronically.

(3) If an audit results in the dispute or denial of a claim, the entity conducting the audit shall allow the Pharmacy, for thirty (30) days following receipt of the preliminary audit report, to produce additional claims documentation using any commercially reasonable method, including fax, mail or email.

(4)(a) Within 120 days after the completion of the appeals process under subsection (5), a final audit report must be delivered to the Pharmacy or its corporate office of record.

(b) The final audit report must include a disclosure of any money recovered by the entity that conducted the audit.

(5) An entity that audits a Pharmacy shall establish a written policy for a Pharmacy to appeal a final audit report. If no remedies are specified by contract or in the pharmacy services manual, the Pharmacy may seek to resolve the dispute through mediation.

B-28 Nebraska Regulatory Addendum to Pharmacy Participation Agreement

This Nebraska Addendum applies to the extent that Pharmacy provides covered drugs to covered persons of hospital service corporations, health maintenance organizations, preferred provider organizations, prepaid limited health service organizations, managed care organizations, insurers or carriers under Nebraska law (collectively and/or individually, "plan sponsor").

In the event of a direct conflict between this Addendum and the Agreement, the applicable provisions of this Addendum shall control if required. This Addendum may be modified from time to time pursuant to the Agreement.

Without limiting the generality of the foregoing, and notwithstanding anything in the Agreement to the contrary, Pharmacy agrees as follows:

To the extent Pharmacy provides covered drugs to covered persons of a health maintenance organization under Nebraska law, Pharmacy agrees:

If PBM or plan sponsor fails to pay for covered drugs as set forth in the Agreement, covered persons shall not be liable to Pharmacy for any sums owed to Pharmacy by PBM or plan sponsor. Pharmacy and its agent, trustee or assignee may not maintain an action at law or attempt to collect from a covered person sums owed to Pharmacy by PBM or plan sponsor. Neb. Stat. § 44-32,141.

If Pharmacy terminates this agreement, Pharmacy must provide PBM with at least 60 days' notice of termination. Neb. Stat. § 44-32,142.

In the event of insolvency of plan sponsor or PBM, Pharmacy shall continue to provide covered drugs to covered persons for the remainder of the period for which premiums have been paid on their behalf or until the covered person's discharge from an inpatient facility, whichever is longer. Neb. Stat. § 44-32,143.

To the extent Pharmacy provides covered drugs to covered persons of a prepaid limited health service organization under Nebraska law, Pharmacy agrees:

If PBM or plan sponsor fails to pay for covered drugs as set forth in the Agreement for any reason whatsoever, including, but not limited to, insolvency or breach of contract, covered persons shall not be liable to Pharmacy for any sums owed to Pharmacy under this agreement. Neb. Stat. § 44-4717(1).

Pharmacy and its agent, trustee or assignee may not maintain an action at law or attempt to collect from covered persons sums owed to Pharmacy by PBM or plan sponsor. Neb. Stat. § 44-4717(2).

Paragraphs 2(a) and (b) shall not prohibit Pharmacy from collecting copays from covered persons. Neb. Stat. § 44-4717(3).

The provisions in paragraphs 2(a), (b) and (c) shall survive the termination of the Agreement, regardless of the reason giving rise to the termination. Neb. Stat. § 44-4717(4).

Termination of the Agreement shall not release Pharmacy from the obligations and duties imposed by the Agreement to complete treatments in progress on covered persons for specific conditions for a period not to exceed 30 days at the same schedule of copay or other applicable charges in effect upon the effective date of termination of the Agreement. Neb. Stat. § 44-4717(5).

Any amendment to the provisions of the Agreement shall be submitted to and be approved by the director of the Nebraska Department of Insurance prior to becoming effective. Neb. Stat. § 44-4717(6).

To the extent Pharmacy provides covered drugs to covered persons of a managed care plan under Nebraska law, Pharmacy agrees:

Pharmacy agrees that in no event, including, but not limited to, nonpayment by PBM or plan sponsor, insolvency of the plan sponsor or PBM, or breach of this agreement, shall Pharmacy bill, charge, collect a deposit from, seek compensation, remuneration, or reimbursement from or have any recourse against covered persons or a person, other than the plan sponsor or PBM, acting on behalf of the covered person for covered drugs provided pursuant to this agreement. This agreement does not prohibit Pharmacy from collecting coinsurance, deductibles or copays, as specifically provided in the evidence of coverage, or fees for uncovered health care services delivered on a fee-for-service basis to covered persons. Nor does this agreement prohibit Pharmacy, except for a health care professional who is employed full time on the staff of plan sponsor and has agreed to provide covered drugs exclusively to plan sponsor's covered persons and no others, and a covered person from agreeing to continue covered drugs solely at the expense of the covered person, as long as Pharmacy has clearly informed the covered person that plan sponsor may not cover or continue to cover a specific health care service or health care services. Except as provided herein, this agreement does not prohibit Pharmacy from pursuing any available legal remedy. Neb. Stat. § 44-7106(2)(b).

If plan sponsor offers a closed plan or combination plan having a closed component and a participating provider, in the event of the insolvency, or other cessation of operations, of the plan sponsor or PBM, covered drugs to covered persons will continue through the period for which a premium has been paid on behalf of the covered person or until the covered person's discharge from an inpatient facility, whichever time is greater. Covered drugs to covered persons confined in an inpatient facility on the date of insolvency or other cessation of operations will continue until their continued confinement in an inpatient facility is no longer medically necessary. Neb. Stat. § 44-7106(2)(c).

The provisions set forth in the preceding paragraphs above shall be construed in favor of the covered person, shall survive the termination of the Agreement regardless of the reason for termination, including the insolvency of the plan sponsor or PBM, and shall supersede any oral or written contrary agreement between Pharmacy and a covered person or the representative of a covered person if the contrary agreement is inconsistent with the preceding paragraphs above. Neb. Stat. § 44-7106(2)(d).

Pharmacy shall make its health records available to state and federal authorities involved in assessing the quality of care or investigating grievances or complaints of covered persons and shall comply with applicable state and federal laws related to the confidentiality of medical or health records. Neb. Stat. § 44-7106(2)(j).

Pharmacy shall not delegate or assign the rights and responsibilities under the Agreement without PBM's prior written consent. Neb. Stat. § 44-7106(2)(l).

In the event there is a contradiction between the provisions and definitions in the Agreement and plan sponsor's managed care plan, the provisions and definitions in the managed care plan will govern. Neb. Stat. § 44-7106(2)(r).

Plan sponsor has the right to disapprove Pharmacy's participation in its benefit plans. Neb. Stat. § 44- 7107(2)(c).

In the event of PBM's insolvency, plan sponsor has the right to require the assignment to it of the provisions of the Agreement addressing Pharmacy's obligation to furnish covered drugs. Nev. Stat. § 44- 1707(2)(h).

To the extent Pharmacy provides covered drugs to covered persons of a discount medical plan organization under Nebraska law, Pharmacy agrees:

The agreement contains a list of the medical or ancillary services and products that Pharmacy has agreed to provide at a discount;

The agreement states the amount of the discounts or, alternatively, a fee schedule that reflects Pharmacy's discounted rates; and

Pharmacy will not charge covered persons more than the discounted rates set forth in the Agreement. Neb. Stat. § 44-8309.

Effective Jan. 1, 2023, without limiting the generality of the foregoing, and notwithstanding anything in the Agreement to the contrary, Pharmacy and PBM agree as follows:

The agreement shall not prohibit or restrict Pharmacy or any pharmacist from, or penalize Pharmacy or pharmacist for, disclosing to any covered person any health care information that Pharmacy or pharmacist deems appropriate regarding:

The nature of treatment, risks or an alternative to such treatment;

The availability of an alternate therapy, consultation, or test;

The decision of a utilization reviewer or similar person to authorize or deny a service;

The process that is used to authorize or deny a health care service or benefit; or

Information on any financial incentive or structure used by the health carrier.

PBM shall not prohibit Pharmacy or a pharmacist from discussing information regarding the total cost for a pharmacist service for a prescription drug or from selling a more affordable alternative to the covered person if a more affordable alternative is available.

PBM shall not prohibit, restrict or limit disclosure of information to the director of the Insurance Department, law enforcement, or a state or federal governmental official, provided that: (a) The recipient of the information represents that such recipient has the authority, to the extent provided by state or federal law, to maintain proprietary information as confidential; and (b) Prior to disclosure of information designated as confidential, the pharmacist or Pharmacy marks as confidential any document in which the information appears, or requests confidential treatment for any oral communication of the information.

PBM shall not terminate the contract with or penalize a pharmacist or Pharmacy due to the pharmacist or Pharmacy: (a) Disclosing information about a PBM practice, except information determined to be a trade secret, as determined by state law or the director; or (b) sharing any portion of the Agreement with the Director pursuant to a complaint or a query regarding whether the Agreement is in compliance with the Pharmacy Benefit Manager Licensure and Regulation Act.

A PBM shall not require a covered person purchasing a covered prescription drug to pay an amount greater than the lesser of the covered person's cost sharing amount under the terms of the health benefit plan or the amount the covered person would pay for the drug if the covered person were paying the cash price. Any such amount paid by a covered person shall be attributable toward any deductible or, to the extent consistent with section 2707 of the federal Public Health Service Act, 42 U.S.C. 300gg-6, as such section existed on Jan. 1, 2022, the annual out-of-pocket maximum under the covered person's health benefit plan. Neb. Stat. § 44-4606.

Contract; pharmacy benefit manager; cost price list; duties; disputes; procedures (NE ST § 44-4608)

(1) With respect to each contract and contract renewal between a PBM and a pharmacy, the PBM shall:

(a) Update any maximum allowable cost price list at least every seven (7) business days, noting any price change from the previous list, and provide a means by which a network pharmacy may promptly review a current price in an electronic, print, or telephonic format within one (1) business day of any such change at no cost to the pharmacy;

(b) Maintain a procedure to eliminate a product from the maximum allowable cost price list in a timely manner to remain consistent with any change in the marketplace; and

(c) Make the maximum allowable cost price list available to each contracted pharmacy in a format that is readily accessible and usable to the contracted pharmacy.

(2) A PBM shall not place a prescription drug on a maximum allowable cost price list unless the drug is available for purchase by pharmacies in this state from a national or regional drug wholesaler and is not obsolete.

(3) Each contract between a PBM and a pharmacy shall include a process to appeal, investigate, and resolve disputes regarding any maximum allowable cost price. The process shall include:

(a) A fifteen-business-day limit on the right to appeal following submission of an initial claim by a pharmacy;

(b) A requirement that any appeal be investigated and resolved within seven (7) business days after the appeal is received by the PBM; and

(c) A requirement that the PBM provide a reason for any denial of an appeal and identify the national drug code for the drug that may be purchased by the pharmacy at a price at or below the price on the maximum allowable cost price list as determined by the PBM.

(4) If an appeal is determined to be valid by the PBM, the PBM shall:

(a) Make an adjustment in the drug price no later than one day after the appeal is resolved; and

(b) Permit the appealing pharmacy to reverse and rebill the claim in question, using the date of the original claim.

Pharmacy benefit manager; 340B entity; 340B contract pharmacy; treatment; discrimination, prohibited (NE ST § 44-4609)

(1) A PBM that reimburses a 340B entity or a 340B contract pharmacy for a drug that is subject to an agreement under 42 U.S.C. 256b shall not reimburse the 340B entity or the 340B contract pharmacy for the pharmacy-dispensed drug at a rate lower than that paid for the same drug to similarly situated pharmacies that are not 340B entities or 340B contract pharmacies, and shall not assess any fee, chargeback, or other adjustment upon the 340B entity or 340B contract pharmacy on the basis that the 340B entity or 340B contract pharmacy participates in the program set forth in 42 U.S.C. 256b.

(2) A PBM shall not discriminate against a 340B entity or 340B contract pharmacy in a manner that prevents or interferes with a covered individual's choice to receive such drug from the corresponding 340B entity or 340B contract pharmacy.

(3) For purposes of this section:

(a) 340B contract pharmacy means any pharmacy under contract with a 340B entity to dispense drugs on behalf of such 340B entity; and

(b) 340B entity means an entity participating in the federal 340B drug discount program, as described in 42 U.S.C. 256b.

Network pharmacy or network pharmacist; decline to provide a drug; when; duties; effect (NE ST § 44-4615)

(1) A network pharmacy or network pharmacist may decline to provide a drug if the pharmacy or pharmacist will be or is paid less than the acquisition cost for the drug.

(2) If a network pharmacy or network pharmacist declines to provide a drug as authorized in subsection (1) of this section, the pharmacy or pharmacist shall provide the covered person with adequate information as to where the prescription for the drug may be filled or shall refer the covered person to his or her plan sponsor.

Retail pharmacy; contract; ancillary delivery services; prohibitions; disclosures (NE ST § 44-4616)

(1) A contract between a retail pharmacy and a PBM or plan sponsor shall not prohibit the retail pharmacy from offering the following as an ancillary service of the retail pharmacy:

(a) The delivery of a prescription drug by mail or common carrier to a covered person or his or her personal representative on request of the covered person or personal representative if the request is made before the drug is delivered; or

(b) The delivery of a prescription to a covered person or his or her personal representative by an employee or contractor of the retail pharmacy.

Pharmacy audit; auditing entity; requirements; recoupment; terms and conditions; documentation requirements; appeal process; audit reports (Neb. Stat. § 44-4607)

(1) Unless otherwise prohibited by federal law, an auditing entity conducting a Pharmacy audit shall:

(a) Give any Pharmacy notice fifteen (15) business days prior to conducting an initial on-site audit;

(b) For any audit that involves clinical or professional judgment, conduct such audit by or in consultation with a pharmacist; and

(c) Audit each Pharmacy under the same standards and parameters as other similarly situated Pharmacies.

(2) Unless otherwise prohibited by federal law, for any pharmacy audit conducted by an auditing entity:

(a) The period covered by the audit shall not exceed 24 months from the date that the claim was submitted to the auditing entity, unless a longer period is required under state or federal law;

(b) If an auditing entity uses random sampling as a method for selecting a set of claims for examination, the sample size shall be appropriate for a statistically reliable sample;

(c) An auditing entity shall provide the Pharmacy a masked list containing any prescription number or date range that the auditing entity is seeking to audit;

(d) No onsite audit shall take place during the first five business days of the month without the consent of the Pharmacy;

(e) No auditor shall enter the area of any Pharmacy where patient-specific information is available without being escorted by an employee of the Pharmacy and, to the extent possible, each auditor shall remain out of the sight and hearing range of any pharmacy customer;

(f) No recoupment shall be deducted from or applied against a future remittance until after the appeal process is complete and both parties receive the results of the final audit;

(g) No pharmacy benefit manager shall require information to be written on a prescription unless such information is required to be written on the prescription by state or federal law;

(h) Recoupment may be assessed for information not written on a prescription if:

(i)(A) Such information is required in the Provider Manual; or

(B) The information is required by the federal Food and Drug Administration or the drug manufacturer's product safety program; and

(ii) The information required under subdivision (i)(A) or (B) of this subdivision (h) is not readily available for the auditing entity at the time of the audit; and

(i) No auditing entity or agent shall receive payment based on a percentage of any recoupment.

(3) For recoupment under the Pharmacy Benefit Manager Licensure and Regulation Act, the auditing entity shall:

(a) Include consumer-oriented parameters based on manufacturer listings in the audit parameters;

(b) Consider the Pharmacy's usual and customary price for a compounded medication as the reimbursable cost, unless the pricing method is outlined in the pharmacy provider contract;

(c) Base a finding of overpayment or underpayment on the actual overpayment or underpayment and not a projection that relies on the number of patients served who have a similar diagnosis, the number of similar orders or the number of refills for similar drugs;

(d) Not use extrapolation to calculate the recoupment or penalties unless required by state or federal law;

(e) Not include a dispensing fee in the calculation of an overpayment, unless a prescription was not actually dispensed, the prescriber denied authorization, the prescription dispensed was a medication error by the Pharmacy or the identified overpayment is solely based on an extra dispensing fee;

(f) Not consider as fraud any clerical or record-keeping error, such as a typographical error, scrivener's error or computer error regarding a required document or record. Such error may be subject to recoupment;

(g) Not assess any recoupment in the case of an error that has no actual financial harm to the covered person or health benefit plan. An error that is the result of the Pharmacy failing to comply with a formal corrective action plan may be subject to recoupment; and

(h) Not allow interest to accrue during the audit period for either party, beginning with the notice of the audit and ending with the final audit report.

(4)(a) To validate a pharmacy record and the delivery of a pharmacy service, the Pharmacy may use an authentic and verifiable statement or record, including a medication administration record of a nursing home, assisted-living facility, hospital, physician or other authorized practitioner or an additional audit documentation parameter located in the Provider Manual.

(b) Any legal prescription that meets the requirements in this section may be used to validate a claim in connection with a prescription, refill or change in a prescription, including a medication administration record, fax, e-prescription or documented telephone call from the prescriber to the prescriber's agent.

(5) The auditing entity conducting the audit shall establish a written appeal process which shall include procedures for appealing both a preliminary audit report and a final audit report.

(6)(a) A preliminary audit report shall be delivered to the Pharmacy within 120 days after the conclusion of the audit.

(b) A Pharmacy shall be allowed at least 30 days following receipt of a preliminary audit report to provide documentation to address any discrepancy found in the audit.

(c) A final audit report shall be delivered to the Pharmacy within 120 days after receipt of the preliminary audit report or the appeal process has been exhausted, whichever is later.

(d) An auditing entity shall remit any money due to a Pharmacy or pharmacist as the result of an underpayment of a claim within 45 days after the appeal process has been exhausted and the final audit report has been issued.

(7) Where contractually required, an auditing entity shall provide a copy to the plan sponsor of any of the plan sponsor's claims that were included in the audit, and any recouped money shall be returned to the health benefit plan or plan sponsor.

(8) This section does not apply to any investigative audit that involves suspected fraud, willful misrepresentation or abuse, or any audit completed by a state-funded health care program.

B-29 Nevada Regulatory Addendum to Pharmacy Participation Agreement

This Nevada Addendum applies to the extent that Pharmacy provides covered drugs to covered persons of insurers, carriers, health maintenance organizations, prepaid limited health service organizations or managed care organizations under Nevada law (collectively and/or individually, "plan sponsor").

In the event of a direct conflict between this Addendum and the Agreement, the applicable provisions of this Addendum shall control if required. This Addendum may be modified from time to time pursuant to the Agreement.

Without limiting the generality of the foregoing, and notwithstanding anything in the Agreement to the contrary, Pharmacy agrees as follows:

If the Agreement is terminated by PBM or plan sponsor for reasons other than medical incompetence or professional misconduct of Pharmacy, Pharmacy agrees to continue to provide services to covered persons who are undergoing a medically necessary course of treatment until the later of the 120th day after the Agreement is terminated or, with respect to covered persons who are pregnant, until 45 days after delivery or the date the pregnancy otherwise ends. During this continuation period, Pharmacy agrees to accept the reimbursement rates and terms of participation in effect under the Agreement before it terminated. Pharmacy further agrees not to seek payment from covered persons for any service provided by Pharmacy during this continuation period that Pharmacy could not have received from the covered persons if the Agreement were still in effect. .Nev. Stat. §§ 689A.04036; 689B.0303; 695C.1691; 695G.164.

PBM shall approve or deny a claim for services within 30 days after it receives the claim. If the claim is approved, plan sponsor or PBM shall pay the claim within 30 days after it is approved. If PBM requires additional information to determine whether to approve or deny the claim, it shall notify Pharmacy of its request for additional information with 20 days after it receives the claim. PBM shall notify Pharmacy of all specific reasons for any delay in approving or denying the claim. PBM shall approve or deny the claim within 30 days after receiving the additional information requested. If the claim is approved, plan sponsor or PBM shall pay the claim within 30 days after it receives the additional information. PBM shall not ask Pharmacy to resubmit information that Pharmacy has already provided, unless PBM provides a legitimate reason for the request and the purpose of the request is not to delay payment of the claim, harass Pharmacy or discourage the filing of clams. Plan sponsor or PBM shall not pay only part of a claim that has been approved and is fully payable. If any approved claim is not paid as set forth in this provision, plan sponsor shall pay interest on the claim at a rate of interest equal to the prime rate at the largest bank in Nevada, as ascertained by the Commissioner of Financial Institutions, on Jan. 1 or July 1, as the case may be, immediately preceding the date on which the payment was due, plus 6%. The interest shall be calculated from 30 days after the date on which the claim is approved until the date on which the claim is paid. Nev. Stat. §§ 695C.185; 695C.187 (See also Nev. Stat. §§ 689A.410; 689B.255; 689C.335; 695A.188; 695B.2505).

If plan sponsor or PBM fails to pay a claim within the time period set forth in the Agreement for an covered person of a plan sponsor contracted to provide managed care to recipients of Medicaid under the Nevada state plan or contracted to provide insurance pursuant to the Children's Health Insurance Program, plan sponsor shall pay Pharmacy interest at a rate equal to the prime rate at the largest bank in Nevada, as ascertained by the commissioner of financial institutions, on Jan. 1 or July 1, as the case may be, immediately preceding the date on which the payment was due, plus 6%. The interest shall be calculated from 30 days after the date on which the claim is approved until the date on which the claim is paid. Nev. Stat. § 695C.128.

Pharmacy releases covered persons from liability for the cost of covered drugs rendered pursuant to the Agreement. If plan sponsor or PBM fails to pay for covered drugs for any reason, including, but not limited to, insolvency or breach of the Agreement, covered persons shall not be liable to Pharmacy for any money owed to Pharmacy pursuant to the Agreement. Neither Pharmacy nor its agent, trustee, nor assignee may maintain an action at law or attempt to collect from a covered person any money that plan sponsor or PBM owes to Pharmacy. This provision does not prohibit the collection of any uncovered charges which a covered person agreed to pay or the collection of any copay from a covered person.

This provision survives termination of the Agreement, regardless of the reason for termination. Nev. Stat. § 695F.220(1)-(4); Nev. Admin. Code §§ 695C.190(2); 695C.530(2); 695F.300(2).

Termination of the Agreement shall not release Pharmacy from its obligation to complete any procedure on a covered person who is receiving treatment for a specific condition for a period not to exceed 60 days, at the same schedule of copay or any other applicable charge in effect when the Agreement is terminated. Nev. Stat. § 695F.220(5).

Any amendment to the Agreement must be submitted to the Nevada Commissioner of Insurance for approval before the amendment is effective. Nev. Stat. § 695F.220(6).

Any party wishing to terminate this Agreement must give the other party at least 90 days' advance written notice. Nev. Admin. Code § 689B.160.

The Agreement shall be effective for at least one year, subject to any right of termination stated in the Agreement and this Regulatory Addendum. Nev. Admin. Code §§ 695C.190(3); 695C.530(5); 695F.300(3).

Pharmacy shall participate in any quality assurance program adopted by plan sponsor or PBM. Nev. Admin. Code §§ 695C.190(4); 695C.530(3); 695F.300(4).

Pharmacy shall provide all medically necessary covered drugs to each covered person for the period for which a premium has been paid to plan sponsor. Nev. Admin. Code §§ 695C.190(5); 695C.530(4); 695F.300(5).

Pharmacy must provide proof of insurance against loss resulting from injuries to third parties from Pharmacy's practice of Pharmacy or a reasonable substitute for it as determined by PBM or plan sponsor. Pharmacy shall indemnity PBM and plan sponsor for any liability resulting from the health care services rendered by Pharmacy. Nev. Admin. Code §§ 695C.190(6); 695C.530(6); 695F.300(6).

Pharmacy agrees that PBM may assign the Agreement to plan sponsor. Nev. Admin. Code § 695C.505(12).

Pharmacy shall transfer or arrange for the maintenance of the records of covered persons who are its patients if the Pharmacy terminates its contract with PBM. Nev. Admin. Code §§ 695C.530(7); 695F.300(7).

B-30 New Hampshire Regulatory Addendum to Pharmacy Participation Agreement

This New Hampshire Addendum applies to the extent that Pharmacy provides covered drugs to covered persons of an accident or health insurer, health service corporation, health maintenance organization and organizations entering into preferred provider agreements under New Hampshire law (collectively and/or individually, "plan sponsor").

In the event of a direct conflict between this Addendum and the Agreement, the applicable provisions of this Addendum shall control if required. This Addendum may be modified from time to time pursuant to the Agreement.

Without limiting the generality of the foregoing, and notwithstanding anything in the Agreement to the contrary, Pharmacy agrees as follows:

In no event, including, but not limited to, nonpayment by plan sponsor or PBM insolvency of plan sponsor or PBM or breach of the Agreement, shall Pharmacy bill, charge, collect a deposit from, seek payment or reimbursement from or have recourse against a covered person or a person acting on behalf of a covered person (other than plan sponsor or PBM) for covered drugs provided pursuant to the Agreement. This provision does not prohibit Pharmacy from collecting coinsurance, deductibles, or copays, as specifically provided in the evidence of coverage, or fees for noncovered services delivered on a fee-for-service basis to covered persons. Nor does this provision prohibit Pharmacy and a covered person from agreeing to continue services solely at the expense of the covered person, as long as Pharmacy has clearly informed the covered person that plan sponsor may not cover or continue to cover a specific service or services. Except as otherwise provided in the Agreement, this provision does not prohibit Pharmacy from pursuing any available legal remedy. Pharmacy agrees that this provision shall survive termination of the Agreement regardless of the cause giving rise to termination and shall be construed to be for the benefit of covered persons. This provision supersedes any oral or written contrary agreement now existing or hereafter entered into between Pharmacy and covered persons or persons acting on their behalf. Any modifications, additions or deletions to this provision shall become effective on a date no earlier than 15 business days after the New Hampshire insurance commissioner has received written notice of such proposed changes. N.H. Stat. § 420-J:8(I).

The Agreement shall not be construed to limit information Pharmacy may disclose to patients or to prospective patients regarding the provisions, terms or requirements of plan sponsor's products as they relate to the needs of Pharmacy's patients except for trade secrets of significant competitive value. N.H. Stat. §§ 420-C:5-a, 420-J:8(V).

Pharmacy shall have 60 days from the postmarked date to review any proposed contract with PBM and any modifications to the Agreement, excluding those modifications that are expressly permitted under the Agreement. N.H. Stat. § 420-J:8(VII).

PBM shall give Pharmacy notice of material changes to the applicable reimbursement at least 60 days in advance of the effective date. N.H. Stat. § 420-J:8(VIII)(d).

Neither PBM nor plan sponsor shall remove Pharmacy from the Network or refuse to renew Pharmacy's enrollment in the network due to Pharmacy's participation in a covered person's internal grievance procedure or external review. N.H. Stat. § 420-J:8(X).

In the event the Agreement is terminated for a reason other than unprofessional behavior by Pharmacy, Pharmacy agrees to continue to provide covered drugs to covered persons for 60 days from the date of termination. Pharmacy agrees to provide covered drugs during this period in accordance with the terms and conditions imposed by the Agreement and agrees to accept as full payment the reimbursement amount that would have applied had the Agreement not terminated. N.H. Stat. § 420-J:8(XI).

In no event shall Pharmacy charge a covered person more than the lower of the Pharmacy's usual and Customary Charge or the covered person's contracted copay. N.H. Stat. §§ 318:47-h(I); 420-J:7-b(X)(a).

Provider Contract Standards for Pharmacy Benefit Managers (NH ST § 402-N:3)

(a) The sources used by the PBM to calculate the drug product reimbursement paid for covered drugs available under the pharmacy health benefit plan administered by the carrier or PBM.

(b) A process to appeal, investigate, and resolve disputes regarding the maximum allowable cost pricing. The process shall include the following provisions:

(1) A provision granting the contracted pharmacy or pharmacist at least thirty (30) business days following the initial claim to file an appeal;

(2) A provision requiring the carrier or PBM to investigate and resolve the appeal within thirty (30) business days;

(3) A provision requiring that, if the appeal is denied, the carrier or pharmacy benefit manager shall:

(A) Provide the reason for the denial; and

(B) Identify the national drug code of a drug product that may be purchased by contracted pharmacies at a price at or below the maximum allowable cost; and

(4) A provision requiring that, if an appeal is granted, the carrier or PBM shall within thirty (30) business days after granting the appeal:

(A) Make the change in the maximum allowable cost; and

(B) Permit the challenging pharmacy or pharmacist to reverse and rebill the claim in question.

II. For every drug for which the PBM establishes a maximum allowable cost to determine the drug product reimbursement, the PBM shall:

(a) Include in the contract with the pharmacy information identifying the national drug pricing compendia or sources used to obtain the drug price data.

(b) Make available to a contracted pharmacy the actual maximum allowable cost for each drug.

(c) Review and make necessary adjustments to the maximum allowable cost for every drug for which the price has changed at least every fourteen (14) days.

Pharmacy rights during audit (N.H. Stat. § 318:62)

Notwithstanding any other provision of law, whenever a managed care company, insurance company, third-party payer or any entity that represents a responsible party conducts an audit of the records of a Pharmacy, the Pharmacy has a right to all of the following:

I. To have at least seven days' advance notice of the initial on-site audit for each audit cycle. A Pharmacy that requests an additional seven days prior to the commencement of an audit shall be granted seven additional days.

II. To have any audit that involves clinical judgment be done with a pharmacist who is licensed and is employed or working under contract with the auditing entity.

III. Not to have clerical or recordkeeping errors, including typographical errors, scrivener's errors and computer errors, on a required document or record, in the absence of any other evidence deemed fraudulent. This subdivision does not prohibit recoupment of fraudulent payments.

IV. If required under the terms of the contract, to have the auditing entity provide a Pharmacy, upon request, all records related to the audit in an electronic format or contained in digital media.

V. To have the properly documented records of a hospital or any person authorized to prescribe controlled substances for the purpose of providing medical or pharmaceutical care for their patients transmitted by any means of communication in order to validate a pharmacy record with respect to a prescription or refill for a controlled substance or narcotic drug, in compliance with state laws.

Appendix B: Regulatory addendums (continued)

VI. If an on-site audit is conducted for a reason other than an identified problem, the audit shall be limited to no more than 250 selected prescriptions and the third-party plan or audit company must provide a masked list of prescriptions to the Pharmacy to assist in preparation. The list is considered masked if the last two numbers of the prescription are marked with an "X." This procedure allows the Pharmacy to pull the book the audited prescription is in, however, it does not allow the Pharmacy to pull the specific prescription audited. Additionally, all of the invoices for actual dispensed prescriptions, with prices redacted, may be obtained from the Pharmacy's wholesaler or distributor upon approval from the Pharmacy.

VI-a. To have the same number of days to respond to a claim in an audit that have passed since the origination of the claim.

VII. To be subject to no more than two audits in one calendar year, unless fraud or misrepresentation is reasonably suspected.

VIII. Except for cases of Food and Drug Administration regulation or drug manufacturer safety programs, to be free of recoupments based on any of the following unless defined within the billing requirements set forth in the Pharmacy Provider Manual:

(a) Documentation requirements in addition to or exceeding requirements for creating or maintaining documentation prescribed by the Pharmacy Board or by the Manual or contract.

(b) A requirement that a Pharmacy or pharmacist perform a professional duty in addition to or exceeding professional duties prescribed by the board.

IX. To be audited under the same standards and parameters as other similarly situated Pharmacies audited by the same entity.

X. To have the period covered by an audit limited to six months from the date a claim was submitted to, or adjudicated by, a managed care company, an insurance company, a third-party payer or any entity that represents responsible parties, unless a longer period is permitted by a federal plan under federal law.

XI. Not to be subject to the initiation or scheduling of audits during the first five calendar days of any month for any Pharmacy that averages in excess of 600 prescriptions per week due to the high volume of prescriptions filled during that time and for patient care considerations, without the express consent of the Pharmacy. The Pharmacy shall cooperate with the auditor to establish an alternate date should the audit fall within the days excluded.

XII. Not to have the accounting practice of extrapolation used in calculating recoupments or penalties for audits, unless otherwise required by federal requirements or federal plans.

XIII. The auditor shall not include dispensing fees in the calculations of overpayments unless the prescription is considered a misfill. A misfill shall be defined as a prescription not dispensed, a medication error, a prescription whereby the prescriber denied authorization or where an extra dispensing fee was charged.

XIV. (a) Auditors shall only have access to previous audit reports on a particular Pharmacy if the previous audit was conducted by the same entity, except as required for compliance with state or federal law.

(b) Additionally, Pharmacies subject to an audit may use the following records at the time of the audit to validate a claim for a prescription, refill or change in a prescription:

(1) Electronic or physical copies of records of a health care facility or a health care provider with prescribing authority.

(2) Any prescription that complies with state law.

Mandatory appeals process. (N.H. Stat. § 318:63)

I. Each entity that conducts an audit of a Pharmacy shall establish an appeals process under which a Pharmacy may appeal within 30 days after they report an unfavorable audit report to Prime.

II. If, following the appeal, the entity finds that an unfavorable audit report or any portion of the unfavorable audit report is unsubstantiated, the entity shall dismiss the unsubstantiated portion of the audit report without any further proceedings unless outlined in the contract.

III. Each entity conducting an audit shall provide a copy, if required under contractual terms, of the audit findings to the plan sponsor after completion of any appeals process.

IV. If any portion of an unfavorable audit report is not dismissed within 30 days after an appeal is made under paragraph I, the Pharmacy may request a hearing from the insurance department pursuant to RSA 400-A:17.

Pharmacy audit recoupments. (N.H. Stat. § 318:64)

I. Recoupments of any disputed funds shall occur only after final internal disposition of an audit, including the appeals process, unless fraud or misrepresentation is reasonably suspected or the discrepant amount exceeds $10,000.

II. Recoupment on an audit shall be refunded to the responsible party as contractually agreed upon by the parties.

III. The entity conducting the audit shall not charge or assess the responsible party, directly or indirectly, based on amounts recouped.

Audit information and reports. (N.H. Stat. § 318:65)

An audit report shall be delivered to the Pharmacy within 75 days, unless otherwise agreed to, after the conclusion of the audit. A Pharmacy shall be allowed at least 30 days, unless otherwise agreed to, following receipt of the audit report to appeal any discrepancy found in the audit. A final audit report shall be delivered to the Pharmacy within 90 days, unless otherwise agreed to, after receipt of the appeal. A chargeback, recoupment or other penalty may not be assessed until the appeal process has been exhausted and the final report issued except as specified in RSA 318:64. Except as provided by state or federal law or contract, audit information may not be shared. Auditors may have access only to previous audit reports on a particular Pharmacy conducted by the same entity.

Applicability. (N.H. Stat. § 318:66)

This subdivision shall not apply to any audit, review or investigation that is based on suspected or alleged fraud, willful misrepresentation or abuse. Nothing in this subdivision shall apply to claims that were paid for in part or in whole by Medicare or Medicaid Program funds.

B-31 New Jersey Regulatory Addendum to Pharmacy Participation Agreement

This New Jersey Addendum applies to the extent that Pharmacy provides covered drugs to covered persons of insurers, carriers and health maintenance organizations ("HMOs") under New Jersey law (collectively and/or individually, "plan sponsor").

In the event of a direct conflict between this Addendum and the Agreement, the applicable provisions of this Addendum shall control if required. This Addendum may be modified from time to time pursuant to the Agreement.

Without limiting the generality of the foregoing, and notwithstanding anything in the Agreement to the contrary, Pharmacy agrees as follows:

Nothing in the Agreement shall be construed to prohibit, directly or indirectly, Pharmacy from charging covered persons for services rendered by Pharmacy that are in addition to charges for the drug, for dispensing the drug, for prescription counseling, and those services required by law, provided that the services rendered shall be subject to the approval of the Board of Pharmacy and provided that Pharmacy disclose to covered persons the charges for the additional services and their out-of-pocket costs for those services before dispensing the drug. N.J. Stat. §§ 17:48-6j(a)(6); 17:48A-7i(a)(6); 17:48E-35.7(a)(6); 17B:26-2.1i(a)(6); 17B:27-46.1i(a)(6); 26:2J-4.7(a)(6).

Neither PBM nor plan sponsor shall terminate the Agreement or penalize Pharmacy solely because Pharmacy filed a complaint or an appeal as permitted by New Jersey law. N.J.A.C. §§ 11:24-15.2(b)(2); 11:24A-4.15(b)(2); 11:24B-5.2(a)(15).

Neither PBM nor plan sponsor shall penalize Pharmacy or terminate the Agreement because Pharmacy acts as an advocate for a covered person in seeking appropriate, medically necessary health care services. N.J. Stat. § 26:2S-9(a); N.J.A.C. §§ 11:24-15.2(b)(3); 11:24A-4.15(b)(3); 11:24B-5.2(a)(15).

Pharmacy agrees that in the event that PBM or plan sponsor fails to pay for covered drugs for any reason whatsoever, including, but not limited to, insolvency of PBM or plan sponsor, or breach of contract, covered persons shall not be liable to Pharmacy for any sums owed Pharmacy under the Agreement.

Pharmacy shall hold covered persons harmless for the cost of covered drugs, whether or not Pharmacy believes its compensation for the covered drugs is made in accordance with the reimbursement provision of the Agreement or is otherwise inadequate. Pharmacy shall not balance bill covered persons who have obtained covered drugs through the network in accordance with the benefit plan. Pharmacy shall not bill, charge or collect a deposit from, seek compensation, remuneration or reimbursement from, or have any recourse against a covered person or a person (other than PBM or plan sponsor) acting on behalf of a covered person for covered drugs provided pursuant to the Agreement. Neither Pharmacy nor its trustee or assignee may maintain an action at law or attempt to collect from covered persons sums owed to Pharmacy by PBM or plan sponsor. This provision shall not be construed to prohibit collection of required copays, deductibles or coinsurance, if any, or uncovered charges consented to and lawfully owed to Pharmacy by covered persons provided Pharmacy informed the covered person that plan sponsor may not cover or continue to cover the services. N.J. Stat. §§ 17:48F-13; 17:48H-18; N.J.A.C. §§ 11:4-37.4(c)(8); 11:24-15.2(b)(7); 11:24B-5.2(a)(10).

Pharmacy has the right to communicate openly with covered persons about all appropriate diagnostic testing and treatment options. N.J. Stat. § 26:2S-9(c); N.J.A.C. §§ 11:24-15.2(b)(13); 11:24A-4.15(b)(11); 11:24B-5.2(a)(14).

Plan sponsor is a third-party beneficiary of the Agreement and shall have privity of contract with Pharmacy such that plan sponsor shall have standing to enforce the Agreement with Pharmacy. N.J.A.C. §§ 11:24-15.2(f); 11:24B-5.7(a).

Pharmacy shall not discriminate in its treatment of covered persons of an HMO plan sponsor or any other plan sponsor. N.J.A.C. §§ 11:24-15.2(b)(8); 11:24A-4.15(b)(7): 11:24B-5.2(a)(16).

Pharmacy shall comply with PBM and plan sponsors' quality assurance and utilization review programs in accordance with the Agreement. Pharmacy's activities and records relevant to the provision of covered drugs may be monitored from time to time by PBM, plan sponsor or a contractor acting on either's behalf in order to perform quality assurance and continuous quality improvement functions. N.J.A.C. §§ 11:24- 15.2(b)(9); 11:24A-4.15(b)(8); 11:24B-5.2(a)(3-4).

Pharmacy shall maintain licensure, certification and adequate malpractice covered in an amount determined sufficient for its anticipated risk, but no less than $1 million per occurrence and $3 million in the aggregate year. N.J.A.C. §§ 11:24-15.2(b)(10); 11:24B-5.2(a)(12).

Covered persons' information shall be kept confidential by Pharmacy, subject to the requirements of state and federal law. However, PBM, plan sponsor, and Pharmacy shall have mutual rights to covered persons' medical records, as well as timely and appropriate communication of patient information, so that each may perform their respective duties efficiently and effectively. N.J.A.C. §§ 11:24-15.2(b)(11); 11:24A-4.15(b)(9).

This Agreement shall be construed in accordance with New Jersey Law. N.J.A.C. § 11:24B-5.2(a)(7).

PBM and Pharmacy agree to meet and confer in good faith to resolve any problems or disputes that may arise under this Agreement. Pharmacy may initiate a formal internal review of any complaint or grievance brought by Pharmacy, including compensation and claims issues, by submitting the complaint or grievance to PBM in writing. PBM will review the complaint or grievance and communicate a written response to Pharmacy in accordance with the requirements of New Jersey Law (which shall not exceed 30 days following receipt of the compliant or grievance). Complaints or grievances brought by Pharmacy relating to payment of claims will be reviewed at no cost to the Pharmacy by employees of PBM who are not responsible for claims payment on a day-to-day basis, and a written response shall be communicated to Pharmacy within 10 business days after receipt of such complaint or grievance, or as otherwise required under New Jersey Law. The written response shall include: (a) the names, titles and qualifying credentials of the persons participating in the internal review; (a) a statement of Pharmacy's grievance; and (c) the decision of the reviewers' along with a detailed explanation of the contractual basis for the decision; (d) a description of the evidence or documentation which supports the decision; and (e) if the decision is adverse to Pharmacy, a description of the method to obtain an external review of the decision.

Pharmacy shall have the right to submit complaints and grievances to DOBI or DHS, depending upon the issue involved, if not satisfied with the resolution of the complaint or grievance through the internal provider compliant mechanism described herein.

If any dispute, or complaint or grievance arising under this Agreement is not satisfactorily resolved by the parties themselves, PBM and Pharmacy agree to submit such dispute, complaint or grievance to binding arbitration. The party wishing to initiate arbitration must notify the other party by written demand. Any such arbitration shall be held in New Jersey. Such arbitration shall be conducted in accordance with the commercial rules of the American Arbitration Association. The costs of the arbitration under this paragraph shall be borne equally by the parities, and the results of the arbitration shall be issued no later than 30 business days from the receipt by the arbitrator of all documentation necessary to complete its review.

N.J.A.C. §§ 11:24A-4.6(b); 11:24-15.2(b)(12); 11:24A-4.15(b)(10); 11:24B-5.2(a)(18).

In the event that any provision of this Agreement is determined to be in conflict with state or federal law, such provision will be deemed modified to the extent necessary to make it conform to the requirements of such law. N.J.A.C. §11:24B-5.2(a)(1).

Notwithstanding anything to the contrary, PBM shall not have a unilateral right, acting in its own accord, or at the request of plan sponsor, to amend the Agreement or to require Pharmacy to abide by amended terms of the Agreement during either a notice of termination period or a continuity of care period in the event Pharmacy elects to terminate the Agreement rather than accept the amendment. This paragraph shall not apply in the event the amendment is required by state of federal law. Notwithstanding the foregoing, to the extent that the Agreement permits unilateral changes, "adverse changes" may only be made with sufficient advance notice to permit termination in advance of the effective date of the change. For purposes of this provision, "adverse change" means any action taken that could reasonably be expected to have a material adverse impact on either the aggregate level of payment to Pharmacy or the administrative expenses incurred by Pharmacy in complying with the change. With respect to the terms of the Agreement that were the subject to negotiation, no changes will be made unilaterally to the administration of the Agreement materially impacting those terms. N.J.A.C. 11:24C-4.3(c)(4). Any adverse change during the term of the Agreement may be made in accordance with the terms of the Agreement (but not upon automatic renewal) upon 90 days' notice prior to the effective date of the change. If Pharmacy declines to accept the amendment, Pharmacy may terminate the Agreement as set forth in N.J.A.C. § 11:24C-4.3(c)(3). N.J.A.C. §§ 11:24B-5.2(c)(2); 11:24C-4.2; 11:24C-4.3.

Nothing in the Agreement shall be construed to provide that Pharmacy will be denied payment with respect to a medically necessary health care service or supply if the service was not pre-certified or pre-authorized to the extent such denial is not permitted by law. Payment to Pharmacy may be reduced by up to 50% of the amount that otherwise would have been paid had pre-certification or pre-authorization been obtained. N.J.A.C. § 11:24B-5.2(c)(6).

This Agreement shall become effective as of the effective date appearing on the signature page hereof, subject to prior approval by the New Jersey Departments of Health and Senior Services and Banking and Insurance and shall continue in effect from year to year unless terminated as provided in the Agreement.

Notwithstanding the foregoing, either party may terminate the Agreement without cause by giving to the other party at least 90 days prior written notice of the date of termination. N.J.A.C. §§ 11:24-15.2(b)(1)(i); 11:24B-5.3(b).

PBM may immediately terminate this Agreement without notice at any time if Pharmacy (i) commits fraud, (ii) fails to meet its obligations or otherwise breaches this Agreement, or (iii) in the sole discretion of the medical director of PBM or plan sponsor, represents an imminent danger to a covered person or the public health, safety and welfare. N.J.A.C. §§ 11:24-3.5(a)(1)(ii); 11:24-15.2(b)(1)(i); 11:24A-4.8(b); 11:24B-5.3(c).

Either party may, subject to applicable state law, terminate this Agreement at any time if the other party is adjudged bankrupt; voluntarily files a petition in or for bankruptcy, reorganization or an arrangement with creditors; or makes a general assignment for the benefit of creditors by giving to the other party at least 90 days' prior written notice of the date of termination.

If PBM terminates this Agreement prior to the renewal date, other than pursuant to b) hereof, PBM shall provide Pharmacy with 90 days prior written notice setting forth the reasons for termination ("termination notice"), setting forth Pharmacy's right to a hearing any exception thereto, and the procedures for exercising that right. Within 10 days of receipt of the termination notice, Pharmacy shall be entitled to request a hearing in writing with respect to the termination ("hearing request"). Within 30 days of receipt of a hearing request, PBM shall hold a hearing before a panel appointed by PBM in accordance with N.J.A.C. §§ 11:24-3.6(b); 11:24A-4.9. The panel shall consist of no less than three people, at least one person on the panel shall be a clinical peer in the same or substantially similar discipline and specialty as Pharmacy, and PBM shall not preclude Pharmacy from being present at the hearing or represented by counsel. The panel shall render a decision in writing within 30 days of the close of the hearing, unless within such 30-day period the panel provides notice to both Pharmacy and PBM of the need for an extension for rendering the decision.

The panel's decision shall set forth the relevant provision of the Agreement and the facts upon which PBM or plan sponsor and Pharmacy relayed at the hearing. The panel shall recommend that Pharmacy be terminated, reinstated, or provisionally reinstated. The panel shall specify the reasons for its recommendations, including the reasons for any conditions for provisional reinstatement. The panel shall specify the conditions for provisional reinstatement, the duration of the conditions and the consequences for failure to meet the conditions. In the event of reinstatement or provisional reinstatement, the panel shall specify the impact of the reinstatement upon the terms of the duration of the Agreement. In the event that panel recommends that Pharmacy be terminated, PBM or plan sponsor shall provide notice of the termination to covered persons in accordance with N.J.A.C. §§ 11:24-3.5.

N.J.A.C. §§ 11:24-3.5(a)(1)(i); 11:24-3.6; 11:24-15.2(b)(1)(i-ii); 11:24A-4.8(a); 11:24A-4.9; 11:24A-4.15(b)(1)(i); 11:24B-5.3(d-e).

In the event the Agreement terminates, Pharmacy agrees to continue to provide covered drugs under the terms of the Agreement, and at the contracted rates under the Agreement, to covered persons for up to four months following the date of termination when it is medically necessary for the covered person to continue such services, except as follows:

i. In the case of pregnancy of a covered person, medical necessity shall be deemed to have been demonstrated and coverage of services under the Agreement by the terminated Pharmacy shall continue to postpartum evaluation of the covered person, up to six weeks after delivery;

ii. In the case of post-operative care, coverage of services under the Agreement by the terminated Pharmacy shall continue for a period up to six months;

iii. In the case of oncological treatment, coverage of services under the Agreement by the terminated Pharmacy shall continue for a period up to one year;

iv. In the case of psychiatric treatment, coverage of services under the Agreement by the terminated Pharmacy shall continue for a period of up to one year; and

v. In the event that the Pharmacy terminates the Agreement, coverage of services under the Agreement by the terminated Pharmacy shall continue for covered persons who received services from the Pharmacy immediately prior to the date of termination for 30 days following the date of termination, but for the remainder of the four-month period under (e) only in cases where it is medically necessary to continue treatment with the terminated Pharmacy or in accordance with Items (1) through (4) above as they may apply. The determination as to the medical necessity of a covered person's treatment with Pharmacy shall be subject to the appeal procedures provided by New Jersey law.

Notwithstanding the forgoing under e), terminated Pharmacy shall not be required to continue to provide covered drugs under the Agreement in the event the Agreement terminates because i) PBM determines that Pharmacy is an imminent danger to one or more covered persons or the public health, safety and welfare, ii) PBM determines that Pharmacy committed fraud, iii) PBM determines that Pharmacy breached the Agreement, or iv) Pharmacy is the subject of disciplinary action by any regulatory agency or board of the state of New Jersey.

N.J.A.C. §§ 11:24-15.2(b)(4); 11:24-3.5(c)(1-4); 11:24A-4.8(d)(1-4) and (7); 11:24A-4.15(b)(4); 11:24B-5.3(f-g).

Pharmacy's participation in the hearing process will not be deemed an abrogation of the Pharmacy's legal rights. N.J.A.C. §§ 11:24-15.2(b)(1)(iv); 11:24A-4.15(b)(1)(iv).

PBM will not make the terms of the Agreement available to any third-party to lease the network unless: (i) the Agreement specifically states that PBM may enter into an agreement with third parties allowing the third parties to obtain the contracting entity's rights and responsibilities as if the third-party were the contracting entity; (ii) every third-party accessing the Agreement is contractually obligated to comply with all of its terms; (iii) all such third parties in existence as of the date the Agreement is entered into are identified; (iv) PBM includes on its website a listing, updated no less frequently than every 90 days, identifying all such third parties; (v) each third-party is required to identify the source of the discount on all remittance advices and/or explanation of payment under which a discount is taken; (vi) the third party is notified of the termination of a provider contract upon issuance of the termination by PBM or upon receipt of notice by Pharmacy; (vii) the third party ceases its right to Pharmacy's discounted rate upon termination of the Agreement between Pharmacy and PBM; and (viii) PBM delivers to Pharmacy a copy of any agreement relied on in the adjudication of a claim within 30 days after the date of a request from Pharmacy. For purposes of this provision, "third party" does not include any employer or other group for whom PBM provides administrative services, including at least the payment of claims. N.J.A.C. § 11:24C-4.3(c)(5).

Duties of pharmacy benefits manager upon execution or renewal of contract (NJ ST 17B:27F-2)

Upon execution or PBM shall, with respect to contracts between a PBM and a pharmacy services administrative organization, or between a PBM and a contracted pharmacy:

a. (1) include in the contract the sources utilized to determine multiple source generic drug pricing, brand drug pricing, and the wholesaler in the State of New Jersey where pharmacies may acquire the product, including, but not limited to, the brand effective rate, generic effective rate, dispensing fee effective rate, maximum allowable cost or any other pricing formula for pharmacy reimbursement;

(2) update that pricing information every seven (7) calendar days; and

(3) establish a reasonable process by which contracted pharmacies have a method to access relevant maximum allowable cost pricing lists, brand effective rate, generic effective rate, and dispensing fee effective rate, or any other pricing formulas for pharmacy reimbursement.

b. Additionally, a PBM shall:

(1) maintain a procedure to eliminate drugs from the list of drugs subject to multiple source generic drug pricing and brand drug pricing, or modify maximum allowable cost rates, brand effective rate, generic effective rate, dispensing fee effective rate or any other applicable pricing formula in a timely fashion and make that procedure easily accessible to the pharmacy services administrative organizations or the pharmacies that they are contractually obligated with to provide that information according to the requirements of this section; and

(2) provide an internal appeal mechanism to resolve any dispute raised by a carrier or pharmacy, regardless of whether the carrier or PBM has a contract to challenge maximum allowable costs for a specified drug. Any dispute regarding the determination of an internal appeal conducted pursuant to this subsection may be referred to arbitration. The Commissioner of Banking and Insurance shall contract with a nationally recognized, independent organization that specializes in arbitration to conduct the arbitration proceedings.

Contract provisions relating to appeal, investigation, and resolution of disputes regarding multiple source generic drug pricing (NJ ST 17B:27F-4)

All contracts between a PBM and a pharmacy services administrative organization, or its contracted pharmacies, and all contracts directly between a PBM and a pharmacy shall include a process to appeal, investigate, and resolve disputes regarding brand and multiple source generic drug pricing, including, if applicable, brand effective rate, generic effective rate, dispensing fee effective rate, and any other pricing formula for pharmacy reimbursement. The contract provision establishing the process shall include the following:

a. The right to appeal shall be limited to fourteen (14) calendar days following the initial claim;

b. The appeal shall be investigated and resolved by the PBM through an internal process within fourteen (14) calendar days of receipt of the appeal by the PBM;

c. A telephone number at which a pharmacy services administrative organization, or a pharmacy may contact the PBM and speak with an individual who is involved in the appeals process; and

d. (1) If the appeal is denied, the PBM shall:

(a) provide the reason for the denial to the pharmacy services administrative organization and its contracted pharmacies, and the pharmacy services administrative organization shall inform its contracted pharmacies of the availability, location and pricing of the appealed drug in the State;

(b) provide the reason for the denial directly to a pharmacy, if it contracts directly with a PBM;

(c) identify the national drug code of a drug product that is available for purchase by the specific contracted pharmacy appealing the claim in this State from wholesalers registered pursuant to P.L.1961, c. 52 (C.24:6B-1 et seq.) at a price which is available to the specific contracted pharmacy appealing the claim and which is equal to or less than the maximum allowable cost or the brand effective rate, generic effective rate or other pricing for the appealed drug as determined by the PBM; and

(d) provide the name of wholesalers registered under P.L.1961, c. 52 (C.24:6B-1 et seq.) from which the appealing pharmacy can obtain the brand or multiple source generic drug at or below the brand effective rate, generic effective rate, dispensing fee effective rate, maximum allowable cost or any other pricing formula for pharmacy reimbursement;

(2) If the appeal is approved, the PBM shall make the price correction, permit the reporting pharmacy to reverse and rebill the appealed claim, and make the price correction effective for all similarly situated pharmacies from the date of the approved appeal.

B-32 New Mexico Regulatory Addendum to Pharmacy Participation Agreement

This New Mexico Addendum applies to the extent that Pharmacy provides covered drugs to covered persons of health plans, health maintenance organizations, multiple employer welfare arrangements, managed health care plans, preferred provider arrangements, nonprofit health care plans, insurers or carriers under New Mexico law (collectively and/or individually, "plan sponsor").

In the event of a direct conflict between this Addendum and the Pharmacy Participation Agreement ("Agreement"), the applicable provisions of this Addendum shall control if required. This Addendum may be modified from time to time pursuant to the Agreement.

Without limiting the generality of the foregoing, and notwithstanding anything in the Agreement to the contrary, Pharmacy and pharmacy benefit manager (PBM) agree as follows:

Notwithstanding anything to the contrary, no provisions in the Agreement shall operate to relieve either party of liability for its actions or inactions. N.M. Stat. § 59A-16-21.1(D).

Pharmacy shall be responsible for providing covered drugs to covered persons subject to the limitations and conditions set forth in the Agreement. N.M. Admin. Code § 13.10.22.12(B).

Pharmacy agrees that in no event, including, but not limited to, nonpayment by plan sponsor or PBM, insolvency of plan sponsor or PBM, or breach of the Agreement, shall Pharmacy bill, charge, collect a deposit from, seek remuneration or reimbursement from or have any recourse against a covered person, or person acting on behalf of the covered person, for covered drugs provided pursuant to the Agreement. This does not prohibit Pharmacy from collecting coinsurance, deductibles or copays as specifically provided in the evidence of coverage, or fees for uncovered health care services delivered on a fee-for-service basis to covered persons referenced above, nor from any recourse against plan sponsor, PBM or their successors. N.M. Stat. Ann. § 59A-46-13(E); N.M. Admin. Code § 13.10.22.12(C). The hold harmless provisions of this paragraph shall survive termination of the Agreement regardless of the reason for termination, including the insolvency of plan sponsor or PBM. N.M. Admin. Code § 13.10.22.12(L).

Pharmacy and PBM have rights and responsibilities with respect to administrative policies and programs as set forth in the Agreement, including, but not limited to, payment systems, utilization review, quality assessment and improvement programs, credentialing, confidentiality requirements and any applicable federal or state programs. N.M. Admin. Code § 13.10.22.12(D).

Pharmacy shall maintain health records necessary to monitor and evaluate the quality of care, to conduct evaluations and audits, and to determine on a concurrent or retrospective basis the medical necessity or appropriateness of health care services provided to covered persons. Pharmacy shall make such health records available to appropriate state and federal authorities involved in assessing the quality of care or in investigating the grievances or complaints of covered persons, they and shall comply with all applicable state and federal laws related to the confidentiality of such records. N.M. Admin. Code § 13.10.22.12(E).

Pharmacy may not assign or delegate its contractual rights or responsibilities under the Agreement without PBM's prior written consent. N.M. Admin. Code § 13.10.22.12(F).

Pharmacy shall maintain adequate professional liability and malpractice insurance and shall notify PBM not more than 10 days after Pharmacy's receipt of notice of any reduction or cancellation of such coverage. N.M. Admin. Code § 13.10.22.12(G).

Pharmacy shall observe, protect and promote the rights of covered persons as patients. N.M. Admin. Code § 13.10.22.12(H).

Pharmacy shall provide covered drugs to covered persons without discrimination on the basis of a patient's participation in the benefit plan, age, gender, ethnicity, religion, sexual orientation, health status or disability and without regard to the source of payments made for health care services rendered to a patient. This requirement shall not apply to circumstances when Pharmacy appropriately does not render services due to limitations arising from its lack of training, experience or skill or due to licensing restrictions. To the extent required by law, Pharmacy is entitled to receive from plan sponsor, at no cost to Pharmacy, interpreters for individuals with limited English proficiency and interpretive services for patients who qualify under the American with Disabilities Act. N.M. Admin. Code § 13.10.22.12(I).

Pharmacy shall be responsible for providing covered drugs to covered persons during the days and hours as set forth in the Agreement and credentialing forms provided hereunder. N.M. Admin. Code § 13.10.22.12(J).

Procedures for dispute resolution mechanisms available to the parties are set forth in the Agreement.

N.M. Admin. Code § 13.10.22.12(K).

Terms used in the Agreement that are defined by New Mexico statutes and insurance division regulations shall be construed in the Agreement in a manner consistent with the definitions contained in such laws and regulations. N.M. Admin. Code § 13.10.22.12(M).

Nothing in the Agreement shall be construed to:

Offer an inducement, financial or otherwise, to provide less than medically necessary services to a covered person;

Penalize Pharmacy for assisting a covered person to seek reconsideration of plan sponsor's or PBM's decision to deny or limit benefits to the covered person;

Prohibit Pharmacy from discussing treatment options with covered persons irrespective of plan sponsor's or PBM's position on treatment options, or from advocating on behalf of a covered person within the utilization review or grievance processes established by plan sponsor or PBM; or

Prohibit Pharmacy from using disparaging language or making disparaging comments when referring to plan sponsor or PBM.

Require Pharmacy to violate any recognized fiduciary duty of its profession or place its license in jeopardy.

N.M. Stat. § 59A-57-6(A); N.M. Admin. Code § 13.10.22.12(N).

The parties acknowledge that a plan sponsor failing to pay Pharmacy or covered person for out-of-pocket covered expenses within 45 days after a clean claim has been received by PBM on plan sponsor's behalf shall be liable for the amount due and unpaid with interest on that amount at the rate at one and one-half times the rate established by a bulletin entered by the superintendent of the New Mexico Division of Insurance in January of each calendar year. For purposes of this paragraph, "clean claim" means a manually or electronically submitted claim that contains all the required data elements for accurate adjudication without the need for additional information from outside PBM's system and contains no deficiency or impropriety, including lack of substantiating documentation currently required by plan sponsor or PBM, or particular circumstances requiring special treatment that prevents timely payment from being made by plan sponsor. N.M. Admin. Code § 13.10.22.12(O).

To the extent Pharmacy provides covered drugs to covered persons of a health maintenance organization under New Mexico law, Pharmacy agrees:

Pharmacy shall provide PBM with at least 60 days' prior written notice of its intent to terminate the Agreement. N.M. Stat. § 59A-46-13(G).

In the event of PBM's or plan sponsor's insolvency, Pharmacy shall provide all medically necessary covered drugs to each covered person for the period for which a premium has been paid to plan sponsor and until covered person's discharge from an inpatient facility. N.M. Stat. Ann. § 59A-46-13(F)(2).

For Pharmacy claims adjudicated on or after July 1, 2019, PBM shall not charge Pharmacy a fee related to the adjudication of a claim, including, but not limited to: (a) the receipt and processing of a Pharmacy claim; (b) the development or management of a claim processing or adjudication network; or (c) participation in a claim processing or claim adjudication network. Any such fees inadvertently charged shall be refunded to Pharmacy. PBM shall not charge Pharmacy other fees not enumerated within this paragraph unless the fee for service is itemized in the Agreement, Addendum or Provider Manual. N.M. Stat. § 59A-61-7.

To the extent applicable, PBM shall abide by the requirements of the Pharmacy Benefits Manager Regulation Act. N.M. Stat. § 59A-61-1 et seq.

Pharmacy reimbursement practices for generic drugs; appeals process required (NM ST § 59A-61-4)

D. A PBM using maximum allowable cost pricing shall:

(1) upon a network pharmacy's request, provide that network pharmacy with the sources used to determine the maximum allowable cost pricing for the maximum allowable cost list specific to that provider;

(2) review and update maximum allowable cost price information at least once every seven (7) business days to reflect any modification of maximum allowable cost pricing;

(3) establish and maintain a process for eliminating products from the maximum allowable cost list or modifying maximum allowable cost prices in at least seven (7) business days to remain consistent with pricing changes and product availability in the marketplace;

(4) provide a procedure that allows a pharmacy to choose the entity to which it will appeal reimbursement for generic drugs. A pharmacy may appeal:

(a) directly to the PBM; or

(b) through a pharmacy services administrative organization;

(5) provide an appeals process that, at a minimum, includes the following:

(a) a dedicated telephone number and electronic mail address or website for the purpose of submitting appeals;

(b) the ability to submit an appeal directly to the PBM; and

(c) the allowance of at least twenty-one (21) business days to file an appeal after the date a pharmacy receives notice of the reimbursement amount;

(6) grant an appeal if the PBM fails to respond to a complete submission as defined by rules promulgated by the superintendent of the appealing party in writing within fourteen (14) business days after the PBM receives the appeal;

(7) if an appeal is granted, notify the challenging pharmacy and its pharmacy services administrative organization, if any, that the appeal is granted and make the change in the maximum allowable cost effective for the appealing pharmacy and for each other pharmacy in its network and permit the appealing pharmacy to reverse and bill again the claim or claims that formed the basis of the appeal;

(8) when an appeal is denied, provide the challenging pharmacy and its pharmacy services administrative organization, if any, the national drug code number and supplier that has the product available for purchase in New Mexico at or below the maximum allowable cost;

(9) within one (1) business day of granting or denying a network pharmacy's appeal, notify all network pharmacies of the decision;

(10) upon granting an appeal, allow other similarly situated network pharmacies to reverse and bill again for like claims that formed the basis of the granted appeal; and

(11) provide for each of its network pharmacy providers and the superintendent a process and mechanism to readily access the maximum allowable cost list specific to that provider.

E. A maximum allowable cost list specific to a provider and maintained by a managed care organization or PBM is confidential.

F. Pursuant to Section 59A-4-3 NMSA 1978, a PBM shall provide information contained in a maximum allowable cost list to the superintendent upon request by the superintendent.

Audit of pharmacy records (N.M. Stat. § 61-11-18.2)

A. An audit of the records of a Pharmacy by Prime shall be conducted in accordance with the following criteria:

(1) Prime shall give the Pharmacy notice at least two weeks prior to conducting the initial on-site audit for each audit cycle;

(2) An audit that involves clinical or professional judgment shall be conducted by or in consultation with a pharmacist;

(3) A clerical or recordkeeping error regarding a required document or record shall not necessarily constitute fraud, and that error:

(a) Shall not be the basis for recoupment unless the error results in overpayment to the Pharmacy, and any amount to be charged back or recouped due to overpayment shall not exceed the amount the Pharmacy was overpaid; and

(b) Shall not be subject to criminal penalties without proof of intent to commit fraud;

(4) A Pharmacy may use the records of a hospital, physician or other authorized practitioner of the healing arts for drugs or medicinal supplies written or transmitted by any means of communication for purposes of validating the pharmacy record with respect to orders or refills of a dangerous drug or controlled substance;

(5) A finding of an overpayment or underpayment shall be based on the actual overpayment or underpayment of a specific individual claim;

(6) Each Pharmacy shall be audited under the same standards and parameters as other similarly situated Pharmacies audited by Prime.

(7) A Pharmacy shall be allowed at least 21 business days, with reasonable extensions allowed, following receipt of the preliminary audit report in which to produce documentation to address any discrepancy found during an audit;

(8) The period covered by an audit shall not exceed two years from the date the claim was submitted to or adjudicated by Prime, unless it conflicts with state or federal law;

(9) An audit shall not be initiated or scheduled during the first five calendar days of a month;

(10) The preliminary audit report shall be delivered to the Pharmacy within 120 days, with reasonable extensions allowed, after conclusion of the audit, and the final report shall be delivered to the Pharmacy within six months after receipt of the preliminary audit report or final appeal, as provided for in Subsection B of this section, whichever is later;

(11) Notwithstanding any other provision in this section, Prime shall not use the accounting practice of extrapolation in calculating recoupments or penalties for audits;

(12) Prime shall not compensate an employee or contractor with which Prime contracts to conduct a pharmacy audit based on the amount claimed or the actual amount recouped from the Pharmacy being audited;

(13) Prime shall not charge a fee for conducting an on-site or a desk audit unless there is a finding of actual fraud;

(14) As a result of an audit finding, a pharmacist or Pharmacy may resubmit a claim within 21 business days to correct clerical or recordkeeping errors in lieu of recoupment of a claim where no actual financial harm to the patient has occurred, provided that the prescription was dispensed according to prescription documentation requirements pursuant to the Pharmacy Act;

(15) The requirements for a valid prescription or a PBM's required operational standards for Pharmacies shall not be more stringent than federal or state requirements;

(16) With notice to the prescriber, a Pharmacy or pharmacist may satisfy state and federal requirements for a valid prescription by affixing or writing additional information on the front or back of a prescription, or, if the required information is electronically recorded, on a patient's profile and is readily retrievable;

(17) The days' supply for unit-of-use items, such as topicals, drops, vials and inhalants, shall not be limited beyond manufacturer recommendations;

(18) If the only commercially available package size exceeds Prime's maximum days' supply, the dispensing of such package size must be accepted by the entity and shall not be the basis for recoupment;

(19) If the only commercially available package size exceeds Prime's maximum days' supply and Prime accepts the refill of such prescription, Prime shall not recoup such claim as an early refill; and

(20) The failure of a Pharmacy to collect a copay shall not be the basis for recoupment if the Pharmacy provides documentation of billing of the claim and a reasonable attempt to collect the copay.

B. Recoupment of any disputed funds shall occur after final internal disposition of the audit, including the appeals process set forth in subsection C of this section. Should the identified discrepancy for an individual audit exceed $25,000, future payments to the Pharmacy may be withheld, pending finalization of the audit.

C. Prime shall establish an appeals process under which a Pharmacy may appeal an unfavorable preliminary audit report to Prime. If, following the appeal, Prime finds that an unfavorable audit report or any portion of the audit is unsubstantiated, Prime shall dismiss the audit report or the unsubstantiated portion of the report of the audit without the necessity of any further proceedings.

D. This section does not apply to any investigative audit that involves probable or potential fraud, waste and abuse or willful misrepresentation.

E. In a wholesale invoice audit conducted by Prime:

(1) Prime shall not audit the claims of another entity;

(2) The following shall not form the basis for recoupment:

(a) The National Drug Code for the dispensed drug is in a quantity that is a subunit or multiple of the purchased drug as reflected on a supporting wholesale invoice;

(b) The correct quantity dispensed is reflected on the audited pharmacy claim; or (c) The drug dispensed by the Pharmacy on an audited pharmacy claim is identical to the strength and dosage form of the drug purchased;

(3) Prime shall accept as evidence:

(a) Supplier invoices issued prior to the date of dispensing the drug underlying the audited claim;

(b) Invoices from any supplier authorized by law to transfer ownership of the drug acquired by the audited Pharmacy;

(c) Copies of supplier invoices in the possession of the audited Pharmacy; and

(d) Reports required by any state board or agency; and

(4) Within five business days of request by the audited Pharmacy, Prime shall provide supporting documentation provided to Prime by the audited pharmacy's suppliers.

F. As used in this section:

(1) "Entity" means a managed care company, insurance company or third-party payer or representative of a managed care company, insurance company or third-party payer, or a PBM or a subcontractor of a PBM; and

(2) "Extrapolation" means a mathematical process or technique used to estimate audit results or findings for a larger batch or group of claims not reviewed.

Provider Grievances – General Rules (NMAC 13.10.8)

Providers have the option to submit a written provider grievance if verbal communications cannot resolve the provider's concern. Additionally, providers have the option to submit a written grievance in the following categories:

- Credentialing deadlines
- Claim payment amount or timing
- Claim submission requirements or compliance
- Network adequacy, including participation determinations based on network composition
- Network composition including provider qualifications
- Utilization management practices
- Provider contract construction or compliance
- Patient care standards or access to care
- Surprise billing reimbursement amount, rate or timing
- Operation of the plan including compliance with any law enforceable by the superintendent, or of any directive
- Discrimination
- Termination

New Mexico pharmacies can continue to submit their grievances through the current process with Prime. Should a pharmacy wish to submit a written provider grievance, please direct it to **ProviderRelations@primetheratpeutics.com.**

For grievances relating to:

- Patient care standards or access to care
- Surprise billing reimbursement amount, rate or timing; OR
- Operation of the plan including compliance with any law enforceable by the superintendent, or of any directive of the superintendent

Please reach out to the members' respective health plan for review and resolution of these grievances.

A pharmacy will be able to submit a grievance within the timelines and policies established by Prime as well as applicable laws and regulations. New Mexico pharmacies can submit a grievance for at least 90 days from the incident that is the subject of the grievance.

If a pharmacy is not satisfied with the outcome of the written grievance, the pharmacy has the option (after all internal grievance options have been exhausted) to submit an appeal to the New Mexico Office of the Superintendent of Insurance

(1) (NM OSI) within 30 days of receiving a response to the grievance from Prime OR the deadline for the response, whichever is earlier. NM OSI will only review an appeal that pertains to:an alleged violation of a law enforceable by the superintendent;

(2) alleged noncompliance with an order of the superintendent; or

(3) a termination based on a provider's alleged failure to comply with a law or order enforceable by the superintendent.

If a pharmacy is submitting an appeal to NM OSI, the pharmacy must include the following information:

- The provider's name, license number, address, daytime telephone number, email address, and any relevant claim number(s);
- The name and phone number of the carrier;
- Certification that the grievance did not pertain to Medicaid or Medicare coverage, excluding Medicare supplement;
- A copy of the carrier's written disposition of the grievance, or certification by the provider that the carrier did not issue a written disposition within the time allowed by law;
- The date the provider received the carrier's written disposition of the grievance, or the date by which the carrier was required to provide a written disposition if no disposition was received; and
- A clear and concise statement of the issue on appeal, and the remedy requested on appeal.

B-33 New York Regulatory Addendum to Pharmacy Participation Agreement

This Addendum has been separately entered into between Prime Therapeutics Management LLC, Prime Therapeutics Management IPA, Prime Therapeutics LLC and its Affiliates, and the undersigned Pharmacy ("Pharmacy").

Whereas PBM and Pharmacy have entered into that certain Pharmacy Participation Agreement, under which Pharmacy has agreed to provide pharmacy services (the "Agreement").

Whereas New York law requires that entities arranging for the provision of pharmacy services for health maintenance organizations or other managed care organizations authorized under article 44 of the New York Public Health Law (collectively, "HMO") be a company organized under the laws of New York to operate as an independent practice association or otherwise exempt from such requirement.

Whereas, IPA is a New York limited liability company, organized under the laws of New York to operate as an independent practice association, and is a wholly owned subsidiary of PBM.

Whereas PBM, Pharmacy and IPA desire to amend the Agreement to add IPA as a party to the Agreement and to clarify IPA's role in providing and maintaining the network of Pharmacies, in which Pharmacy participates, that provide covered drugs to covered persons of HMOs and to otherwise amend the Agreement as set forth in this Addendum.

Now, therefore, for purposes of Pharmacy's participation in the pharmacy networks that provide covered drugs to covered persons of HMOs, PBM, Pharmacy and IPA agree as follows:

In the event any provision in this Addendum conflicts with the terms of the Agreement, the terms of this Addendum shall govern.

Notwithstanding anything in the Agreement to the contrary, Pharmacy understands and agrees that the pharmacy networks providing covered drugs to covered persons of HMOs in which Pharmacy participates are provided and maintained by IPA.

Pharmacy agrees that it will participate in all IPA pharmacy networks in which (i) Pharmacy participates in as of the date of the acceptance of this Agreement by IPA; (ii) Pharmacy executes a network participation addendum accepted by IPA for such pharmacy network(s); and/or (iii) Pharmacy agrees to participate as evidenced by its provision of covered drugs to covered persons of an HMOs utilizing such pharmacy network(s).

In addition to the entities listed in the indemnification provision of the Agreement, Pharmacy's indemnification obligations under such provision shall extend to IPA and HMOs. Neither IPA nor PBM is responsible or liable for Pharmacy's professional judgment in its provision of prescription drugs and services.

Pharmacy must provide to IPA or PBM, upon request, evidence of all such licenses, certifications and insurance policies referenced in the Agreement.

Pharmacy, IPA and PBM are independent entities. Pharmacy shall perform all services under the Agreement and this Addendum as an independent contractor and shall exercise its own professional judgment in providing such services. Except for the indemnity provisions of the Agreement, no provision of the Agreement is for the benefit of any person or entity who is not a party hereto, and no such party will have any right or cause of action hereunder. Neither the Agreement nor this Addendum shall be assigned, subcontracted, delegated, or transferred by Pharmacy without the prior written consent of IPA and PBM.

This Addendum shall be in effect from the date of acceptance by IPA.

IPA will act as representative for Pharmacy with regard to the payment of claims by an HMO or its delegatee, and in IPA's capacity as representative will assist Pharmacy in resolving any claims adjudication issues, complaints or concerns that Pharmacy may have with an HMO or its delegatee. To the extent that Pharmacy has any complaints with respect to receipt of payments from an HMO or its delegatee for services rendered pursuant to this Agreement, those complaints should be directed to IPA and not to the HMO.

To the extent that Pharmacy shall provide pharmacy services to covered persons enrolled with an HMO, Pharmacy agrees to comply with any requirements for participation as a Pharmacy in New York. Without limiting the generality of the foregoing, and notwithstanding anything in the Agreement or this Addendum to the contrary, Pharmacy agrees as follows:

The "New York State Department of Health Standard Clauses for Managed Care Provider/IPA/ACO Contracts," attached to the Agreement as Appendix A, are expressly incorporated into this Agreement, and are binding upon the article 44 plans and providers that contract with such plans, and who are a party to this Agreement. In the event of any inconsistent or contrary language between the standard clauses and any other part of the Agreement, including, but not limited to, appendices, amendments and exhibits, the parties agree that the provisions of the standard clauses shall prevail, except to the extent applicable law requires otherwise and/or to the extent a provision of the Agreement exceeds the minimum requirements of the Standard Clauses.

New York State Department of Health Standard Clauses for Managed Care Provider/IPA Contracts

Exhibit A Notwithstanding any other provision of this agreement, contract or amendment (hereinafter "the Agreement " or "this Agreement") the article 44 plans and providers that contract with such plans, and who are a party agree to be bound by the following clauses which are hereby made a part of the Agreement. Further, if this Agreement is between a managed care organization and an IPA/ACO, or between an IPA/ACO and an IPA/ACO, such clauses must be included in IPA/ACO contracts with providers, and providers must agree to such clauses.

A. Definitions for purposes of this appendix

"Managed care organization" or "MCO" shall mean the person, natural or corporate, or any groups of such persons, certified under Public Health Law article 44, who enter into an arrangement, agreement or plan or any combination of arrangements or plans which provide or offer a comprehensive health services plan, or a health and long-term care services plan.

"Independent practice association" or "IPA" shall mean an entity formed for the limited purpose of contracting for the delivery or provision of health services by individuals, entities and facilities licensed and/or certified to practice medicine and other health professions, and as appropriate, ancillary medical services and equipment. Under these arrangements, such health care providers and suppliers will provide their service in accordance with and for such compensation as may be established by a contract between such entity and one or more MCOs. "IPA" may also include, for purposes of this Agreement, a Pharmacy or laboratory with the legal authority to contract with other Pharmacies or laboratories to arrange for or provide services to enrollees of a New York State MCO.

"Provider" shall mean physicians, dentists, nurses, pharmacists and other health care professionals, Pharmacies, hospitals, and other entities engaged in the delivery of health care services which are licensed, registered and/or certified as required by applicable federal and state law.

B. General terms and conditions

This agreement is subject to the approval of the New York State Department of Health (DOH) and if implemented prior to such approval, the parties agree to incorporate into this Agreement any and all modifications required by DOH for approval or, alternatively, to terminate this Agreement, if so directed by DOH, effective 60 days subsequent to notice, subject to Public Health Law §4403 (6)(e). This Agreement is the sole agreement between the parties regarding the arrangement established herein.

Appendix B: Regulatory addendums (continued)

Any material amendment to this Agreement is subject to the prior approval of DOH, and any such amendment shall be submitted for approval in accordance with the appropriate procedures and timelines described in Sections III and VII of the New York State Department of Health Provider Contract Guidelines for MCOs and IPA/ACOs. To the extent the MCO provides and arranges for the provision of comprehensive health care services to enrollees served by the Medical Assistance Program, the MCO shall notify and/or submit a copy of such material amendment to DOH, as may be required by the Medicaid Managed Care contract between the MCO and DOH.

Assignment of an agreement between an MCO and (1) an IPA/ACO, (2) an institutional network provider, or (3) a medical group provider that serves 5% or more of the enrolled population in a county, or the assignment of an agreement between an IPA/ACO and (1) an institutional provider or (2) a medical group provider that serves 5% or more of the enrolled population in a county, requires the prior approval of the Commissioner of Health.

The provider agrees, or if the Agreement is between the MCO and an IPA/ACO or between an IPA/ACO and an IPA/ACO, the IPA/ACO agrees and shall require the IPA/ACO's providers to agree, to comply fully and abide by the rules, policies and procedures that the MCO (a) has established or will establish to meet general or specific obligations placed on the MCO by statute, regulation, contract, or DOH or DFS guidelines or policies and (b) has provided to the provider at least 30 days in advance of implementation including, but not limited to:

- Quality improvement/management;
- Utilization management, including, but not limited to, precertification procedures, referral process or protocols, and reporting of clinical encounter data;
- Member grievances; and
- Provider credentialing.

The provider or, if the Agreement is between the MCO and an IPA/ACO, or between an IPA/ACO and an IPA/ACO, the IPA/ACO agrees, and shall require its providers to agree, to not discriminate against an enrollee based on color, race, creed, age, gender, sexual orientation, disability, place of origin, source of payment or type of illness or condition.

If the provider is a primary care practitioner, the provider agrees to provide 24-hour coverage and backup coverage when the provider is unavailable. The provider may use a 24-hour backup call service provided appropriate personnel receive and respond to calls in a manner consistent with the scope of their practice.

The MCO or IPA/ACO that is a party to this Agreement agrees that nothing within this Agreement is intended to, or shall be deemed to, transfer liability for the MCO's or IPA/ACO's own acts or omissions, by indemnification or otherwise, to a provider.

Notwithstanding any other provision of this Agreement, the parties shall comply with the provisions of the Managed Care Reform Act of 1996 (Chapter 705 of the Laws of 1996) Chapter 551 of the Laws of 2006, Chapter 451 of the Laws of 2007, Chapter 237 of the Laws of 2009, Chapter 297 of the Laws of 2012, Chapter 199 of the Laws of 2014, Part H, Chapter 60, of the Laws of 2014 and Chapter 6 of the Laws of 2015 with all amendments thereto.

To the extent the MCO enrolls individuals covered by the Medical Assistance Program, this Agreement incorporates the pertinent MCO obligations under the Medicaid Managed Care contract between the MCO and DOH as set forth fully herein, including:

- The MCO will monitor the performance of the provider or IPA/ACO under the Agreement and will terminate the Agreement and/or impose other sanctions if the provider's or IPA/ACO's performance does not satisfy the standards set forth in the Medicaid Managed Care contract.

Appendix B: Regulatory addendums (continued)

- The provider or IPA/ACO agrees that the work it performs under the Agreement will conform to the terms of the Medicaid managed care contract between the MCO and DOH and that it will take corrective action if the MCO identifies deficiencies or areas of needed improvement in the provider´s or IPA/ACO´s performance.
- The provider or IPA/ACO agrees to be bound by the confidentiality requirements set forth in the Medicaid Managed Care contract between the MCO and DOH.
- The MCO and the provider or IPA/ACO agree that a woman´s enrollment in the MCO´s Medicaid Managed Care product is sufficient to provide services to her newborn, unless the newborn is excluded from the enrollment in Medicaid Managed Care or the MCO does not offer a Medicaid Managed Care product in the mother´s county of fiscal responsibility.
- The MCO shall not impose obligations and duties on the provider or IPA/ACO that are inconsistent with the Medicaid Managed Care contract or that impair any rights accorded to DOH, the local Department of Social Services, or the United States Department of Health and Human Services.
- The provider or IPA/ACO agrees to provide medical records to the MCO for purposes of determining newborn eligibility for Supplemental Security Income where the mother is a member of the MCO and for quality purposes at no cost to the MCO.
- The provider or IPA/ACO agrees, pursuant to 31 U.S.C. §1352 and CFR Part 93, that no federally appropriated funds have been paid or will be paid to any person by or on behalf of the provider/IPA/ACO for the purpose of influencing or attempting to influence an officer or employee of any agency, a member of Congress, an officer or employee of Congress, or an employee of any member of Congress in connection with the award of any federal loan, the entering into of any cooperative agreement, or the extension, continuation, renewal, amendment or modification of any federal contract, grant, loan or cooperative agreement. The provider or IPA/ACO agrees to complete and submit the “Certification Regarding Lobbying,” Appendix A-1 attached hereto and incorporated herein, if this Agreement exceeds $100,00. If any funds other than federally appropriated funds have been paid or will be paid to any person for the purpose of influencing or attempting to influence an officer or employee of any agency, a member of congress, an officer or employee of a member of Congress, in connection with the award of any federal contract, the making of any federal grant, the making of any federal loan, the entering of any cooperative agreement or the extension, continuation, renewal, amendment or modification of any federal contract, grant loan or cooperative agreement, and the Agreement exceeds $100,00 the provider or IPA/ACO shall complete and submit Standard Form–LLL “Disclosure Form to Report Lobbying,” in accordance with its instructions.
- The provider or IPA/ACO agrees to disclose to the MCO, on an ongoing basis, any managing employee who has been convicted of a misdemeanor or felony in relation to the employee´s involvement in any program under Medicare, Medicaid, or a Title XX services program (block grant programs).
- The provider or IPA/ACO agrees to monitor its employees and staff against the List of Excluded Individuals and Entities (LEIE), the Social Security Administration Death Master List, and the National Plan provider Enumeration System (NPPES).
- The provider or IPA/ACO agrees to disclose to the MCO complete ownership, control, and relationship information.
- The provider or IPA/ACO agrees to obtain for the MCO ownership information from any subcontractor with whom the provider has had a business transaction totaling more than $25,000 during the 12–month period ending on the date of the request made by DOH, Office of the Medicaid Inspector General (OMIG) or the United States Department of Health and Human Services (DHHS). The information requested shall be provided to the MCO within 35 days of such request.

  - The provider or IPA/ACO agrees to have an officer, director or partner of the provider execute and deliver to DOH a certification, using a form provided by DOH through OMIG´s website, within five days of executing this agreement, stating that:
- The provider or IPA/ACO is subject to the statutes, rules, regulations, and applicable Medicaid updates of the Medicaid program and of DOH related to the furnishing of care, services or supplies provided directly by, or under the supervision of, or ordered, referred, or prescribed by the provider. This includes 18 NYCCR 515.2 except to the extent that any reference in the regulation establishing rates, fees and claiming instructions will refer to the rates, fees and claiming instructions set by the MCO.
- All claims submitted for payment by the provider/IPA/ACO are for care, services or medical supplies that have been provided.
- Payment requests are submitted in accordance with applicable law.
  - The provider or IPA/ACO agrees to require that an officer, director, or partner of all subcontractors if they are not natural persons, or the subcontractor itself if it is a natural person, execute a certification, using a form provided by DOH through OMIG´s website, before the subcontractor requests payment under the subcontract, acknowledging that:
- The subcontractor is subject to the statutes, rules, regulations and applicable Medicaid updates of the Medicaid program and of DOH related to the furnishing of care, services or supplies provided directly by, or under the supervision of, or ordered, referred or prescribed by the subcontractor. This includes 18 NYCCR 515.2 except to the extent that any reference in the regulation establishing rates, fees and claiming instructions will refer to the rates, fees and claiming instructions set by the MCO.
- All claims submitted for payment by the subcontractor are for care, services or medical supplies that have been provided.
- Payment requests are submitted in accordance with applicable law.

The parties to this Agreement agree to comply with all applicable requirements of the federal Americans with Disabilities Act.

The provider agrees, or if the Agreement is between the MCO and an IPA/ACO or between an IPA/ ACO and an IPA/ACO, the IPA/ACO agrees and shall require the IPA´s providers to agree, to comply with all applicable requirements of the Health Insurance Portability and Accountability Act, the HIV confidentiality requirements of Article 27–F of the Public Health Law, and Mental Hygiene Law § 33.13.

Compliance program. The provider agrees that if it claims, orders or is paid $500,000 or more per year from the Medical Assistance Program, including, in the aggregate, claims submitted to or paid directly by the Medical Assistance Program and/or claims submitted to or paid by any MCO under the Medicaid Managed Care Program, that it shall adopt and implement a compliance program which meets the requirements of New York State Social Services Law § 363–d(2) and 18 NYCCR § 521-1.3

Compliance program certification. The provider agrees that if it is subject to the requirements of Section B (12) of this Appendix, it shall certify to DOH, using a form provided by OMIG on its website, within 30 days of entering into a provider Agreement with the MCO, if they have not so certified within the past year that a compliance program meeting the requirements of 18 NYCCR §521-1.3 and Social Services Law § 363–d(2) is in place. The provider shall recertify during the month of December each year thereafter using a form provided by OMIG on OMIG´s website.

C. Payment and risk arrangements

Enrollee non–liability. Provider agrees that in no event, including, but not limited to, nonpayment by the MCO or IPA/ACO, insolvency of the MCO or IPA/ACO, or breach of this Agreement, shall provider bill; charge; collect a deposit from; seek compensation, remuneration or reimbursement from; or have any recourse against a subscriber, an enrollee or person (other than the MCO or IPA/ACO) acting on his/her/their behalf, for services provided pursuant to the subscriber contract or Medicaid Managed Care contract and this Agreement, for the period covered by the paid enrollee premium. In addition, in the case of Medicaid Managed Care, provider agrees that, during the time an enrollee is enrolled in the MCO, provider will not bill DOH or the City of New York for covered services within the Medicaid Managed Care benefit package as set forth in the Agreement between the MCO and DOH. This provision shall not prohibit the provider, unless the MCO is a Managed Long-Term Care plan designated as a Program of All–Inclusive Care for the Elderly (PACE), from collecting copays, coinsurance amounts, or permitted deductibles, as specifically provided in the evidence of coverage, or fees for uncovered services delivered on a fee–for– service basis to a covered person, provided that provider shall have advised the enrollee in writing that the service is uncovered and of the enrollee´s liability therefore prior to providing the service. Where the provider has not been given a list of services covered by the MCO, and/or provider is uncertain as to whether a service is covered, the provider shall make reasonable efforts to contact the MCO and obtain a coverage determination prior to advising an enrollee as to coverage and liability for payment and prior to providing the service. This provision shall survive termination of this Agreement for any reason and shall supersede any oral or written agreement now existing or hereafter entered into between provider and enrollee or person acting on his or her behalf.

Coordination of benefits (COB). To the extent otherwise permitted in this Agreement, the provider may participate in collection of COB on behalf of the MCO, with COB collectibles accruing to the MCO or to the provider. However, with respect to enrollees eligible for medical assistance or participating in Child Health Plus, the provider shall maintain and make available to the MCO records reflecting COB proceeds collected by the provider or paid directly to enrollees by third-party payers, and amounts thereof, and the MCO shall maintain or have immediate access to records concerning collection of COB proceeds.

If the provider is a health care professional licensed, registered or certified under Title 8 of the Education Law, the MCO or the IPA/ACO must provide notice to the provider at least 90 days prior to the effective date of any adverse reimbursement arrangement as required by Public Health Law §4406–c(5–c). Adverse reimbursement change shall mean a proposed change that could reasonably be expected to have a material adverse impact on the aggregate level of payment to a health care professional. This provision does not apply if the reimbursement change is required by law, regulation or applicable regulatory authority; is required as a result of changes in fee schedules, reimbursement methodology or payment policies established by the American Medical Association current procedural terminology (CPT) codes, reporting guidelines and conventions; or such change is expressly provided for under the terms of this Agreement by the inclusion or reference to a specific fee or fee schedule, reimbursement methodology or payment policy indexing scheme.

The parties agree to comply with and incorporate the requirements of Physician Incentive Plan (PIP) Regulations contained in 42 CFR §422.208, and 42 CFR §422.210 into any contracts between the contracting entity (provider, IPA/ACO, hospital, etc.) and other persons/entities for the provision of services under this Agreement. No specific payment will be made directly or indirectly under the plan to a physician or physician group as an inducement to reduce or limit medically necessary services furnished to an enrollee.

The parties agree that, where required by Public Health Law §4903, a claim for certain continued, extended or additional health care services cannot be denied on the basis of medical necessity or a lack of prior authorization while a utilization review determination is pending if all necessary information was provided within the required timeframes and under the circumstances described in Public Health Law §4903.

Appendix B: Regulatory addendums (continued)

The parties agree to follow section 3224–a of the Insurance Law providing timeframes for the submission and payment of provider claims to the MCO.

The parties agree to follow section 3224–b(a) of the Insurance Law requiring an MCO to accept and initiate the processing of all claims submitted by physicians that conform to the American Medical Association´s Current Procedural Technology (CPT) codes, reporting guidelines and conventions, or to the Centers for Medicare & Medicaid Services´ Healthcare Common Procedure Coding System (HCPCS).

The parties agree to follow section 3224–b(b) of the Insurance Law prohibiting an MCO from initiating overpayment recovery efforts more than 24 months after the original payment was received by a health care provider, except where: (1) the plan makes overpayment recovery efforts that are based on a reasonable belief of fraud or other intentional misconduct or abusive billing; (2) for the Medicaid Managed Care and Family Health Plus programs, the overpayment recovery period for such programs is six years from date payment was received by the health care provider with written notice 30 days prior to engaging in overpayment recovery efforts. Such notice must state the patient´s name, service date, payment amount, proposed adjustment and a reasonably specific explanation of the proposed adjustment.

The parties agree to follow section 3224–c of the Insurance Law providing that claims cannot be denied solely on the basis that the MCO has not received from the member information concerning other insurance coverage.

The parties agree that this contract does not waive, limit, disclaim or in any way diminish the rights that any provider may have pursuant to section 3238 of the Insurance Law to the receipt of claims payment for services where preauthorization was required and received from the appropriate person or entity prior to the rendering of the service.

The parties agree that for a contract involving Tier 2 or 3 arrangements as described in section VII.B of the guidelines, the contract must:

- Provide for the MCO´s ongoing monitoring of provider financial capacity and/or periodic provider financial reporting to the MCO to support the transfer of risk to the provider; and
- Include a provision to address circumstance where the provider´s financial condition indicates an inability to continue accepting such risk; and
- Address MCO monitoring of the financial security deposit, describing the method and frequency of monitoring and recourse for correcting underfunding of the deposit to be maintained by the MCO; and
- Include a provision that the provider will submit any additional documents or information related to its financial condition to the MCO, if requested by DOH.
- The parties agree that for any contract involving an MCO and IPA/ACO, the contract must include provisions whereby: (i) the parties expressly agree to amend or terminate the contract at the direction of DOH (applies to Tier 1, Tier 2 and Tier 3); and (ii) the IPA/ACO will submit annual financial statements to the MCO, as well as any additional documents required by the MCO as necessary to assess the IPA/ACO´s progress towards achieving value-based payment goals as specified in the Roadmap, and the MCO will notify DOH of any substantial change in the financial condition of the IPA/ACO (applies to Tier 2 and Tier 3); and (iii) the IPA/ACO will submit any additional documents or information related to its financial condition to the MCO, if requested by DOH (applies to Tier 2 and Tier 3); and (iv) the parties agree that all provider contracts will contain provision prohibiting providers, in the event of a default by the IPA/ACO, from demanding payment from the MCO for any covered services rendered to the MCO´s enrollees for which payment was made by the MCO to the IPA/ACO pursuant to the risk agreement (applies to Tier 2 and Tier 3).

D. Records and access

Pursuant to appropriate consent/authorization by the enrollee, the provider will make the enrollee´s medical records and other personally identifiable information (including encounter data for government sponsored programs) available to the MCO (and IPA/ACO if applicable) for purposes including preauthorization, concurrent review, quality assurance, (including Quality Assurance Reporting Requirements (QARR)), payment processing and qualification for government programs, including, but not limited to, newborn eligibility for Supplemental Security Income (SSI) and for MCO/Manager analysis and recovery of overpayments due to fraud and abuse. The provider will also make enrollee´s medical records available to the state for management audits, financial audits, program monitoring and evaluation, licensure or certification of facilities or individuals and as otherwise required by state law. The provider shall provide copies of such records to DOH at no cost. The provider (or IPA/ACO if applicable) expressly acknowledges that the provider shall also provide to the MCO and the state (at no expense to the State), on request, all financial data and reports, and information concerning the appropriateness and quality of services provided, as required by law. These provisions shall survive termination of the contract for any reason.

When such records pertain to Medicaid reimbursable services, the provider agrees to disclose the nature and extent of services provided and to furnish records to DOH and/or the United States Department of Health and Human Services, the County Department of Social Services, the Comptroller of the State of New York, the Office of the Medicaid Inspector General, the New York State Attorney General, and the Comptroller General of the United States and their authorized representatives upon request. This provision shall survive the termination of this Agreement regardless of the reason.

The parties agree that medical records shall be retained for a period of six years after the date of service, and in the case of a minor, for three years after majority or six years after the date of service, whichever is later, or for such longer period as specified elsewhere within this Agreement. This provision shall survive the termination of this Agreement regardless of the reason.

The MCO and the provider agree that the MCO will obtain consent directly from enrollees at the time of enrollment or at the earliest opportunity, or that the provider will obtain consent from enrollees at the time of service is rendered or at the earliest opportunity, for disclosure of medical records to the MCO, to an IPA/ACO or to third parties. If the Agreement is between an MCO and an IPA/ACO, or between an IPA/ACO and an IPA/ACO, the IPA/ACO agrees to require the providers with which it contracts to agree as provided above. If the Agreement is between an IPA/ACO and a provider, the provider agrees to obtain consent from the enrollee if the enrollee has not previously signed consent for disclosure of medical records.

E. Termination and transition

Termination or non–renewal of an agreement between an MCO and an IPA/ACO, institutional network provider, or medical group provider that serves 5% or more of the enrolled population in a county, or the termination or non–renewal of an agreement between an IPA/ACO and an institutional provider or medical group provider that serves 5% or more of the enrolled population in a county, requires notice to the Commissioner of Health. Unless otherwise provided by statute or regulation, the effective date of termination shall not be less than 45 days after receipt of notice by either party, provided, however, that termination by the MCO may be effected on less than 45 days´ notice provided the MCO demonstrates to the satisfaction of DOH, prior to termination, that circumstances exist which threaten imminent harm to enrollees or which result in provider being legally unable to deliver the covered services and, therefore, justify or require immediate termination.

If this Agreement is between the MCO and a health care professional, the MCO shall provide to such health care professional a written explanation of the reasons for the proposed contract termination, other than non–renewal and an opportunity for a review as required by state law. The MCO shall provide the health care professional 60 days´ notice of its decision to not renew this Agreement.

If this Agreement is between an MCO and an IPA/ACO, and the Agreement does not provide for automatic assignment of the IPA/ACO's provider contracts to the MCO upon termination of the MCO/IPA/ACO contract, in the event either party gives notice of termination of the Agreement, the parties agree, and the IPA/ACO's providers agree, that the IPA/ACO providers shall continue to provide care to the MCO's enrollees pursuant to the terms of this Agreement for 180 days following the effective date of termination, or until such time as the MCO makes other arrangements, whichever occurs first. This provision shall survive termination of this Agreement regardless of the reason for the termination.

Continuation of treatment. The provider agrees that in the event of MCO or IPA/ACO insolvency or termination of this contract for any reason, the provider shall continue, until medically appropriate discharge or transfer, or completion of a course of treatment, whichever occurs first, to provide services pursuant to the subscriber contract or Medicaid Managed Care contract, to an enrollee confined in an inpatient facility, provided the confinement or course of treatment was commenced during the paid premium period. For purposes of this clause, the term "provider" shall include the IPA/ACO and the IPA/ACO's contracted providers if this Agreement is between the MCO and an IPA/ACO. This provision shall survive termination of this Agreement.

Notwithstanding any other provision herein, to the extent that the provider is providing health care services to enrollees under the Medicaid Program, the MCO or IPA/ACO retains the option to immediately terminate the Agreement when the provider has been terminated or suspended from the Medicaid Program.

In the event of termination of this Agreement, the provider agrees, and, where applicable, the IPA/ACO agrees to require all participating providers of its network to assist in the orderly transfer of enrollees to another provider.

F. Arbitration

To the extent that arbitration or alternative dispute resolution is authorized elsewhere in this Agreement, the parties to this Agreement acknowledge that the Commissioner of Health is not bound by arbitration or mediation decisions. Arbitration or mediation shall occur within New York State, and the Commissioner of Health will be given notice of all issues going to arbitration or mediation and copies of all decisions.

G. IPA/ACO–specific provisions

Any reference to IPA/ACO Quality Assurance (QA) activities within this Agreement is limited to the IPA/ACO's analysis of utilization patterns and quality of care on its own behalf and as a service to its contractual providers.

Exhibit A-1 Certification regarding lobbying

The undersigned certifies, to the best of his or her knowledge, that:

No federal appropriated funds have been paid or will be paid to any person by or on behalf of the provider for the purpose of influencing or attempting to influence an officer or employee of any agency, a member of Congress, an officer or employee of a member of Congress in connection with the award of any federal loan, the entering into any cooperative agreement, or the extension, continuation, renewal, amendment or modification of any federal contract, grant, loan or cooperative agreement.

If any funds other than federal appropriated funds have been paid or will be paid to any person for the purpose of influencing or attempting to influence an officer or employee of any agency, a member of Congress in connection with the award of any federal contract, the making of any federal grant, the making of any federal loan, the entering into any cooperative agreement or the extension, continuation, renewal, amendment or modification of this federal contract, grant, loan or cooperative agreement, and the Agreement exceeds $100,000, the provider shall complete and submit Standard Form-LLL "Disclosure Form to Reporting Lobby," in accordance with its instructions.

This certification is a material representation of fact upon which reliance was placed when this transaction was made or entered into. Submission of this certification is a prerequisite for making or entering into this transaction pursuant to U.S.C. section 1352. The failure to file the required certification shall subject the violator to a civil penalty of not less than $10,000 and not more than $100,000 for each such failure.

Pharmacy benefit managers (NY PUB HEALTH § 280-a)

4. Appeals. A PBM shall, with respect to contracts between a PBM and a pharmacy or, alternatively, a pharmacy benefit manager and a pharmacy's contracting agent, such as a pharmacy services administrative organization, include a reasonable process to appeal, investigate and resolve disputes regarding multi-source generic drug pricing. The appeals process shall include the following provisions:

(a) the right to appeal by the pharmacy and/or the pharmacy's contracting agent shall be limited to thirty (30) days following the initial claim submitted for payment;

(b) a telephone number through which a network pharmacy may contact the PBM for the purpose of filing an appeal and an electronic mail address of the individual who is responsible for processing appeals;

(c) the PBM shall send an electronic mail message acknowledging receipt of the appeal. The PBM shall respond in an electronic message to the pharmacy and/or the pharmacy's contracting agent filing the appeal within seven (7) business days indicating its determination. If the appeal is determined to be valid, the maximum allowable cost for the drug shall be adjusted for the appealing pharmacy effective as of the date of the original claim for payment. The PBM shall require the appealing pharmacy to reverse and rebill the claim in question in order to obtain the corrected reimbursement;

(d) if an update to the maximum allowable cost is warranted, the PBM or covered entity shall adjust the maximum allowable cost of the drug effective for all similarly situated pharmacies in its network in the state on the date the appeal was determined to be valid; and

(e) if an appeal is denied, the PBM shall identify the national drug code of a therapeutically equivalent drug, as determined by the federal Food and Drug Administration, that is available for purchase by pharmacies in this state from wholesalers registered pursuant to subdivision four of section sixty-eight hundred eight of the education law at a price which is equal to or less than the maximum allowable cost for that drug as determined by the PBM.

Pharmacy audits by pharmacy benefit managers (N.Y. Public Health § 280-c)

1. When conducting an audit of a pharmacy's records, a pharmacy benefit manager shall:

(a) Not conduct an on-site audit of a Pharmacy at any time during the first three calendar days of a month;

(b) Notify the Pharmacy or its contracting agent no later than 15 days before the date of initial on-site audit. Such notification to the Pharmacy or its contracting agent shall be in writing delivered either (i) by mail or common carrier, return receipt requested, or (ii) electronically with electronic receipt confirmation, addressed to the supervising pharmacist of record and pharmacy corporate office where applicable, at least 15 days before the date of an initial on-site audit;

(c) Limit the audit period to 24 months after the date a claim is submitted to or adjudicated by the pharmacy benefit manager;

(d) Include in the written advance notice of an on-site audit the list of specific prescription numbers to be included in the audit that may or may not include the final two digits of the prescription numbers;

(e) Use the written and verifiable records of a hospital, physician or other authorized practitioner, which are transmitted by any means of communication, to validate the pharmacy records in accordance with state and federal law;

(f) Limit the number of prescriptions audited to no more than 100 randomly selected in a 12-month period, except in cases of fraud;

(g) Provide the Pharmacy or its contracting agent with a copy of the preliminary audit report within 45 days after the conclusion of the audit;

(h) Be allowed to conduct a follow-up audit on-site if a remote or desk audit reveals the necessity for a review of additional claims;

(i) In the case of invoice audits, accept as validation invoices from any wholesaler registered with the department of education from which the Pharmacy has purchased prescription drugs or, in the case of durable medical equipment or sickroom supplies, invoices from an authorized distributor other than a wholesaler;

(j) Provide the Pharmacy or its contracting agent with the ability to provide documentation to address a discrepancy or audit finding, provided that such documentation must be received by the pharmacy

(k) benefit manager no later than 45 days after the preliminary audit report was provided to the Pharmacy or its contracting agent. The pharmacy benefit manager shall consider a reasonable request from the Pharmacy for an extension of time to submit documentation to address or correct any findings in the report; and

(l) Provide the Pharmacy or its contracting agent with the final audit report no later than 60 days after the initial audit report was provided to the Pharmacy or its contracting agent.

2. Any claim that was retroactively denied for a clerical error, typographical error, scrivener's error or computer error shall be paid if the prescription was properly and correctly dispensed, unless a pattern of such errors exists, fraudulent billing is alleged or the error results in actual financial loss to the entity. A clerical error is an error that does not result in actual financial harm to the covered entity or consumer and does not include the dispensing of an incorrect dose, amount or type of medication or dispensing a prescription drug to the wrong person.

3. This section shall not apply to:

(a) Audits in which suspected fraudulent activity or other intentional or willful misrepresentation is evidenced by a physical review, review of claims data or statements or other investigative methods; or

(b) Audits of claims paid for by federally funded programs; or

(c) Concurrent reviews or desk audits that occur within three business days of transmission of a claim and where no chargeback or recoupment is demanded.

B-34 North Carolina Regulatory Addendum to Pharmacy Participation Agreement

This North Carolina Addendum applies to the extent that Pharmacy provides covered drugs to persons covered by a health maintenance organization, health benefit plan, preferred provider benefit plan or insurer licensed under North Carolina law (collectively and/or individually, "plan sponsor").

In the event of a direct conflict between this Addendum and the Pharmacy Participation Agreement ("Agreement"), the applicable provisions of this Addendum shall control if required. This Addendum may be modified from time to time, pursuant to the Agreement.

Without limiting the generality of the foregoing, and notwithstanding anything in the Agreement to the contrary, Pharmacy agrees as follows:

In the event of termination of this Agreement or the insolvency of plan sponsor or pharmacy benefit manager (PBM), Pharmacy agrees to continue to provide covered drugs: (1) to covered persons receiving inpatient care until the covered persons are ready for discharge; and (2) to covered persons for the duration of the period after the plan sponsor's insolvency for which the covered person's premium payment has been made. 11 N.C.A.C. 20.0202(5)(b); N.C. Stat. § 58-67-120(2).

In the event of termination of this Agreement or the insolvency of plan sponsor or PBM, Pharmacy agrees to cooperate in the transition of administrative duties and records. 11 N.C.A.C. 20.0202(5)(a).

Pharmacy shall maintain licensure, accreditation and credentials sufficient to meet PBM's and plan sponsor's credential verification program requirements and shall notify PBM of subsequent changes in status of any information relating to Pharmacy's professional credentials. 11 N.C.A.C. 20.0202(6).

Pharmacy shall maintain professional liability insurance coverage in an amount acceptable to PBM and must notify PBM of subsequent changes in status of professional liability insurance in a timely manner. 11 N.C.A.C. 20.0202(7).

Pharmacy shall not bill any covered person for covered services, except for specified coinsurance, copays and applicable deductibles. This provision does not prohibit Pharmacy and a covered person from agreeing to continue noncovered services at the covered person's expense, as long as Pharmacy has notified the covered person in advance that the plan sponsor may not cover or continue to cover specific services and that the covered person chooses to receive the service. 11 N.C.A.C. 20.0202(8).

Pharmacy agrees to arrange for call coverage or other backup to provide service in accordance with PBM's and plan sponsor's standards for Pharmacy accessibility. 11 N.C.A.C. 20.0202(9).

PBM or plan sponsor shall provide mechanisms to allow Pharmacy to verify, before rendering services, that the patient for which the prescription has been claimed is a covered person and is entitled to covered drugs based on current information possessed by PBM and plan sponsor. 11 N.C.A.C. 20.0202(10).

Pharmacy shall: (1) maintain confidentiality of covered persons' medical records and personal information as required by N.C. Gen. Stat. 58, Art. 39 and other health records as required by law; (2) maintain adequate medical and other health records according to industry and benefit plan standards; (3) make copies of such records available to PBM, plan sponsor and the North Carolina Department of Insurance ("Department") in conjunction with its regulation of plan sponsor. 11 N.C.A.C. 20.0202(11).

Pharmacy shall cooperate fully and timely in the investigation and resolution of any complaint or grievance filed by a covered person or their authorized representative. 11 N.C.A.C. 20.0202(12).

Pharmacy shall not discriminate against covered persons on the basis of race, color, national origin, gender, age, religion, marital status, health status or health insurance coverage. 11 N.C.A.C. 20.0202(13).

PBM or plan sponsor shall provide advance notice of, and Pharmacy shall comply with, PBM's and plan sponsor's policies on benefit exclusions, administrative and utilization management programs, credentialing and quality assessment programs and provider sanction programs, provided that none of these programs shall override the professional or ethical responsibility of Pharmacy or interfere with

Pharmacy's ability to provide information or assistance to covered persons. PBM or plan sponsor shall provide notice of changes to such policies and provide Pharmacy with sufficient time to comply with such changes. 11 N.C.A.C. 20.0202(15)(b) and (16).

PBM or plan sponsor shall provide Pharmacy with performance feedback reports if Pharmacy's compensation is related to efficiency criteria. 11 N.C.A.C. 20.0202(15)(a).

Pharmacy authorizes and PBM agrees to include Pharmacy's name (or that of its parent company) in the provider directory distributed to plan sponsor's covered persons, if applicable to pharmacies. 11 N.C.A.C. 20.0202(17).

Pharmacy shall not assign, delegate or transfer its duties and obligations under this Agreement without PBM's prior written consent. PBM or plan sponsor shall notify Pharmacy, in writing, of any duties or obligations that are to be delegated or transferred before such delegation or transfer. 11 N.C.A.C. 20.0202(19).

In the event that PBM or plan sponsor fails to pay for covered drugs as set forth in this Agreement, the covered person shall not be liable to Pharmacy for any sums owed by PBM or plan sponsor. No other provision of this Agreement shall, under any circumstances, change the effect of this section. Pharmacy, its agent, trustee or assignee may not maintain any action at law against a covered person to collect any sums owed by PBM or plan sponsor. N.C. Stat. § 58-67-115.

Pharmacy acknowledges and agrees that plan sponsor retains the right and ability to approve or disapprove Pharmacy's participation as well as the ability to monitor and oversee Pharmacy's offering of services to covered persons. 11 N.C.A.C. 20.0204.

PBM or plan sponsor shall provide Pharmacy with information about plan sponsor's benefit designs and incentives that are used to encourage covered persons to use preferred providers. N.C. Stat. § 58-50-56(f).

The reimbursement methodology under the Agreement is fee-for-service. 11 N.C.A.C. 20.0202(14).

To the extent definitions within the Agreement conflict with those set forth in the benefit plan, the benefit plan documents shall control. 11 N.C.A.C. 20.0202(2).

Notices required to be given to a party pursuant to the Agreement shall be in writing and addressed to the party at the address set forth in the Agreement and shall be deemed given and received: (i) five business days following the date the notices were placed, first-class postage prepaid, in the United States mail; (ii) on the day the notice is hand delivered; (iii) for certified or registered mail, the date on the return receipt; or (iv) for commercial courier service, the date of delivery. N.C. Stat. § 58-50-275(b).

Notwithstanding anything to the contrary in the Agreement, nothing herein shall:

Prohibit or grant PBM or plan sponsor an option to prohibit Pharmacy from contracting with another health insurance carrier to provide health care services at a rate that is equal to or lower than the payment specified in the contract;

Require Pharmacy to accept a lower payment rate in the event that the Pharmacy agrees to provide health care services to any other health insurance carrier at a rate that is equal to or lower than the payment specified in the contract;

Require or grant PBM or plan sponsor an option to require termination or renegotiation of an existing health care contract in the event that Pharmacy agrees to provide health care services to any other health insurance carrier at a rate that is equal to or lower than the payment specified in the contract;

Require or grant PBM or plan sponsor an option to require Pharmacy to disclose, directly or indirectly, Pharmacy's contractual rates with another health insurance carrier;

Require or grant PBM or plan sponsor an option to require the non-negotiated adjustment by the issuer of Pharmacy's contractual rate to equal the lowest rate Pharmacy has agreed to charge any other health insurance carrier; or

Require or grant PBM or plan sponsor an option to require Pharmacy to charge another health insurance carrier a rate that is equal to or more than the reimbursement rate specified in the contract. N.C. Stat. § 58-50-295.

Maximum allowable cost price (NC ST § 58-56A-5)

(a) In order to place a prescription drug on the maximum allowable cost price list, the drug must be available for purchase by pharmacies in North Carolina from national or regional wholesalers, must not be obsolete, and must meet one of the following conditions:

(1) The drug is listed as "A" or "B" rated in the most recent version of the United States Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the Orange Book.

(2) The drug has a "NR" or "NA" rating, or a similar rating, by a nationally recognized reference.

(b) A PBM shall adjust or remove the maximum allowable cost price for a prescription drug to remain consistent with changes in the national marketplace for prescription drugs. A review of the maximum allowable cost prices for removal or modification shall be completed by the PBM at least once every seven (7) business days, and any removal or modification shall occur within seven (7) business days of the review. A PBM shall provide a means by which the contracted pharmacies may promptly review current prices in an electronic, print, or telephonic format within one business day of the removal or modification.

(c) A PBM shall ensure that dispensing fees are not included in the calculation of maximum allowable cost price.

(d) A PBM shall establish an administrative appeals procedure by which a contracted pharmacy or pharmacist, or a designee, may appeal the provider's reimbursement for a prescription drug subject to maximum allowable cost pricing if the amount of reimbursement for the drug is less than the net amount that the network provider paid to the suppliers of the drug. The reasonable administrative appeal procedure must include all of the following:

(1) A dedicated telephone number and email address or website for the purpose of submitting administrative appeals.

(2) The ability to submit an administrative appeal regarding the pharmacy benefits plan or program directly to the PBM or through a pharmacy service administrative organization if the pharmacy service administrative organization has a contract with the PBM that allows for the submission of appeals.

(3) No less than ten (10) calendar days after the applicable prescription fill date to file an administrative appeal.

(4) A period of no more than ten (10) calendar days after receipt of notice of the filing of the administrative appeal by the PBM for a decision to be made on the appeal.

(5) A requirement that if an appeal is upheld, then, within ten (10) calendar days of the decision, the PBM shall take all of the following actions:

a. Notify the appellant of the decision.

b. Apply the change in the maximum allowable cost effective as of the date the appeal was resolved and make the change effective for all similarly situated pharmacies or pharmacists, as defined by the payor subject to the Maximum Allowable Cost list.

c. Permit the appellant to reverse and rebill the claim that was appealed.

(6) A requirement that if the appeal is denied, then, within ten (10) calendar days of the decision, the PBM shall notify the appellant of the decision and provide all of the following information:

a. The reason for denial.

b. The National Drug Code number for the prescription drug that is the subject of the appeal.

c. The names of the national or regional pharmaceutical wholesalers operating in the State.

Declaration of pharmacy rights during audit (N.C. Stat. § 90-85.50)

(b) Notwithstanding any other provision of law, whenever a managed care company, insurance company, third-party payer or any entity that represents a responsibility conducts an audit of the records of a pharmacy, the Pharmacy has a right to all of the following:

(1) To have at least 14 days' advance notice of the initial on-site audit for each audit cycle.

(2) To have any audit that involves clinical judgment be done with a pharmacist who is licensed and employed or working under contract with the auditing entity.

(3) Not to have clerical or recordkeeping errors, including typographical errors, scrivener's errors and computer errors, on a required document or record, in the absence of any other evidence, deemed fraudulent. This subdivision does not prohibit recoupment of fraudulent payments.

(4) If required under the terms of the contract, to have the auditing entity provide a Pharmacy, upon request, all records related to the audit in an electronic format or contained in digital media.

(5) To have the properly documented records of a hospital or any person authorized to prescribe controlled substances for the purpose of providing medical or pharmaceutical care for their patients transmitted by any means of communication in order to validate a pharmacy record with respect to a prescription or refill for a controlled substance or narcotic drug.

(6) To have a projection of an overpayment or underpayment based on either the number of patients served with a similar diagnosis or the number of similar prescription orders or refills for similar drugs. This subdivision does not prohibit recoupments of actual overpayments, unless the projection for overpayment or underpayment is part of a settlement by the Pharmacy.

(7) Prior to the initiation of an audit, if the audit is conducted for an identified problem, the audit is limited to claims that are identified by prescription number.

(8) If an audit is conducted for a reason other than described in subdivision (6) of this subsection, the audit is limited to 100 selected prescriptions.

(9) If an audit reveals the necessity for a review of additional claims, to have the audit conducted on site.

(10) Except for audits initiated for the reason described in subdivision (6) of this subsection, to be subject to no more than one audit in one calendar year, unless fraud or misrepresentation is reasonably suspected.

(11) Except for cases of Food and Drug Administration regulation or drug manufacturer safety programs, to be free of recoupments based on any of the following unless defined within the billing requirements set forth in the pharmacy Provider Manual not inconsistent with current North Carolina Board of Pharmacy regulations:

a. Documentation requirements in addition to or exceeding requirements for creating or maintaining documentation prescribed by the State Board of Pharmacy.

b. A requirement that a Pharmacy or pharmacist perform a professional duty in addition to or exceeding professional duties prescribed by the State Board of Pharmacy.

(12) To be subject to recoupment only following the correction of a claim and to have recoupment limited to amounts paid in excess of amounts payable under the corrected claim.

(13) Except for Medicare claims, to be subject to reversals of approval for drug, prescriber or patient eligibility upon adjudication of a claim only in cases in which the Pharmacy obtained the adjudication by fraud or misrepresentation of claim elements.

(14) To be audited under the same standards and parameters as other similarly situated pharmacies audited by the same entity.

(15) To have at least 30 days following receipt of the preliminary audit report to produce documentation to address any discrepancy found during an audit.

(16) To have the period covered by an audit limited to 24 months from the date a claim was submitted to, or adjudicated by, a managed care company, an insurance company, a third-party payer or any entity that represents responsible parties, unless a longer period is permitted by a federal plan under federal law.

(17) Not to be subject to the initiation or scheduling of audits during the first five calendar days of any month due to the high volume of prescriptions filled during that time, without the express consent of the Pharmacy. The Pharmacy shall cooperate with the auditor to establish an alternate date should the audit fall within the days excluded.

(18) To have the preliminary audit report delivered to the Pharmacy within 120 days after conclusion of the audit.

(19) To have a final audit report delivered to the Pharmacy within 90 days after the end of the appeals period, as provided for in N.C. Stat. § 90-85.51.

(20) Not to have the accounting practice of extrapolation used in calculating recoupments or penalties for audits, unless otherwise required by federal requirements or federal plans.

(21) Not to be subject to recoupment on any portion of the reimbursement for the dispensed product of a prescription, unless otherwise provided in this subdivision:

a. Recoupment of reimbursement, or a portion of reimbursement, for the dispensed product of a prescription may be had in the following cases:

1. Fraud or other intentional and willful misrepresentation evidenced by a review of the claims data, statements, physical review or other investigative methods.
2. Dispensing in excess of the benefit design, as established by the plan sponsor.
3. Prescriptions not filled in accordance with the prescriber's order.
4. Actual overpayment to the Pharmacy.

b. Recoupment of claims in cases set out in sub-subdivision a. of this subdivision shall be based on the actual financial harm to the entity or the actual underpayment or overpayment. Calculations of overpayments shall not include dispensing fees unless one of the following conditions is present:

1. A prescription was not actually dispensed.
2. The prescriber denied authorization.
3. The prescription dispensed was a medication error by the Pharmacy. For purposes of this subdivision, a medication error is dispensation of the wrong drug, dispensation to the wrong patient or dispensation with the wrong directions.
4. The identified overpayment is based solely on an extra dispensing fee.
5. The Pharmacy was noncompliant with Risk Evaluation and Mitigation Strategies program guidelines.
6. There was insufficient documentation, including electronically stored information, as described in this subsection.
7. Fraud or other intentional and willful misrepresentation by the Pharmacy.

(22) To have an audit based only on information obtained by the entity conducting the audit and not based on any audit report or other information gained from an audit conducted by a different auditing entity. This subdivision does not prohibit an auditing entity from using an earlier audit report prepared by the auditing entity for the same Pharmacy. Except as required by state or federal law, an entity conducting an audit may have access to a Pharmacy's previous audit report only if the previous report was prepared by that entity.

(23) If the audit is conducted by a vendor or subcontractor, that entity is required to identify the responsible party on whose behalf the audit is being conducted without having this information being requested.

(24) To use any prescription that complies with federal or state laws and regulations at the time of dispensing to validate a claim in connection with a prescription, prescription refill or a change in a prescription.

Mandatory appeals process (N.C. Stat. § 90-85.51)

(a) Each entity that conducts an audit shall establish an appeals process under which a Pharmacy may appeal an unfavorable preliminary audit report to the entity.

(b) If, following the appeal, the entity finds that an unfavorable audit report or any portion of the unfavorable audit report is unsubstantiated, the entity shall dismiss the unsubstantiated portion of the audit report without any further proceedings.

(c) Each entity conducting an audit shall provide a copy, if required under contractual terms, of the audit findings to the plan sponsor after completion of any appeals process.

Pharmacy audit recoupments (N.C. Stat. § 90-85.52)

(a) The entity conducting an audit shall not recoup any disputed funds, charges or other penalties from a Pharmacy until (i) the deadline for initiating the appeals process established pursuant to N.C. Stat. § 90-85.51 has elapsed or (ii) after the final internal disposition of an audit, including the appeals process as set forth in N.C. Stat. § 90-85.51, whichever is later, unless fraud or misrepresentation is reasonably suspected.

(b) Recoupment on an audit shall be refunded to the responsible party as contractually agreed upon by the parties.

(c) The entity conducting an audit may charge or assess the responsible party, directly or indirectly, based on amounts recouped if both of the following conditions are met:

(1) The responsible party and the entity conducting the audit have entered a contract that explicitly states the percentage charge or assessment to the responsible party.

(2) A commission or other payment to an agent or employee of the entity conducting the audit is not based, directly or indirectly, on amounts recouped.

Applicability (N.C. Stat. § 90-85.53)

This article does not apply to any audit, review or investigation that involves alleged Medicaid fraud, Medicaid abuse, insurance fraud or other criminal fraud or misrepresentation.

Disclosure of ownership requirements (N.C. Stat. §58-56B-10)

(d) *Updates to Required Disclosure*. If there is any material change in ownership or control of a PSAO relating to any disclosure required under N.C. Stat. §58-56B-10, then a PSAO shall notify the Department and all relevant independent pharmacies, PBMs and third-party payers of this change within 10 calendar days of the change.

Contract Requirements (N.C Stat. § 58-56B-15)

(b) A contract between a PSAO and an independent pharmacy, PBM or third-party payer shall include the requirement that the PSAO update disclosures in accordance with NC ST §58-56B-10(d).

B-35 North Dakota Regulatory Addendum to Pharmacy Participation Agreement

This North Dakota Addendum applies to the extent that Pharmacy provides covered drugs to covered persons of health maintenance organizations, managed care organizations, health service corporations, insurers or carriers under North Dakota law (collectively and/or individually, "plan sponsor").

In the event of a direct conflict between this Addendum and the Agreement, the applicable provisions of this Addendum shall control if required. This Addendum may be modified from time to time pursuant to the Agreement.

Without limiting the generality of the foregoing, and notwithstanding anything in the Agreement to the contrary, Pharmacy agrees as follows:

Pharmacy will in no event (including, but not limited to, nonpayment by PBM or any plan sponsor, PBM or any plan sponsor's insolvency, or breach of this Agreement) bill, charge, collect a deposit from, seek compensation, remuneration or reimbursement from or have any recourse against, a covered person or other persons acting on their behalf. Neither Pharmacy or its agents, trustees, or assignees may maintain an action at law or attempt to collect from covered persons amounts owed to Pharmacy by plan sponsor or PBM. This provision does not prohibit the collection of copays or charges for noncovered services or items consented to by covered persons. This limitation shall survive termination of this Agreement for any reason. N.D. Code §§ 26.1-17.1-16; 26.1-18.1-12.(4)

Notwithstanding anything to the contrary in the Agreement, Pharmacy shall not be required to indemnify PBM or plan sponsor for negligence, willful misconduct or breach of contract committed by PBM or plan sponsor, and Pharmacy shall not be deemed to have waived any right to seek legal redress against PBM or plan sponsor. N.D. Code § 26.1-04-03(16).

To the extent Pharmacy services covered persons of an HMO under North Dakota Law, Pharmacy agrees that notwithstanding anything in the Agreement to the contrary, Pharmacy must give PBM at least 60 days' advance notice of termination of the Agreement. N.D. Code § 26.1-18.1-12(6).

Maximum allowable cost lists for pharmaceuticals — Pharmacy benefits managers — Penalty (ND ST 19-02.1-14.2)

2. With respect to each contract between a PBM and a pharmacy, each PBM shall:

a. Provide to the pharmacy, at the beginning of each contract and contract renewal, the sources utilized to determine the maximum allowable cost pricing of the PBM.

b. Update any maximum allowable cost price list at least every seven (7) business days, and provide prompt notification of the pricing changes to network pharmacies.

c. Disclose the sources utilized for setting maximum allowable cost price rates on each maximum allowable cost price list included under the contract and identify each maximum allowable cost price list that applies to the contracted pharmacy. A PBM shall make the list of the maximum allowable costs available to a contracted pharmacy in a format that is readily accessible and usable to the contracted pharmacy.

d Ensure maximum allowable cost prices are not set below sources utilized by the PBM.

e. Provide a reasonable administrative appeals procedure to allow a dispensing pharmacy provider to contest a listed maximum allowable price rate. The PBM shall provide a determination to a provider that has contested a maximum allowable price rate within seven (7) business days. If an update to the maximum allowable price rate for an appealed drug is warranted, the PBM shall make the change based on the date of the determination and make the adjustment effective for all similarly situated pharmacy providers in this state within the network.

f. Ensure dispensing fees are not included in the calculation of maximum allowable cost price reimbursement to pharmacy providers.

3. A PBM may not place a prescription drug on a maximum allowable price list unless:

a. The drug has at least two nationally available, therapeutically equivalent, multiple source drugs or a generic drug is available only from one manufacturer;

b. The drug is listed as therapeutically equivalent and pharmaceutically equivalent or "A" or "B" rated in the United States food and drug administration's most recent version of the "Orange Book" or the drug is "Z" rated; and

c. The drug is generally available for purchase by pharmacies in the state from national or regional wholesalers and not obsolete.

4. This section does not apply to state Medicaid programs.

Pharmacy benefits manger audit — Rules (N.D. Code § 19-03.6-02)

1. An entity conducting an audit of a Pharmacy shall:

a. If conducting an onsite audit, give the Pharmacy a written notice at least 14 business days before conducting an initial audit.

b. If the audit involves clinical or professional judgment, ensure the audit is conducted by or in consultation with a pharmacist licensed in any state and employed by or contracted with the pharmacy benefit manager.

c. Limit the audit to no more than 24 months from the date that the claim was submitted to or adjudicated by the entity. A claim may not be reviewed that is older than 24 months from the date of the audit, unless a longer period is permitted under federal law.

d. Refrain from conducting the audit during the first five business days of the month unless otherwise consented to by the pharmacy.

e. Refrain from entering the pharmacy area where patient-specific information is available and remain out of sight and hearing range of the pharmacy customers. The Pharmacy shall designate an area for auditors to conduct their business.

f. Allow the Pharmacy to use the records, including a medication administration record, of a hospital, physician or other authorized practitioner to validate the pharmacy record and delivery.

g. Allow the Pharmacy to use any legal prescription, including medication administration records, electronic documents or documented telephone calls from the prescriber or the prescriber's agents to validate claims in connection with prescriptions and refills or changes in prescriptions.

2. An audit may not allow a recoupment to be assessed for items on the face of a prescription not required by rules adopted by the State Board of Pharmacy with respect to patient hard copy prescription forms for controlled and uncontrolled drugs.

3. A finding of overpayment or underpayment may be based only on the actual overpayment or underpayment and not on a projection based on the number of patients served having a similar diagnosis or on the number of similar orders or refills for similar drugs. A calculation of an overpayment may not include dispensing fees, unless a prescription was not dispensed or the prescriber denied authorization. In the case of an error that has no financial harm to the patient or plan, the pharmacy benefit manager may not assess any chargeback. The entity conducting the audit may not use extrapolation in calculating the recoupment or penalties for audits. Any recoupment may not be deducted against future remittances and must be invoiced to the Pharmacy for payment. An entity performing an audit may not receive payment based on a percentage of the amount recovered. Interest may not accrue during the audit period, which begins with the notice of audit and ends with the final audit report.

4. A clerical or recordkeeping error may not be considered fraud but may be subject to recoupment. A person is not subject to any criminal penalty for a clerical or recordkeeping error without proof of intent to commit fraud.
5. The parameters of an audit must comply with consumer-oriented parameters based on manufacturer listings or recommendations for the following:

a. The days' supply for eye drops must be calculated so that the consumer pays only one 30-day copay if the bottle of eye drops is intended by the manufacturer to be a 30-day supply.

b. The days' supply for insulin must be calculated so that the highest dose prescribed is used to determine the days' supply and consumer copay.

c. The days' supply for a topical product must be determined by the judgment of the pharmacist based upon the treated area.

6. Unless an alternate price is published in a provider contract and signed by both parties, the usual and customary price charged by a Pharmacy for compounded medications is considered to be the reimbursable cost.
7. An entity conducting an audit shall utilize the same standards and parameters in auditing a Pharmacy the entity uses with other similarly situated pharmacies.
8. An entity conducting an audit shall establish a written appeals process.

Audit reports — Disclosure — Distribution of recouped funds – Review of auditor (N.D. Code § 19- 03.6-03)

1. A preliminary audit report must be delivered to the Pharmacy within 120 days after the conclusion of the audit.
2. A Pharmacy must be allowed at least 60 days following receipt of the preliminary audit to provide documentation to address any discrepancy found in the audit.
3. A final audit report must be delivered to the Pharmacy within 90 days after receipt of the preliminary audit report or final appeal, whichever is later.
4. No chargeback, recoupment or other penalty may be assessed until the appeal process has been exhausted and the final report issued.
5. An entity shall remit any money due to a Pharmacy or pharmacist as a result of an underpayment of a claim within 30 days after the appeals process has been exhausted and the final audit report has been issued.
6. An auditing entity shall provide a copy of the final report to the plan sponsor for which claims were included in the audit. Any funds recouped must be returned to the plan sponsor.

Applicability (N.D. Code § 19-03.6-04)

2. This chapter does not apply to any audit, review or investigation that is initiated based upon alleged fraud, willful misrepresentation or abuse, including:

a. Insurance fraud as defined in chapter 26.1-02.1.

b. Billing for services not furnished or supplies not provided.

c. Billing that appears to be a deliberate application for duplicate payment for the same services or supplies, billing both the beneficiary and the pharmacy benefit manager or payer for the same service.

d. Altering claim forms, electronic claim records or medical documentation to obtain a higher payment amount.

e. Soliciting, offering or receiving a kickback or bribe.

f. Participating in any scheme that involves collusion between a provider and a beneficiary or between a supplier and a provider which results in higher costs or charges to the entity.

g. Misrepresenting a date or description of services furnished or the identity of the beneficiary or the individual who furnished the services.

h. Billing for a prescription without a prescription on file in a situation in which an over-the-counter item is dispensed.

i. Dispensing a prescription using an out-of-date drug.

j. Billing with an incorrect National Drug Code or billing for a brand name when a generic drug is dispensed.

k. Failing to credit the payer for a medication or a portion of a prescription that was not obtained by the payer within 14 days unless extenuating circumstances exist.

l. Billing the payer a higher price than the Usual and Customary Charge of the Pharmacy to the general public.

m. Billing for a product without proof that the purchaser purchased the product.

3. Any case of suspected fraud or violation of law must be reported by an auditor to the licensing board.

4. This chapter does not apply to state Medicaid programs.

B-36 Ohio Regulatory Addendum to Pharmacy Participation Agreement

This Ohio Addendum applies to the extent that Pharmacy provides covered drugs to covered persons of insurers, health insuring corporations, health maintenance organizations and health benefit plans under Ohio law (collectively and/or individually, "plan sponsor").

In the event of a direct conflict between this Addendum and the Agreement, the applicable provisions of this Addendum shall control if required. This Addendum may be modified from time to time pursuant to the Agreement.

Without limiting the generality of the foregoing, and notwithstanding anything in the Agreement to the contrary, Pharmacy agrees as follows:

Pharmacy agrees to provide services to covered persons as further set forth in the Agreement. Ohio Code § 1751.13(C)(1).

Pharmacy agrees that in no event, including, but not limited to, nonpayment by plan sponsor or PBM, insolvency of plan sponsor or PBM, or breach of the Agreement, shall Pharmacy bill, charge, collect a deposit from, seek remuneration or reimbursement from, or have any recourse against a covered person to whom health care services have been provided, or person acting on behalf of the covered person, for health care services provided pursuant to the Agreement. This does not prohibit Pharmacy from collecting coinsurance, deductibles or copays as specifically provided in the evidence of coverage, or fees for uncovered health care services delivered on a fee-for-service basis to persons referenced above, nor from any recourse against plan sponsor or its successor. This provision shall survive termination of the Agreement with respect to covered drugs provided during the time the Agreement was in effect, regardless of the reason for the termination, including the insolvency of PBM or plan sponsor. Ohio Code §§ 1751.13(C)(2), (12); 1751.60(C).

In the event of PBM or plan sponsor's insolvency or discontinuance of operations, Pharmacy shall continue to provide covered drugs to covered persons as needed to complete any medically necessary procedures commenced but unfinished at the time of the insolvency or discontinuance of operations. The completion of a medically necessary procedure shall include the rendering of all covered drugs that constitute medically necessary follow-up care for that procedure. If a covered person is receiving necessary inpatient care at a hospital, Pharmacy shall continue to provide services until the earliest of the following: (a) the covered person's discharge from the hospital; (b) the determination by the covered person's attending physician that inpatient care is no longer medically indicated; (c) the covered person's reaching the limit for contractual benefits; or (d) the effective date of any new coverage. This provision shall not require Pharmacy to continue to provide covered drugs after the occurrence of any of the following:

The end of the 30-day period following the entry of a liquidation order under chapter 3909 of the Ohio revised code;

The end of the covered person's period of coverage for a contractual prepayment or premium;

The covered person obtains equivalent coverage with another health insuring corporation or insurer, or the covered person's employer obtains such coverage for the covered person;

The covered person or the covered person's employer terminates coverage under the benefit plan; or

A liquidator affects a transfer of the plan sponsor's obligations under the benefit plan pursuant to Ohio law. Ohio Code § 1751.13(C)(3).

Pharmacy shall abide by PBM and plan sponsor's administrative policies and programs, including, but not limited to, payment systems, utilization review, quality assurance, assessment, improvement programs, credentialing, confidentiality requirements and any applicable federal or state programs as further set forth in the Agreement. Ohio Code § 1751.13(C)(4).

Pharmacy agrees to make available its records to PBM and plan sponsor to monitor and evaluate the quality of care, to conduct evaluations and audits, and to determine on a concurrent or retrospective basis the necessity of and appropriateness of health care services provided to covered persons as set forth in the Agreement. Pharmacy agrees to make its health records available to state and federal authorities involved in assessing the quality of care or investigating the grievances or complaints of covered persons. Pharmacy further agrees to comply with applicable state and federal laws related to the confidentiality of medical or health records. Ohio Code § 1751.13(C)(5).

Pharmacy shall not assign or delegate the contractual rights and responsibilities under the Agreement without the prior written consent of PBM. Ohio Code § 1751.13(C)(6).

Pharmacy shall maintain adequate professional liability and malpractice insurance as set forth in the Agreement. Pharmacy shall notify PBM not more than 10 days after Pharmacy's receipt of notice of any reduction or cancellation of such coverage. Ohio Code § 1751.13(C)(7).

Pharmacy shall observe, protect and promote the rights of covered persons as patients. Ohio Code § 1751.13(C)(8).

Pharmacy shall provide health care services without discrimination on the basis of the covered person's participation in the benefit plan, age, sex, ethnicity, religion, sexual preference, health status or disability, and without regard to the source of payments made for service rendered to covered persons. This requirement shall not apply to circumstances when Pharmacy does not render services due to limitations arising from Pharmacy's lack of training, experience or skill, or due to licensing restrictions. Ohio Code § 1751.13(C)(9).

Resolution of disputes arising out of the Agreement shall be resolved pursuant to the terms set forth therein. Ohio Code § 1751.13(C)(11).

Terms used in the Agreement that are defined by Title XVII [17], Chapter 1751, Ohio revised code, shall be construed in a manner consistent with those statutory definitions. Ohio Code § 1751.13(C)(13).

Plan sponsor retains the right to approve or disapprove Pharmacy's participation under the Agreement. Ohio Code §§ 1751.13(E), (F)(3).

Pharmacy acknowledges that plan sponsor is a third-party beneficiary of the Agreement. Ohio Code § 1751.13(F)(2).

Pharmacy acknowledges that plan sponsor retains statutory responsibility to monitor and oversee the offering of covered drugs to its covered persons. Ohio Code § 1751.13(G).

Maximum allowable cost lists (OH ST § 3959.111)

(A)(1)(a) In each contract between a PBM and a pharmacy, the pharmacy shall be given the right to obtain from the PBM, within ten (10) days after any request, a current list of the sources used to determine maximum allowable cost pricing. In each contract between a PBM and a pharmacy, the PBM shall be obligated to update and implement the pricing information at least every seven (7) days and provide a means by which contracted pharmacies may promptly review maximum allowable cost pricing updates in an electronic format that is readily available, accessible, and secure and that can be easily searched.

Subject to division (A)(1) of this section, a PBM shall utilize the most up-to-date pricing data when calculating drug product reimbursements for all contracting pharmacies within one (1) business day of any price update or modification.

(b) A PBM shall maintain a written procedure to eliminate products from the list of drugs subject to maximum allowable cost pricing in a timely manner. The written procedure, and any updates, shall promptly be made available to a pharmacy upon request.

(2) In each contract between a PBM and a pharmacy, a PBM shall be obligated to ensure that all of the following conditions are met prior to placing a prescription drug on a maximum allowable cost list:

(a) The drug is listed as "A" or "B" rated in the most recent version of the United States food and drug administration's approved drug products with therapeutic equivalence evaluations, or has an "NR" or "NA" rating or similar rating by nationally recognized reference.

(b) The drug is generally available for purchase by pharmacies in this state from a national or regional wholesaler and is not obsolete.

(3) Each contract between a PBM and a pharmacy shall include an electronic process to appeal, investigate, and resolve disputes regarding maximum allowable cost pricing that includes all of the following:

(a) A twenty-one (21) day limit on the right to appeal following the initial claim;

(b) A requirement that the appeal be investigated and resolved within twenty-one (21) days after the appeal;

(c) A telephone number at which the pharmacy may contact the PBM to speak to a person responsible for processing appeals;

(d) A requirement that a PBM provide a reason for any appeal denial, including the national drug code and the identity of the national or regional wholesalers from whom the drug was generally available for purchase at or below the benchmark price determined by the PBM;

(e) A requirement that if the appeal is upheld or granted, then the PBM shall adjust the drug product reimbursement to the pharmacy's upheld appeal price;

(f) A requirement that a PBM make an adjustment not later than one (1) day after the date of determination of the appeal. The adjustment shall be retroactive to the date the appeal was made and shall apply to all situated pharmacies as determined by the PBM. This requirement does not prohibit a PBM from retroactively adjusting a claim for the appealing pharmacy or for any other similarly situated pharmacies.

Conditions for auditing entity (Ohio Code § 3901.811)

(A) Except as provided in division (B) of this section, an auditing entity is subject to all of the following conditions when performing a pharmacy audit in this state:

(1) If it is necessary that the pharmacy audit be performed on the premises of a Pharmacy, the auditing entity shall give the Pharmacy that is the subject of the audit written notice of the date or dates on which the audit will be performed and the range of prescription numbers from which the auditing entity will select pharmacy records to audit. Notice of the date or dates on which the audit will be performed shall be given not less than 10 business days before the date the audit is to commence. Notice of the range of prescription numbers from which the auditing entity will select pharmacy records to audit shall be received by the Pharmacy not less than seven business days before the date the audit is to commence.

(2) The auditing entity shall not include in the pharmacy audit a review of a claim for payment for the provision of dangerous drugs or pharmacy services if the date of the Pharmacy's initial submission of the claim for payment occurred more than 24 months before the date the audit commences.

(3) Absent an indication that there was an error in the dispensing of a drug, the auditing entity or payer shall not seek to recoup from the pharmacy that is the subject of the audit any amount that the pharmacy audit identifies as being the result of clerical or recordkeeping errors in the absence of financial harm. For purposes of this provision, an error in the dispensing of a drug is any of the following: selecting an incorrect drug, issuing incorrect directions or dispensing a drug to the incorrect patient.

(4) The auditing entity shall not use the accounting practice of extrapolation when calculating a monetary penalty to be imposed or amount to be recouped as the result of the pharmacy audit.

(B)(1) The condition in division (A)(1) of this section does not apply if, prior to the audit, the auditing entity has evidence, from its review of claims data, statements, or physical evidence or its use of other investigative methods, indicating that fraud or other intentional or willful misrepresentation exists.

(2) The condition in division (A)(3) of this section does not apply if the auditing entity has evidence, from its review of claims data, statements or physical evidence or its use of other investigative methods, indicating that fraud or other intentional or willful misrepresentation exists.

(3) Division (A)(4) of this section does not apply when the accounting practice of extrapolation is required by state or federal law.

Pharmacy powers (Ohio Code § 3901.812)

A Pharmacy may do any of the following when a pharmacy audit is performed:

(A) Validate a pharmacy record by using original or photocopied records from hospitals, physicians or other health care providers;

(B) Validate one or more claims for payment for the provision of dangerous drugs or pharmacy services by using either of the following:

(1) An original pharmacy record or photocopy of the record;

(2) An original prescription or photocopy of the prescription in any form that constitutes a valid prescription in this state, including a written prescription, a prescription made through an electronic prescribing system, a prescription delivered by facsimile, a prescription made by issuing an order for medication administration and the record a pharmacist maintains under section 4729.37 of the revised code documenting a prescription received by telephone.

(C) Resubmit a disputed or denied claim for payment using any commercially reasonable method of resubmission, including resubmission by facsimile, mail or electronic means, as long as the time period for resubmissions established by the relevant payer has not expired.

Post-audit procedures (Ohio Code § 3901.813)

(A) Except as provided in division (B) of this section, all of the following apply after a pharmacy audit is completed:

(1) A Pharmacy shall be given not less than 30 days from the date of the on-site audit to provide the auditing entity any additional information necessary to complete the preliminary audit report.

(2) Not later than 60 business days after the audit is completed, the auditing entity shall deliver a preliminary audit report to the Pharmacy that was the subject of the audit.

(3) A Pharmacy that disputes any finding in the preliminary audit report may submit documentation to the auditing entity to appeal the finding. A Pharmacy shall be given not less than 30 business days to make the submission and may request an extension of the time period given. The auditing entity shall grant a request for an extension if it is reasonable.

A pharmacy's submission of documentation to appeal the finding shall be made in accordance with the procedure the auditing entity has established under section 3901.814 of the revised code.

(4)(a) An auditing entity shall deliver a final audit report to the Pharmacy that was the subject of the audit. Except as provided in division (A)(4)(b) of this section, the report shall be delivered not later than 120 business days after the pharmacy's receipt of a preliminary audit report.

(b) If an auditing entity has granted a pharmacy's request for an extension of the time to submit documentation to appeal a finding in the preliminary audit report under division (A)(3) of this section, the time limit described in division (A)(4)(a) of this section for the delivery of the final audit report is waived. Instead, the auditing entity shall deliver the final audit report not later than 120 days after the pharmacy's submission of the documentation.

(B) The provisions of division (A) of this section do not apply if the auditing entity has evidence, from its review of claims data, statements or physical evidence or its use of other investigative methods, indicating that fraud or other intentional or willful misrepresentation exists.

Appeal procedures (Ohio Code § 3901.814)

Each auditing entity in this state shall establish in writing separate procedures for a Pharmacy to appeal one or more findings in a preliminary audit report issued under section 3901.813 of the revised code.

Applicability (Ohio Code § 3901.815)

Sections 3901.811 to 3901.814 of the revised code shall not apply to an auditing entity that is a Medicaid managed care organization if application of those sections to the entity would be in violation of federal law.

B-37 Oklahoma Regulatory Addendum to Pharmacy Participation Agreement

This Oklahoma Addendum applies to the extent that Pharmacy provides covered drugs to covered persons of health maintenance organizations, preferred provider organizations, health services corporations, multiple employer welfare arrangements, health insurance service organizations and insurers under Oklahoma law (collectively and/or individually, "plan sponsor").

In the event of a direct conflict between this Addendum and the Agreement, the applicable provisions of this Addendum shall control if required. This Addendum may be modified from time to time pursuant to the Agreement.

Without limiting the generality of the foregoing, and notwithstanding anything in the Agreement to the contrary, Pharmacy agrees as follows:

To the extent Pharmacy provides covered drugs to covered persons of a health maintenance organization under Oklahoma law, Pharmacy agrees:

In the event that plan sponsor or PBM fails to pay for covered drugs as set forth in the Agreement, covered person shall not be liable to Pharmacy for any sums owed by plan sponsor or PBM. 36 Okla. Stat. § 6913(D)(1).

Pharmacy shall provide covered drugs for the duration of the period after plan sponsor's insolvency for which premium payment has been made and until the covered person's discharge from an inpatient facility. 36 Okla. Stat. § 6913(E)(2).

If Pharmacy terminates the Agreement, Pharmacy shall provide PBM at least 90 days' written notice. 36 Okla. Stat. § 6913(F).

Pharmacy benefits manager — Contractual duties to provider (OK ST T. 59 § 360)

A. The PBM shall, with respect to contracts between a PBM and a provider, including a pharmacy service administrative organization:

1. Include in such contracts the specific sources utilized to determine the maximum allowable cost (MAC) pricing of the pharmacy, update MAC pricing at least every seven (7) calendar days, and establish a process for providers to readily access the MAC list specific to that provider;
2. In order to place a drug on the MAC list, ensure that the drug is listed as "A" or "B" rated in the most recent version of the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the Orange Book, and the drug is generally available for purchase by pharmacies in the state from national or regional wholesalers and is not obsolete;
3. Ensure dispensing fees are not included in the calculation of MAC price reimbursement to pharmacy providers;
4. Provide a reasonable administration appeals procedure to allow a provider, a provider's representative and a pharmacy service administrative organization to contest reimbursement amounts within fourteen (14) calendar days of the final adjusted payment date. The PBM shall not prevent the pharmacy or the pharmacy service administrative organization from filing reimbursement appeals in an electronic batch format. The PBM must respond to a provider, a provider's representative and a pharmacy service administrative organization who have contested a reimbursement amount through this procedure within ten (10) calendar days. The PBM must respond in an electronic batch format to reimbursement appeals filed in an electronic batch format. The PBM shall not require a pharmacy or pharmacy services administrative organization to log into a system to upload individual claim appeals or to download individual appeal responses. If a price update is warranted, the PBM shall make the change in the reimbursement amount, permit the dispensing pharmacy to reverse and rebill the claim in question, and make the reimbursement amount change retroactive and effective for all contracted providers; and

5. If a below-cost reimbursement appeal is denied, the PBM shall provide the reason for the denial, including the National Drug Code (NDC) number from, and the name of, the specific national or regional wholesalers doing business in this state where the drug is currently in stock and available for purchase by the dispensing pharmacy at a price below the PBM's reimbursement price. If the NDC number provided by the PBM is not available below the acquisition cost obtained from the pharmaceutical wholesaler from whom the dispensing pharmacy purchases the majority of the prescription drugs that are dispensed, the PBM shall immediately adjust the reimbursement amount, permit the dispensing pharmacy to reverse and rebill the claim in question, and make the reimbursement amount adjustment retroactive and in effect for all contracted providers for future claims billed.

Pharmacy audit requirements — Computerized medical records — Written report — Copy — Recoupment (59 Okla. Stat. § 356.2)

A. The entity conducting an audit of a Pharmacy shall:

1. Identify and specifically describe the audit and appeal procedures in the pharmacy contract. Prescription claim documentation and recordkeeping requirements shall not exceed the requirements set forth by the Oklahoma Pharmacy Act or other applicable state or federal laws or regulations;
2. Give the Pharmacy written notice by certified letter to the Pharmacy and the Pharmacy's contracting agent, including identification of specific prescription numbers and fill dates to be audited, at least two weeks prior to conducting the audit, including, but not limited to, an on-site audit, a desk audit or a wholesale purchase audit, request for documentation related to the dispensing of a prescription drug or any reimbursed activity by a pharmacy provider; provided, however, that wholesale purchase audits shall require a minimum of 30 days' written notice. The Pharmacy shall have the opportunity to reschedule the audit no more than seven days from the date designated on the original audit notification;
3. Not interfere with the delivery of pharmacist services to a patient and shall utilize every reasonable effort to minimize inconvenience and disruption to pharmacy operations during the audit process;
4. Conduct any audit involving clinical or professional judgment by means of or in consultation with a licensed pharmacist;
5. Not consider as fraud any clerical or recordkeeping error, such as a typographical error, scrivener's error or computer error, including, but not limited to, a miscalculated days' supply, incorrectly billed prescription written date or prescription origin code, and such errors shall not be subject to recoupment. The Pharmacy shall have the right to submit amended claims electronically to correct clerical or recordkeeping errors in lieu of recoupment. To the extent that an audit results in the identification of any clerical or recordkeeping errors such as typographical errors, scrivener's errors or computer errors in a required document or record, the Pharmacy shall not be subject to recoupment of funds by the pharmacy benefit manager unless the pharmacy benefit manager can provide proof of intent to commit fraud. A person shall not be subject to criminal penalties for errors provided for in this paragraph without proof of intent to commit fraud;
6. Permit a Pharmacy to use the records of a hospital, physician or other authorized practitioner of the healing arts for drugs or medicinal supplies written or transmitted by any means of communication for purposes of validating the pharmacy record with respect to orders or refills of a legend or narcotic drug;
7. Not include the dispensing fee amount or the actual invoice cost of the prescription dispensed in a finding of an audit recoupment unless a prescription was not actually dispensed or a physician denied authorization of a dispensing order;
8. Audit each Pharmacy under identical standards, regularity and parameters as other similarly situated Pharmacies and all pharmacies owned or managed by the pharmacy benefit manager conducting or having conducted the audit;

9. Not exceed one year from the date the claim was submitted to or adjudicated by a managed care company, nonprofit hospital or medical service organization, insurance company, third-party payer, pharmacy benefit manager, a health program administered by a department of this state or any entity that represents the companies, groups, or departments for the period covered by an audit;
10. Not schedule or initiate an audit during the first seven calendar days of any month unless otherwise consented to by the Pharmacy;
11. Disclose to any plan sponsor whose claims were included in the audit any money recouped in the audit; and
12. Not require pharmacists to break open packaging labeled “for single-patient-use only.” Packaging labeled “for single-patient-use only” shall be deemed to be the smallest package size available.

B. 1. Any entity that conducts wholesale purchase review during an audit of a pharmacist or Pharmacy shall not require the pharmacist or Pharmacy to provide a full dispensing report. Wholesaler invoice reviews shall be limited to verification of purchase inventory specific to the pharmacy claims paid by the health benefits plan or pharmacy benefit manager conducting the audit.

2. Any entity conducting an audit shall not identify or label a prescription claim as an audit discrepancy when:

a. The National Drug Code for the dispensed drug is in a quantity that is a subunit or multiple of the drug purchased by the pharmacist or Pharmacy as supported by a wholesale invoice,

b. The pharmacist or Pharmacy dispensed the correct quantity of the drug according to the prescription, and

c. The drug dispensed by the pharmacist or pharmacy shares all but the last two digits of the National Drug Code of the drug reflected on the supplier invoice.

3. An entity conducting an audit shall accept as evidence, subject to validation, to support the validity of a pharmacy claim related to a dispensed drug:

a. Redacted copies of supplier invoices in the pharmacist’s or Pharmacy’s possession, or

b. Invoices and any supporting documents from any supplier as authorized by federal or state law to transfer ownership of the drug acquired by the pharmacist or Pharmacy.

4. An entity conducting an audit shall provide, no later than five business days after the date of a request by the pharmacist or Pharmacy, all supporting documents the pharmacist’s or Pharmacy’s purchase suppliers provided to Prime

C. A Pharmacy shall be allowed to provide the Pharmacy’s computerized patterned medical records or the records of a hospital, physician or other authorized practitioner of the healing arts for drugs or medicinal supplies written or transmitted by any means of communication for purposes of supporting the pharmacy record with respect to orders or refills of a legend or narcotic drug.

D. The entity conducting the audit shall not audit more than 50 prescriptions, with specific date of service, per calendar year. The annual limit to the number of prescription claims audited shall be inclusive of all audits, including any prescription-related documentation requests from the health insurer, pharmacy benefit manager or any third-party company conducting audits on behalf of any health insurer or pharmacy benefit manager during a calendar year.

E. If paper copies of records are requested by the entity conducting the entity, the entity shall pay 25 cents per page to cover the costs incurred by the Pharmacy. Prime shall provide the Pharmacy with accurate instructions, including any required form for obtaining reimbursement for the copied records

F. The entity conducting the audit shall :

1. Deliver a preliminary audit findings report to the Pharmacy and the Pharmacy’s contracting agent within 45 calendar days of conducting the audit;

2. Allow the Pharmacy at least 90 calendar days following receipt of the preliminary audit findings report in which to produce documentation to address any discrepancy found during the audit; provided, however, a Pharmacy may request an extension, not to exceed an additional 45 calendar days;
3. Deliver a final audit findings report to the Pharmacy and the Pharmacy's contracting agent signed by the auditor within 10 calendar days after receipt of additional documentation provided by the Pharmacy, as provided for in Section 356.3 of this title;
4. Allow the Pharmacy to reverse and resubmit claims electronically within 30 days of receipt of the final audit report in lieu of the auditing entity recouping discrepant claim amounts from the Pharmacy;
5. Not recoup any disputed funds until after final disposition of the audit findings, including the appeals process as provided for in Section 356.3 of this title; and
6. Not accrue interest during the audit and appeal period.

G. Each entity conducting an audit shall provide a copy of the final audit results, and a final audit report upon request, after completion of any review process to the plan sponsor.

H. 1. The full amount of any recoupment on an audit shall be refunded to the plan sponsor. Except as provided for in paragraph 2 of this subsection, a charge or assessment for an audit shall not be based, directly or indirectly, on amounts recouped.

2. This subsection does not prevent the entity conducting the audit from charging or assessing the responsible party, directly or indirectly, based on amounts recouped if both of the following conditions are met:

a. The plan sponsor and the entity conducting the audit have a contract that explicitly states the percentage charge or assessment to the plan sponsor, and

b. A commission to an agent or employee of the entity conducting the audit is not based, directly or indirectly, on amounts recouped.

I. Unless superseded by state or federal law, auditors shall only have access to previous audit reports on a particular Pharmacy conducted by the auditing entity for the same pharmacy benefit manager, health plan or insurer. An auditing vendor contracting with multiple pharmacy benefits managers or health insurance plans shall not use audit reports or other information gained from an audit on a Pharmacy to conduct another audit for a different pharmacy benefit manager or health insurance plan.

Appeals process — Dismissal — Fraud or willful misrepresentation — Application of act (59 Okla. Stat. § 356.3)

A. Each entity conducting an audit shall establish a written appeals process under which a Pharmacy may appeal an unfavorable preliminary audit report and/or final audit report to the entity.

B. Following an appeal, if the entity finds that an unfavorable audit report or any portion thereof is unsubstantiated, the entity shall dismiss the audit report or the unsubstantiated portion of the audit report without any further action.

C. Any final audit report, following the final audit appeal period, with a finding of fraud or willful misrepresentation shall be referred to the district attorney having proper jurisdiction or the attorney general for prosecution upon completion of the appeals process.

D. This act does not apply to any audit, review or investigation that is initiated based on or that involves fraud, willful misrepresentation or abuse.

Extrapolation audit prohibited (59 Okla. Stat. § 356.4)

A. For the purposes of the Pharmacy Audit Integrity Act, "extrapolation audit" means an audit of a sample of prescription drug benefit claims submitted by a Pharmacy to the entity conducting the audit that is then used to estimate audit results for a larger batch or group of claims not reviewed by the auditor.

B. The entity conducting the audit shall not use the accounting practice of extrapolation in calculating recoupments or penalties for audits.

Retrospective application — Audits not covered by act (59 Okla. Stat. § 356.5)

A. The audit criteria set forth in the Pharmacy Audit Integrity Act shall apply only to audits of claims for services provided and claims submitted for payment after this act becomes law.

B. The Pharmacy Audit Integrity Act shall not apply to any audit, including, but not limited to, audits conducted by or on behalf of a state agency, which involves fraud, willful misrepresentation, abuse or Medicaid payments including, without limitation, investigative audits or any other statutory provision which authorizes investigations relating to insurance fraud.

B-38 Oregon Regulatory Addendum to Pharmacy Participation Agreement

This Oregon Addendum applies to the extent that Pharmacy provides covered drugs to covered persons of insurers, carriers, health maintenance organizations, health care service contractors and discount medical plan organizations under Oregon law (collectively and/or individually, "plan sponsor").

In the event of a direct conflict between this Addendum and the Agreement, the applicable provisions of this Addendum shall control if required. This Addendum may be modified from time to time pursuant to the Agreement.

Without limiting the generality of the foregoing, and notwithstanding anything in the Agreement to the contrary, Pharmacy agrees as follows:

Pharmacy will in no event (including, but not limited to, nonpayment by PBM or any plan sponsor, PBM or any plan sponsor's insolvency, or breach of this Agreement) bill, charge, collect a deposit from, seek compensation, remuneration, or reimbursement from, or have any recourse against, a covered person or other persons acting on their behalf. This provision does not prohibit the collection of copays or charges for noncovered services or items. This provision will survive the termination of this Agreement and

supersedes any oral or written contrary agreement now existing or hereafter entered into between Pharmacy and covered person or someone acting on covered person's behalf. Or. Stat. §§ 743B.204; 750.095(2).

To the extent Pharmacy services covered persons of a discount medical plan organization under Oregon law, Pharmacy agrees:

The Agreement and applicable fee schedule(s) identify pharmacy services to be provided to covered persons and the applicable reimbursement rates under such program. Or. Stat. §735.633(2)(a), (b).

In no event will Pharmacy charge a covered person more than the lower of the Pharmacy's usual and customary charge or the applicable discounted rate. Or. Stat. § 735.633(2)(c).

In the event Pharmacy is a Tribal Health Provider, as defined by the state of Oregon, for services to be offered through a health benefit plan certified by the exchange as a Qualified Health Plan (QHP), Pharmacy shall so notify PBM in writing of such status, in which case the parties shall use the QHP Addendum for Indian Health Care Providers to supplement and amend the Agreement. Pharmacy acknowledges and agrees that the exchange may amend the QHP Addendum for Indian Health Care

Providers, in which case the parties will be required to amend the Agreement to reflect such change(s) within 90 days of adoption of the change. Pharmacy acknowledges that the exchange may be notified of Tribal Health Provider contractual relationships hereunder. Or. Admin. R. § 945-020-0040.

Establishment of maximum allowable costs for drugs; duties of pharmacy benefit managers (OR ST § 735.534)

(5) A PBM must establish a process by which a network pharmacy may appeal its reimbursement for a drug subject to maximum allowable cost pricing. A network pharmacy may appeal a maximum allowable cost if the reimbursement for the drug is less than the net amount that the network pharmacy paid to the supplier of the drug. The process must allow a network pharmacy a period of no less than sixty (60) days after a claim is reimbursed in which to file the appeal. An appeal requested under this section must be completed within thirty (30) calendar days of the pharmacy making the claim for which appeal has been requested.

(6) A PBM shall allow a network pharmacy to submit the documentation in support of its appeal on paper or electronically and may not:

(a) Refuse to accept an appeal submitted by a person authorized to act on behalf of the network pharmacy;

(b) Refuse to adjudicate an appeal for the reason that the appeal is submitted along with other claims that are denied; or

(c) Impose requirements or establish procedures that have the effect of unduly obstructing or delaying an appeal.

(7) A PBM must provide as part of the appeals process established under subsection (5) of this section:

(a) A telephone number at which a network pharmacy may contact the PBM and speak with an individual who is responsible for processing appeals;

(b) A final response to an appeal of the reimbursement for a drug within seven (7) business days; and

(c) If the appeal is denied, the reason for the denial and the national drug code of a drug that may be purchased by similarly situated pharmacies at a price that is equal to or less than the maximum allowable cost.

(8)(a) If an appeal is upheld under this section, the PBM shall:

(A) Make an adjustment for the pharmacy that requested the appeal from the date of initial adjudication forward; and

(B) Allow the pharmacy to reverse the claim and resubmit an adjusted claim without any additional charges.

(b) If the request for an adjustment has come from a critical access pharmacy, as defined by the Oregon Health Authority by rule for purposes related to the Oregon Prescription Drug Program, the adjustment approved under paragraph (a) of this subsection shall apply only to critical access pharmacies.

Entities and independent third parties auditing claims; procedural requirements (Or. Stat. § 735.542)

An entity that audits claims or an independent third party that contracts with Prime to audit claims:

(1) Must establish, in writing, a procedure for a Pharmacy to appeal the entity's findings with respect to a claim and must provide a Pharmacy with a notice regarding the procedure, in writing or electronically, prior to conducting an audit of the pharmacy's claims;

(2) May not conduct an audit of a claim more than 24 months after the date the claim was adjudicated by the entity;

(3) Must give at least 15 days' advance written notice of an on-site audit to the Pharmacy or corporate headquarters of the Pharmacy;

(4) May not conduct an on-site audit during the first five days of any month without the Pharmacy's consent;

(5) Must conduct the audit in consultation with a pharmacist who is licensed by this or another state if the audit involves clinical or professional judgment;

(6) May not conduct an on-site audit of more than 250 unique prescriptions of a pharmacy in any 12-month period except in cases of alleged fraud;

(7) May not conduct more than one on-site audit of a Pharmacy in any 12-month period;

(8) Must audit each Pharmacy under the same standards and parameters that the entity uses to audit other similarly situated Pharmacies;

(9) Must pay any outstanding claims of a Pharmacy no more than 45 days after the earlier of the date all appeals are concluded or the date a final report is issued under ORS 735.550 (3);

(10) May not include dispensing fees or interest in the amount of any overpayment assessed on a claim unless the overpaid claim was for a prescription that was not filled correctly;

(11) May not recoup costs associated with:

(a) Clerical errors; or

(b) Other errors that do not result in financial harm to the entity or a consumer; and

(12) May not charge a Pharmacy for a denied or disputed claim until the audit and the appeals procedure established under subsection (1) of this section are final.

Grounds for findings relating to claims (Or. Stat. § 735.544)

An entity's finding that a claim was incorrectly presented or paid must be based on identified transactions and not based on probability sampling, extrapolation or other means that project an error using the number of patients served who have a similar diagnosis or the number of similar prescriptions or refills for similar drugs.

Entities contracting with independent third parties to conduct audits; prohibited actions (Or. Stat. § 735.546)

An entity that contracts with an independent third party to conduct audits may not:

(1) Agree to compensate the independent third party based on a percentage of the amount of overpayments recovered; or

(2) Disclose information obtained during an audit except to the contracting entity, the Pharmacy subject to the audit or the holder of the policy or certificate of insurance that paid the claim.

Evidence of validation of claim which must be allowed by auditor (Or. Stat. § 735.548)

For purposes of ORS 735.540 to 735.552, an entity, or an independent third-party that contracts with an entity to conduct audits, must allow as evidence of validation of a claim:

(1) An electronic or physical copy of a prescription that complies with ORS chapter 689 if the prescribed drug was, within 14 days of the dispensing date:

(a) Picked up by the patient or the patient's designee;

(b) Delivered by the Pharmacy to the patient; or

(c) Sent by the Pharmacy to the patient using the United States Postal Service or other common carrier;

(2) Point-of-sale electronic register data showing purchase of the prescribed drug, medical supply or service by the patient or the patient's designee; or

(3) Electronic records, including electronic beneficiary signature logs, electronically scanned and stored patient records maintained at or accessible to the audited Pharmacy's central operations and any other reasonably clear and accurate electronic documentation that corresponds to a claim.

Provision of preliminary and final audit reports to Pharmacy; resubmittal of claims; recoupment of disputed funds (Or. Stat. § 735.550)

(1)(a) After conducting an audit, an entity must provide the Pharmacy that is the subject of the audit with a preliminary report of the audit. The preliminary report must be received by the Pharmacy no later than 45 days after the date on which the audit was completed and must be sent:

(A) By mail or common carrier with a return receipt requested; or

(B) Electronically with electronic receipt confirmation.

(b) An entity shall provide a Pharmacy receiving a preliminary report under this subsection no fewer than 45 days after receiving the report to contest the report or any findings in the report in accordance with the appeals procedure established under ORS 735.542 (1) and to provide additional documentation in support of the claim. The entity shall consider a reasonable request for an extension of time to submit documentation to contest the report or any findings in the report.

(2) If an audit results in the dispute or denial of a claim, the entity shall allow the Pharmacy to resubmit the claim using any commercially reasonable method, including facsimile, mail or email.

(3) An entity must provide a Pharmacy that is the subject of an audit with a final report of the audit no later than 60 days after the later of the date the preliminary report was received or the date the Pharmacy contested the report using the appeals procedure established under ORS 735.542 (1). The final report must include a final accounting of all moneys to be recovered by the entity.

(4) Recoupment of disputed funds from a Pharmacy by an entity or repayment of funds to an entity by a Pharmacy, unless otherwise agreed to by the entity and the Pharmacy, shall occur after the audit and the appeals procedure established under ORS 735.542 (1) are final. If the identified discrepancy for an individual audit exceeds $40,000, any future payments to the Pharmacy may be withheld by the entity until the audit and the appeals procedure established under ORS 735.542 (1) are final.

Fraud; application of provisions (Or. Stat. § 735.552)

ORS 735.540 to 735.552 do not:

(1) Preclude an entity from instituting an action for fraud against a Pharmacy;

(2) Apply to an audit of pharmacy records when fraud or other intentional and willful misrepresentation is evidenced by physical review, review of claims data or statements or other investigative methods; or

(3) Apply to a state agency that is conducting audits or a person that has contracted with a state agency to conduct audits of pharmacy records for prescription drugs paid for by the state medical assistance program.

B-39 Pennsylvania Regulatory Addendum to Pharmacy Participation Agreement

This Pennsylvania Addendum applies to the extent that Pharmacy provides covered drugs to covered persons of medical service corporations, managed care insurance plans, health maintenance organizations and insurers under Pennsylvania law (collectively and/or individually, "plan sponsor").

In the event of a direct conflict between this Addendum and the Agreement, the applicable provisions of this Addendum shall control if required. This Addendum may be modified from time to time pursuant to the Agreement.

Without limiting the generality of the foregoing, and notwithstanding anything in the Agreement to the contrary, Pharmacy agrees as follows:

To the extent Pharmacy provides covered drugs to covered persons of a health maintenance organization under Pennsylvania law, Pharmacy agrees:

If Pharmacy terminates the Agreement, it must give PBM at least 60 days' advance notice. 31 Pa. Admin. Code § 301.124.

Pharmacy hereby agrees that in no event including, but not limited to, nonpayment by PBM or plan sponsor, insolvency of PBM or plan sponsor, or breach of this Agreement, shall Pharmacy bill, charge, collect a deposit from, seek compensation, remuneration or reimbursement from, or have any recourse against covered persons or persons other than plan sponsor acting on behalf of the covered person for covered drugs as set forth in this Agreement. This provision shall not prohibit collecting supplemental charges or copays in accordance with the terms of the applicable agreement between plan sponsor and the covered person. 31 Pa. Admin. Code § 301.122.

Pharmacy further agrees that (i) the hold harmless provisions in paragraph 1(b) above shall survive the termination of the Agreement regardless of the cause giving rise to termination and shall be construed to be for the benefit of the covered person and that (ii) this hold harmless provision supersedes any oral or written contrary agreement now existing or hereafter entered into between Pharmacy and covered persons or persons acting on their behalf. 31 Pa. Admin. Code § 301.122.

Any modification, addition or deletion to the provisions in paragraphs 1(a), (b) or (c) above shall become effective on a date no earlier than 15 days after the Pennsylvania Secretary of Health has received written notice of such proposed changes. 31 Pa. Admin. Code § 301.122.

In the event of the insolvency of PBM or plan sponsor, Pharmacy shall continue to provide covered drugs for the duration of the period after the insolvency for which premium payment has been made or until the covered person's discharge from an inpatient facility or expiration of benefits (limited to covered drugs directly related to the condition which occasioned the admission), whichever is longer. 31 Pa. Admin. Code § 301.123(b)(2).

Pharmacy acknowledges and agrees that any delegation by plan sponsor to PBM for performance of quality assurance, utilization management, credentialing, provider relations and other medical management systems shall be subject to plan sponsor's oversight and monitoring of PBM's performance. 28 Pa. Admin. Code § 9.725(2).

Pharmacy acknowledges and agrees that plan sponsors, upon failure of PBM to properly implement and administer the systems, or to take prompt corrective action after identifying quality, enrollee satisfaction or other problems, may terminate their contracts with PBM, and that as a result of the termination, Pharmacy's participation in plan sponsor's benefit plans may also be terminated. 28 Pa. Admin. Code § 9.725(3).

To the extent Pharmacy provides covered drugs to covered persons of a managed care organization under Pennsylvania law, Pharmacy agrees:

Pharmacy acknowledges and agrees that nothing in the Agreement limits the following:

viii. The authority of plan sponsor to ensure Pharmacy's participation in and compliance with plan sponsor's quality assurance, utilization management, enrollee complaint and grievance systems and procedures or limits.

ix. The Department of Health's authority to monitor the effectiveness of plan sponsor's systems and procedures or the extent to which plan sponsors adequately monitor any function delegated to PBM, or to require plan sponsor to take prompt corrective action regarding quality of care or consumer grievances and complaints.

x. Plan sponsor's authority to sanction or terminate a Pharmacy found to be providing inadequate or poor-quality care or failing to comply with plan sponsor systems, standards or procedures as agreed to by PBM.

28 Pa. Admin. Code § 9.725(1).

Pharmacy acknowledges and agrees that any delegation by plan sponsor to PBM for performance of quality assurance, utilization management, credentialing, provider relations and other medical management systems shall be subject to plan sponsor's oversight and monitoring of PBM's performance. 28 Pa. Admin. Code § 9.725(2).

Pharmacy acknowledges and agrees that plan sponsors, upon failure of PBM to properly implement and administer the systems, or to take prompt corrective action after identifying quality, enrollee satisfaction or other problems, may terminate their contracts with PBM, and that as a result of the termination, Pharmacy's participation in plan sponsor's benefit plans may also be terminated. 28 Pa. Admin. Code § 9.725(3).

In no event, including, but not limited to, nonpayment by plan sponsor or PBM, insolvency of plan sponsor or PBM, or a breach of this Agreement, shall Pharmacy bill, charge, collect a deposit from, seek compensation or reimbursement from, or have any recourse against the covered person or persons other than plan sponsor acting on behalf of the covered person for covered drugs set forth in this Agreement. This provision does not prohibit collecting supplemental charges or copays in accordance with the terms of the Agreement between plan sponsor and the covered person. 28 Pa. Admin. Code § 9.722(e)(1)(iii); 28 Pa. Admin. Code § 9.725(4).

Pharmacy further agrees that (i) the hold harmless provisions in paragraph 2(b) above shall survive the termination of the Agreement regardless of the cause giving rise to termination and shall be construed to be for the benefit of the covered person and that (ii) this hold-harmless provision supersedes any oral or written contrary agreement now existing or hereafter entered into between Pharmacy and covered persons or persons acting on their behalf. 28 Pa. Admin. Code § 9.722(e)(1); 28 Pa. Admin. Code § 9.725(4).

Pharmacy shall keep confidential records of covered persons in accordance with 40 Pa. Stat. § 991.2131 and all applicable state and federal regulations. Pharmacy agrees to grant access to records to the employees and agents of the Pennsylvania Department of Health, Insurance Department, and

Department of Public Welfare with direct responsibility for quality assurance, investigation of complaints or grievances, enforcement or other activities related to compliance with state law. 28 Pa. Admin. Code § 9.722(e)(2).

Pharmacy agrees to participate in and abide by the decisions of PBM's and plan sponsor's quality assurance, utilization review and covered person complaint and grievance systems. 28 Pa. Admin. Code § 9.722(e)(3).

Pharmacy agrees to resolve all disputes, controversies and claims in the manner set forth in the Agreement and any related attachments. 28 Pa. Admin. Code § 9.722(e)(4); 40 Pa. Stat. § 991.2162(f).

Pharmacy agrees to adhere to all state and federal laws and regulations. 28 Pa. Admin. Code § 9.722(e)(5).

PBM shall make payment to Pharmacy for covered drugs rendered to covered persons within the time required by state law, which currently requires payment within 45 days after the date a claim for payment is received with all documentation reasonably necessary for PBM to process the claim. 28 Pa. Admin. Code § 9.722(e)(6).

Notwithstanding anything to the contrary in the Agreement, PBM and Pharmacy shall provide each other at least 60 days prior written notice if either party terminates the Agreement without cause. 28 Pa. Admin. Code § 9.722(e)(7).

PBM shall give Pharmacy at least 30 days prior written notice of any changes to contracts, policies or procedures affecting Pharmacy or the provision or payment of health care services to covered persons, unless the change is required by Law. 28 Pa. Admin. Code § 9.722(e)(8).

To the extent Pharmacy provides covered drugs to covered persons of a preferred provider organization under Pennsylvania Law, Pharmacy agrees:

Pharmacy hereby agrees that in no event including, but not limited to, nonpayment by PBM or plan sponsor, insolvency of PBM or plan sponsor, or breach of this Agreement, shall Pharmacy bill, charge, collect a deposit from, seek compensation, remuneration or reimbursement from, or have any recourse against covered persons or persons other than PBM or plan sponsor acting on behalf the covered person for covered drugs as set forth in this Agreement. This provision shall not prohibit collecting supplemental charges or copays in accordance with the terms of the applicable agreement between plan sponsor and the covered person. 31 Pa. Admin. Code §§ 152.14, 152.104(a)(3)(i).

Pharmacy agrees to participate in and abide by the decisions of PBM's and plan sponsor's quality assurance, utilization review and covered person complaint and grievance systems. 31 Pa. Admin. Code § 152.104(a)(3)(ii), (iii).

Pharmacy agrees to abide by plan sponsor's rules and regulations for preferred providers, including those regarding hospital privileges, credentialing, in-office reviews and similar rules. 31 Pa. Admin. Code § 152.104(a)(3)(iv).

Pharmacy shall keep confidential records of covered persons in accordance with 40 Pa. Stat. § 991.2131 and all applicable state and federal regulations. Pharmacy agrees to grant access to records to the employees and agents of the Pennsylvania Department of Health, Insurance Department, and

Department of Public Welfare with direct responsibility for quality assurance, investigation of complaints or grievances, enforcement or other activities related to compliance with state law. 31 Pa. Admin. Code § 152.104(a)(3)(v).

Pharmacy agrees that plan sponsor may immediately terminate Pharmacy's participation and preferred status if Pharmacy is found to be harming covered persons. 31 Pa. Admin. Code § 152.104(a)(3)(vi).

Multiple source drug pricing appeals process (PA ST 40 P.S. § 4533)

(a) *Process to be established.* --All contracts between a PBM or a pharmacy or, alternatively, a pharmacy's contracting agent, such a PSAO, shall include a process to appeal, investigate and resolve disputes regarding multiple source drug pricing. The contract provision establishing the process shall include the following:

(1) The right to appeal shall be limited to fourteen (14) calendar days following the initial claim.

(2) The appeal shall be investigated and resolved by the PBM through an internal process within fourteen (14) calendar days of receipt of the appeal by the PBM.

(3) A telephone number at which a pharmacy may contact the PBM and speak with an individual who is involved in the appeals process.

(b) *Denial.*--If a PBM denies an appeal, the PBM shall provide the reason for the denial and identify the national drug code of an equivalent drug that is available for purchase by network retail pharmacies in this Commonwealth from wholesalers at a price that is equal to or less than the maximum allowable cost for the appealed drug as determined by the PBM.

(c) *Approval.*--If a PBM grants an appeal, the PBM shall make the price correction, permit the reporting pharmacy to reverse and rebill the appealed claim and make the price correction effective for all similarly situated pharmacies from the date of the approved appeal.

Procedures for conducting pharmacy (40 Pa. Stat. § 4511)

(a) Procedure — An entity conducting a pharmacy audit under this chapter shall conform to the following rules:

(1) Except as otherwise provided by federal or state law, an auditing entity conducting a pharmacy audit may have access to a Pharmacy's previous audit report only if the report was prepared by that auditing entity.

(2) Information collected during a pharmacy audit shall be confidential by law, except that the auditing entity conducting the pharmacy audit may share the information with the pharmacy benefit manager and covered entity for which a pharmacy audit is being conducted.

(3) The auditing entity conducting a pharmacy audit may not solely compensate an employee or contractor with which an auditing entity contracts to conduct a pharmacy audit, solely based on the amount claimed or the actual amount recouped by the Pharmacy being audited.

(4) The auditing entity shall provide the Pharmacy being audited with at least 14 calendar days' prior written notice before conducting a pharmacy audit, unless both parties agree otherwise. If a delay is requested by the Pharmacy, the Pharmacy shall provide notice to the PBM within 72 hours of receiving notice of the audit.

(5) The auditing entity may not initiate or schedule a pharmacy audit during the first five business days of any month for a Pharmacy that averages in excess of 600 prescriptions filled per week, without the express consent of the Pharmacy.

(6) The auditing entity shall accept paper or electronic signature logs that document the delivery of prescription or nonproprietary drugs and pharmacist services to a health plan beneficiary or the beneficiary's caregiver or guardian.

(7) The auditing entity shall provide to the representative of the Pharmacy, prior to leaving the Pharmacy at the conclusion of the on-site portion of the pharmacy audit, a complete list of pharmacy records reviewed.

(8) A pharmacy audit that involves clinical judgment shall be conducted by or in consultation with a pharmacist.

(9) A pharmacy audit may not cover:

(i) A period of more than 24 months after the date a claim was submitted by the Pharmacy to the pharmacy benefit manager or covered entity unless a longer period is required by law; or

(ii) More than 250 prescriptions, provided that a refill does not constitute a separate prescription for the purposes of this subparagraph.

(10) The auditing entity may not use extrapolation to calculate penalties or amounts to be charged back or recouped unless otherwise required by federal requirements or federal plans.

(11) The auditing entity may not include dispensing fees in the calculation of overpayments unless a prescription is considered a misfill. As used in this paragraph, "misfill" means a prescription that was not dispensed, a prescription error, a prescription where the prescriber denied the authorization request or a prescription where an extra dispensing fee was charged.

(12) A Pharmacy may do any of the following when a pharmacy audit is performed:

(i) To validate the pharmacy record and delivery, a Pharmacy may use authentic and verifiable statements or records, including, but not limited to, medication administration records of a nursing home, assisted living facility, hospital or health care practitioner with prescriptive authority.

(ii) To validate claims in connection with prescriptions or changes in prescriptions, or refills of prescription or nonproprietary drugs, a Pharmacy may use any valid prescription, including, but not limited to, medication administration records, facsimiles, electronic prescriptions, electronically stored images of prescriptions, electronically created annotations or documented telephone calls from the prescribing health care practitioner or practitioner's agent. Documentation of an oral prescription order that has been verified by the prescribing health care practitioner shall meet the provisions of this subparagraph for the initial audit review.

(b) Written report — An auditing entity shall provide the Pharmacy with a written report of the pharmacy audit and comply with the following requirements:

(1) A preliminary pharmacy audit report must be delivered to the Pharmacy or its corporate parent within 60 calendar days after the completion of the pharmacy audit. The preliminary report shall include contact information for the auditing entity who conducted the pharmacy audit and an appropriate and accessible point of contact, including telephone number, facsimile number, email and auditing firm, so that audit results, discrepancies and procedures can be reviewed. The preliminary pharmacy audit report shall include, but not be limited to, claim level information for any discrepancy found and total dollar amount of claims subject to recovery.

(2) A Pharmacy shall be allowed 30 calendar days following receipt of the preliminary audit report to respond to the findings of the preliminary report.

(3) A final audit report shall be delivered to the Pharmacy or its corporate parent not later than 60 calendar days after any responses from the Pharmacy or corporate parent are received by the auditing entity. The auditing entity shall issue a final pharmacy audit report that takes into consideration any responses provided to the auditing entity by the Pharmacy or corporate parent.

(4) The final audit report may be delivered electronically.

(5) A Pharmacy may not be subject to a chargeback or recoupment for a clerical or recordkeeping error in a required document or record, including a typographical error, scrivener's error or computer error, unless the error resulted in overpayment to the Pharmacy.

(6) An auditing entity conducting a pharmacy audit or person acting on behalf of the entity may not assess a changeback or recoupment or collect penalties from a Pharmacy until the time period to file an appeal of a final pharmacy audit report has passed or the appeals process has been exhausted, whichever is later.

(7) If an identified discrepancy in a pharmacy audit exceeds $25,000, future payments to the Pharmacy in excess of that amount may be withheld pending adjudication of an appeal.

(8) No interest shall accrue for any party during the audit period, beginning with the notice of the pharmacy audit and ending with the conclusion of the appeals process.

Appeals process (40 Pa. Stat. § 4512)

A Pharmacy may appeal a final audit report in accordance with the procedures established by the entity conducting the pharmacy audit.

Limitations (40 Pa. Stat. § 4513)

(a) General rule — The provisions of this chapter do not apply to an investigative audit of pharmacy records when:

(1) fraud, waste, abuse or other intentional misconduct is indicated by physical review or review of claims data or statements; or

(2) other investigative methods indicate a Pharmacy is or has been engaged in criminal wrongdoing, fraud or other intentional or willful misrepresentation.

(b) Federal law.-This chapter does not supersede any audit requirements established by federal law.

B-40 Rhode Island Regulatory Addendum to Pharmacy Participation Agreement

This Rhode Island Addendum applies to the extent that Pharmacy provides covered drugs to covered persons of a health maintenance organization, health plan, insurer or carrier licensed under Rhode Island law (collectively and/or individually, "plan sponsor").

In the event of a direct conflict between this Addendum and the Agreement, the applicable provisions of this Addendum shall control if required. This Addendum may be modified from time to time pursuant to the Agreement.

Without limiting the generality of the foregoing, and notwithstanding anything in the Agreement to the contrary, Pharmacy agrees as follows:

Notwithstanding anything to the contrary in the Agreement, PBM shall not terminate Pharmacy "without cause;" provided, however, that "cause" shall include lack of need due to economic considerations. 230 R.I. Code Reg. 20-30-9.9(G).

PBM shall afford Pharmacy due process for all adverse decisions resulting in a change of Pharmacy's status as a Participating Pharmacy. PBM shall notify Pharmacy of the proposed actions and the reasons for the proposed action. PBM shall give Pharmacy the opportunity to contest the proposed action and participate in the internal appeals process set forth in the Agreement. 30 R.I. Code Reg. 20-30-9.9(C).

Pharmacy agrees that in the event of the insolvency of plan sponsor or PBM, covered persons shall not be liable to Pharmacy for charges for covered drugs received before the time of insolvency. R.I. Stat. § 27-41-13(h).

Pharmacy and PBM shall provide at least 90 days written notice of any termination of the Agreement and notice of such termination may be provided by PBM to plan sponsor to the director of insurance as required by law. R.I. Stat. § 27-41-13(i).

In the event of the insolvency of plan sponsor or PBM, Pharmacy shall continue to provide covered drugs to covered persons confined in hospitals, skilled nursing facilities, intermediate care facilities or home health agencies at the time of insolvency until the earlier of discharge or 90 days following the insolvency or, for covered persons of federally qualified health maintenance organizations, for that period of time required by federal standards for confinement coverage. Pharmacy shall continue to provide covered drugs to all other covered persons for a period of 30 days following the insolvency. R.I. Stat. §§ 27-41-13(h) (1), (2).

Pharmacy agrees that covered persons shall not be liable to Pharmacy for charges for covered health services, except for amounts due for copays or deductibles billed in accordance with the terms of plan sponsor's subscriber agreement. 30 R.I. Code Reg. 20-30-9.9(A)(1)(c).

Pharmacy benefit manager requirements with respect to multi-source generic pricing updates to pharmacies (RI ST § 27-18-33.2)

(b) Upon each contract execution or renewal, a PBM shall, with respect to contracts between a PBM and a pharmacy or, alternatively, a PBM and a pharmacy's contracting representative or agent, such as a pharmacy services administrative organization (PSAO):

(1) Include in such contracts a requirement to update pricing information on the MAC list at least every ten (10) calendar days;

(2) Maintain a procedure to eliminate products from the list of drugs subject to such pricing, or modify MAC rates when such drugs do not meet the standards and requirements of this section as set forth, in order to remain consistent with pricing changes in the marketplace.

(c) PBM requirements for inclusion of products on a list of drugs subject to MAC pricing. In order to place a particular prescription drug on a MAC list, the PBM must, at a minimum, ensure that:

(1) The product must be listed as "A", "AB", or "B" rated in the most recent version of the United States Food and Drug Administration's approved drug products with therapeutic equivalence evaluations, also known as the orange book, or has an "NR" or "NA" rating or similar rating by a nationally recognized reference; and

(2) The product must be nationally available.

(d) Standards for pharmacy appeals. All contracts between a PBM, a contracted pharmacy or, alternatively, a PBM and a pharmacy's contracting representative or agent, such as a pharmacy services administrative organization (PSAO), shall include a process to appeal, investigate, and resolve disputes regarding MAC pricing. The process shall include the following provisions:

(1) The right to appeal shall be limited to fifteen (15) days following the initial claim;

(2) The appeal shall be investigated and resolved within fifteen (15) days following receipt of the appeal;

(3) A process by which a network pharmacy may contact the PBM regarding the appeals process;

(4) If the appeal is denied, the PBM shall provide the reason for the denial and identify the national drug code of a drug product that is available in adequate supply;

(5) If an appeal is upheld, the PBM shall make an adjustment to the list effective no later than one day after the date of determination; and

(6) The department of health shall exercise oversight and enforcement of this section.

Audits (R.I. Stat. § 5-19.1-35)

(a) When an on-site audit of the records of a Pharmacy is conducted by a carrier or its intermediary, the audit must be conducted in accordance with the following criteria:

(1) A finding of overpayment or underpayment must be based on the actual overpayment or underpayment, and not a projection based on the number of patients served having a similar diagnosis, or on the number of similar orders or refills for similar drugs, unless the projected overpayment or denial is a part of a settlement agreed to by the Pharmacy or pharmacist;

(2) The auditor may not use extrapolation in calculating recoupments or penalties unless required by state or federal laws or regulations;

(3) Any audit that involves clinical judgment must be conducted by, or in consultation with, a pharmacist; and

(4) Each entity conducting an audit shall establish an appeal process under which a Pharmacy may appeal an unfavorable preliminary audit report to the entity.

(b) This section does not apply to any audit, review or investigation that is initiated based on or involving suspected or alleged fraud, willful misrepresentation or abuse.

(c) Prior to an audit, the entity conducting an audit shall give the Pharmacy 14 days' advance written notice of the audit and the range of prescription numbers involved in the audit. The carrier or its intermediary may mask the last two digits of the numbers. Additionally, the number of prescriptions shall not exceed 150 prescription claims and their applicable refills. The time allotted must be adequate to collect all samples. The examination of signature logs shall not exceed 25 signature logs in number.

(d) A Pharmacy has the right to execute the dispute resolution contained in their contract.

(e)(1) A preliminary audit report must be delivered to the Pharmacy or its corporate office within 60 days after the conclusion of the audit. A Pharmacy must be allowed at least 30 days following receipt of the preliminary audit to provide documentation to address any discrepancy found in the audit. A final audit report must be delivered to the Pharmacy or its corporate office within 90 days after receipt of the preliminary audit report or final appeal, whichever is later. A chargeback recoupment or other penalty may not be assessed until the appeal process provided by the pharmacy benefit manager has been exhausted and the final report issued. If the identified discrepancy for a single audit exceeds $25,000, future payments in excess of that amount may be withheld pending the adjudication of an appeal. Auditors shall only have access to previous audit reports on a particular Pharmacy conducted for the same entity.

(2) Auditors may initiate a desk audit prior to an on-site audit unless otherwise specified in the law.

(3) Contracted auditors cannot be paid based on the findings within an audit.

(4) Scanned images of all prescriptions including all scheduled controlled substances are allowed to be used by the pharmacist for an audit. Verbally received prescriptions must be accepted upon validation by the auditing entity and applicable for the initial desk or on-site audit.

(5) The period covered by an audit may not exceed two years.

(6) Within five business days of receiving the audit notification, Pharmacies are allowed, at a minimum, one opportunity to reschedule with the auditor if the scheduled audit presents a scheduling conflict for the pharmacist.

(f) Any clerical error, typographical error, scrivener's error or computer error regarding a document or record required under the Medicaid program does not constitute a willful violation and is not subject to criminal penalties without proof of intent to commit fraud.

(g) Limitations.

(1) Exceptions. The provisions of this chapter do not apply to an investigative audit of pharmacy records when:

(i) Fraud, waste, abuse or other intentional misconduct is indicated by physical review or review of claims data or statements; or

(ii) Other investigative methods indicate a Pharmacy is or has been engaged in criminal wrongdoing, fraud or other intentional or willful misrepresentation.

(2) Frequency of audits. A pharmacy shall not be subject to more than one on-site audit in connection with a carrier every twelve (12) months, unless there is an identified problem or fraud or misrepresentation is suspected.

(3) Federal law. This chapter does not supersede any audit requirements established by federal law.

(h) Enforcement. The Rhode Island attorney general shall have the authority to enforce and ensure compliance with this section.

B-41 South Carolina Regulatory Addendum to Pharmacy Participation Agreement

This South Carolina Addendum applies to the extent that Pharmacy provides covered drugs to covered persons of health maintenance organizations, health benefit plans, insurers or carriers under South Carolina law (collectively and/or individually, "plan sponsor").

In the event of a direct conflict between this Addendum and the Agreement, the applicable provisions of this Addendum shall control if required. This Addendum may be modified from time to time pursuant to the Agreement.

Without limiting the generality of the foregoing, and notwithstanding anything in the Agreement to the contrary, Pharmacy agrees as follows:

Pharmacy agrees not to bill, charge, collect a deposit from, seek compensation, remuneration or reimbursement from, or have recourse against covered persons or persons acting on their behalf, for covered drugs rendered to covered persons by Pharmacy, and which are covered under the covered person's benefit plan. This agreement extends to all covered drugs furnished to the covered person during the time he is enrolled in, or otherwise entitled to benefits promised by the plan sponsor. This agreement further applies in all circumstances, including, but not limited to, nonpayment by PBM or plan sponsor and insolvency of PBM or plan sponsor. This agreement shall not prohibit collection of copays from covered persons by Pharmacy in accordance with the terms of the benefit plan. Pharmacy further agrees that this agreement shall be construed to be for the benefit of covered persons and that this agreement supersedes any oral or written contrary agreement now existing or hereafter entered into between Pharmacy and such covered persons, or persons acting on their behalf. Pharmacy further agrees to complete any additional forms or certifications in support of this agreement as may be required by the department of insurance. S.C. Code § 38-33-130(B).

In connection with covered drugs provided to plan sponsors that are employers with more than 50 eligible employees and utilizing a closed panel health plan to provide major medical, hospitalization and surgical coverage, in the event Pharmacy terminates its participation under the Agreement, Pharmacy shall, if requested, continue to provide covered drugs to covered persons, subject to the terms of the Agreement, for a period of 90 days or the anniversary date of the benefit plan, whichever occurs first.
S.C. Code § 38-71-1730(A)(3).

In the event Pharmacy's participation under the Agreement is terminated or nonrenewed, and Pharmacy is then providing covered drugs to covered persons with a serious medical condition, Pharmacy agrees to continue to provide covered drugs to such covered persons for 90 days or until termination of the covered person's benefit period, whichever is greater. During this period of continued care, Pharmacy shall accept as payment in full the rates set forth in the Agreement and, except for applicable deductibles or copays, shall not bill or otherwise hold a covered person financially responsible for covered drugs rendered in the continuation of care. For purposes of this paragraph, "serious medical condition" means a health condition or illness, that requires medical attention, and where failure to provide the current course of treatment through Pharmacy would place the person's health in serious jeopardy, and includes cancer, acute myocardial infarction and pregnancy. The provisions of this paragraph shall not apply in the event Pharmacy's license is suspended or revoked. S. C. Code §§ 38-71-243(C); 38-71-246

Placement of drug on Maximum Allowable Cost List. (SC ST § 38-71-2240)

(A) Before a PBM places or continues to place a particular drug on a Maximum Allowable Cost List, the drug must:

(1) be listed as "A" or "B" rated in the most recent version of the Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the Orange Book, or has an "NR" or "NA" rating, or a similar rating, by a nationally recognized reference;

(2) be available for purchase in the State from national or regional wholesalers operating in this State; and

(3) not be obsolete.

(B) A PBM shall:

(1) provide a process for network pharmacy providers to readily access the maximum allowable cost specific to that provider;

(2) update its Maximum Allowable Cost List at least once every seven (7) calendar days;

(3) provide a process for each pharmacy subject to the Maximum Allowable Cost List to access any updates to the Maximum Allowable Cost List;

(4) ensure that dispensing fees are not included in the calculation of maximum allowable cost;

(5) establish a reasonable internal appeal procedure by which a contracted pharmacy can appeal the provider's reimbursement for a drug subject to maximum allowable cost pricing if the reimbursement for the drug is less than the net amount that the network provider paid to the suppliers of the drug. The reasonable internal appeal procedure must include:

(a) a dedicated telephone number and email address or website for the purpose of submitting internal appeals; and

(b) the ability to submit an internal appeal directly to the PBM regarding the pharmacy benefits plan or program or through a pharmacy service administrative organization if the pharmacy service administrative organization has a contract with the PBM that allows for the submission of such appeals;

(6) participate in a reasonable external review procedure by which a contracted pharmacy can request an external review of a PBM's denial of an internal appeal by an independent review organization in accordance with the procedures promulgated by the director in subsection (F) of this section; and

(7) permit an unaffiliated retail pharmacy to participate in programs that reconcile payments with actual cost on the same basis as retail PBM affiliates.

(C) A pharmacy must be allowed no less than ten (10) calendar days after the applicable fill date to file an internal appeal or request for an external review of a denied internal appeal.

(D) If an internal appeal is initiated, the PBM shall within ten (10) calendar days after receipt of notice of the appeal either:

(1) if the internal appeal is upheld:

(a) notify the pharmacy or pharmacist or his designee of the decision;

(b) make the change in the maximum allowable cost effective as of the date the internal appeal is resolved;

(c) permit the appealing pharmacy or pharmacist to reverse and rebill the claim in question; and

(d) make the change effective for each similarly situated pharmacy as defined by the payor subject to the Maximum Allowable Cost List effective as of the date the internal appeal is resolved; or

(2) if the internal appeal is denied:

(a) provide the appealing pharmacy or pharmacist the reason for the denial, the National Drug Code number, and the name of the national or regional pharmaceutical wholesalers operating in this State; and

(b) notify the pharmacy or pharmacist in writing of the right to request an external review of the internal appeal and include clear and concise documents describing the external review process.

Pharmacy Benefit Managers - External Review (SC ADC 69-77)

A. Application of Section

(1) This section applies to external review of denials by PBMs of internal appeals of provider reimbursements and appeals of recoupments arising out of pharmacy audits. The Director or his designee may delegate the review and resolution of a pharmacy's appeal under this paragraph to an independent review organization (IRO), and any decision by the IRO shall have the same force and effect as a decision by the Director.

(2) A contracted pharmacy that receives a provider's reimbursement for a drug subject to maximum allowable cost pricing that is less than the net amount that the network provider paid to the suppliers of the drug shall have the right, after denial of an internal appeal, to appeal the decision of the PBM to the Director for an external review.

(3) Any pharmacy that believes recoupment amounts arising out of a PBM's final audit report were calculated in violation of the Code shall have the right to appeal the recoupment to the Director or his designee for an external review.

B. Requests for External Review

(1) An appeal filed pursuant to Section (A) above must:

(a) Be submitted electronically on a form made available by the Department on its website within 60 calendar days of the pharmacy's receipt of the PBM's final determination resolving the pharmacy's initial appeal or within 30 calendar days of the pharmacy's receipt of the PBM's final audit report; unless a different timeframe is approved in writing through the Director or the Director designee's assigned independent review organization:

(b) Contain a summary of:

(i) The grounds of the appeal to the Director;

(ii) The relief requested by the pharmacy; and

(iii) The basis on which the pharmacy believes it is due the relief

(c) Include a copy of the written decision rendered by the PBM;

(d) Contain a copy of the invoice(s) showing the pharmacy's purchase price for the drug or medical product or device at issue, if applicable;

(e) Contain a list of all discounts, price concessions, rebates or other reductions, excluding cash discounts, that were, or should have been, reported to the PBM including supporting documentation for each discount, price concession, rebate or other reduction, if applicable;

(f) Contain a certification by the applicant that all information submitted is true and accurate to the best of the applicant's knowledge; and

(g) Provide any other documentation or information requested by the director or his designee regarding the pharmacy's appeal.

(2) A pharmacy is not entitled to an external review of an appeal denial until the pharmacy has exhausted the PBM's internal appeal process.

(3) Within seven (7) business days from the date a request for an external review is filed or the date all information requested by the Director or his designee has been received, the Director or his designee shall:

(a) Assign an independent review organization from the list of approved IROs compiled and maintained to conduct an external review, and send the documents and any information considered in making the adverse determination to the independent review organization; or

(b) Inform the pharmacy in writing that the request does not meet the criteria for external review pursuant to this regulation and include the reason for nonacceptance.

(4) Within 7 business days after the IRO's receipt from the Director or his designee of the request for external review, the IRO shall determine whether all the information, certifications, and forms required to process the external review have been provided. The IRO shall immediately notify the pharmacy provider and/or PBM in writing if additional information is required.

(5) If the request for an external review is not:

(a) complete, the IRO shall inform the pharmacy provider what information or materials are needed to make the request complete; or

(b) accepted for external review, the IRO shall inform the pharmacy and the PBM in writing of the reasons for its nonacceptance.

(6) If a request for external review is accepted for external review, the IRO shall notify the PBM and the pharmacy.

(7) Upon receipt of the request for external review, the IRO shall render a decision within thirty (30) days unless a written extension is granted by the Director or his designee.

C. External Review Findings

(1) If the IRO determines the PBM reimbursed a pharmacy or pharmacist in an amount inconsistent with the provisions of this regulation and SC ST 38-71-2230 et seq., the PBM must:

(a) Promptly make the change in the reimbursement rate effective as of the date the external review is resolved;

(b) Permit the appealing pharmacy or pharmacist to reverse and rebill the claim in question;

(c) Reimburse the pharmacy the amount of the filing fee; and

(d) Promptly make the change effective for each similarly situated pharmacy as defined by the payor subject to the Maximum Allowable Cost List effective as of the date the external review is resolved.

(2) If the IRO determines the recoupments of any funds disputed on the basis of an audit were calculated in violation of SC ST 38-71-1810 et seq, then the PBM must promptly refund any amounts due to the responsible party as contractually agreed upon by the parties in the audit and the PBM must reimburse the pharmacy the amount of the filing fee.

(3) An external review decision is binding on the PBM and the appealing pharmacy or pharmacist. An appealing pharmacy or pharmacist may not file a subsequent request for an external review involving the same type of prescription drug unless there is an update to the reimbursement metric that would change the circumstances of the pharmacy's or pharmacist's reimbursement.

(4) The PBM must pay for all costs related to the external review except for the initial filing fee if not reimbursable by the PBM under subsections (C)(1) or (2) of this regulation.

(5) The filing fee associated with a pharmacist's request for an external review is to be retained by the department for administration of Chapter 71. This filing fee shall be set by the department and published on its website.

(6) If the Director determines the pharmacy or pharmacist has abused the external review process, he may require the pharmacy or pharmacist to pay for costs related to the external review.

Pharmacy audit rights (S.C. Code § 38-71-1810)

(B) If a managed care organization, insurer, third-party payer or any entity that represents a responsible party conducts an audit of the records of a Pharmacy, then, with respect to this audit, the Pharmacy has a right to:

(1) Not have an audit initiated or scheduled during the first five days of any month without the express consent of the Pharmacy, which shall cooperate with the auditor to establish an alternate date if the audit would fall within the excluded days, and no audit may be performed during a state of emergency declared by the governor that applies to the pharmacy location unless the state of emergency extends beyond 90 days or is agreed to by the pharmacy location;

(2) Have an audit that involves clinical judgment be conducted with a pharmacist who is licensed and employed by or working under contract with the auditing entity;

(3) Not have clerical or recordkeeping errors, including typographical errors, scrivener's errors and computer errors, on a required document or record considered fraudulent in the absence of any other evidence or serve as the sole basis of rejection of a claim; however, the provisions of this item do not prohibit recoupment of fraudulent payments;

(4) Have the auditing entity to provide the Pharmacy, upon request, all records related to the audit in an electronic format or contained in digital media;

(5) Have at least 30 days to respond to an audit notice and to submit records requested by the auditing entity related to the audit in electronic format or by certified mail. If a Pharmacy requests an extension during this 30-day period, it must be granted an additional 30 days to respond. The auditing entity must confirm receipt of all materials and documentation provided by the Pharmacy to the auditing entity;

(6) Have the properly documented records of a hospital or of a person authorized to prescribe controlled substances for the purpose of providing medical or pharmaceutical care for their patients transmitted by any means of communication approved by the auditing entity in order to validate a pharmacy record with respect to a prescription or refill for a controlled substance or narcotic drug pursuant to federal and state regulations;

(7) Have a projection of an overpayment or underpayment based on either the number of patients served with a similar diagnosis or the number of similar prescription orders or refills for similar drugs; however, the provisions of this item do not prohibit recoupments of actual overpayments unless the projection for overpayment or underpayment is part of a settlement by the Pharmacy;

(8) Prior to the initiation of an audit, if the audit is conducted for an identified problem, have the audit limited to claims that are identified by prescription number or by range of prescription numbers;

(9) If an audit is conducted for a reason other than described in item (8), have the audit limited to 100 selected prescriptions per pharmacy benefit manager;

(10) If an audit reveals the necessity for a review of additional claims, the audit may be conducted on-site;

(11) Except for audits initiated for the reason described in items (8) or (10), be subject to no more than one audit in one calendar year, unless fraud or misrepresentation is reasonably suspected;

(12) Be free of recoupments based on either of the following subitems unless defined within the billing, submission or audit requirements set forth in the pharmacy Provider Manual not inconsistent with current State Board of Pharmacy regulations, except for cases of Food and Drug Administration regulation or drug manufacturer safety programs in accordance with federal or state regulations:

(a) Documentation requirements in addition to, or exceeding requirements for, creating or maintaining documentation prescribed by the State Board of Pharmacy;

(b) A requirement that a Pharmacy or pharmacist perform a professional duty in addition to, or exceeding, professional duties prescribed by the State Board of Pharmacy unless otherwise agreed to by contract with the auditing entity;

(13) Be subject, so long as a claim is made within the contractual claim submission time period, to recoupment only following the correction of a claim and to have recoupment limited to amounts paid in excess of amounts payable under the corrected claim unless a prescription error occurs. For purposes of this subsection, a prescription error includes, but is not limited to, wrong drug, wrong strength, wrong dose or wrong patient;

(14) Be subject to reversals of approval, except for Medicare claims, for drug, prescriber or patient eligibility upon adjudication of a claim only in cases in which the pharmacy obtained the adjudication by fraud or misrepresentation of claim elements;

(15) Be audited under the same standards and parameters as other similarly situated Pharmacies audited by the same entity;

(16) Have at least 30 days following receipt of the preliminary audit report to produce documentation to address any discrepancy found during an audit;

(17) Have the option of providing documentation in electronic format or by certified mail;

(18) Have the period covered by an audit limited to 24 months from the date a claim was submitted to, or adjudicated by, a managed care organization, an insurer, a third-party payer or an entity that represents responsible parties, unless a longer period is permitted by or under federal law;

(19) Have the preliminary audit report delivered to the Pharmacy within 120 days after conclusion of the audit;

(20) Have a final audit report delivered to the Pharmacy within 90 days after the end of the appeals period;

(21) Not have the accounting practice of extrapolation used in calculating recoupments or penalties for audits, unless otherwise required by federal requirements or federal plans; and

(22) Have the right to an external review pursuant to section 38-71-2240 for any denied appeals of recoupment if the Pharmacy believes the recoupment amounts were calculated in violation of this article.

(C) Notwithstanding section 38-71-1840, the auditing entity shall provide the Pharmacy, if requested, a masked list that provides a prescription number range the auditing entity is seeking to audit.

Appeals process; dismissal; copy of audit findings (S.C. Code § 38-71-1820)

(A) Each entity that conducts an audit of a Pharmacy shall establish an appeals process under which a Pharmacy may appeal an unfavorable preliminary audit report to the entity.

(B) If, following the appeal, the entity finds that an unfavorable audit report or any portion of the unfavorable audit report is unsubstantiated, the entity shall dismiss the unsubstantiated portion of the audit report without any further proceedings.

(C) Each entity conducting an audit shall provide a copy, if required under the terms of the contract with the responsible party, of the audit findings to the plan sponsor after completion of any appeals process.

Recoupment (S.C. Code § 38-71-1830)

(A) Recoupments of any funds disputed on the basis of an audit must occur only after final internal disposition of the audit, including the appeals process as provided for in section 38-71-1820 or the external review pursuant to section 38-71-2240, unless fraud or misrepresentation is reasonably suspected.

(B) Recoupment on an audit must be refunded to the responsible party as contractually agreed upon by the parties involved in the audit.

(C) The entity conducting the audit may charge or assess the responsible party, directly or indirectly, based on amounts recouped if both of the following conditions are met:

(1) The responsible party or payer and the entity conducting the audit have entered into a contract that explicitly states the percentage charge or assessment to the responsible party; and

(2) A commission or other payment to an agent or employee of the entity conducting the audit is not based, directly or indirectly, on amounts recouped.

Exemptions (S.C. Code § 38-71-1840)

The provisions of this article do not apply to an audit, review or investigation:

(1) That involves alleged insurance fraud or abuse, Medicare fraud or abuse, or other fraud or misrepresentation;

(2) Conducted by or on the behalf of the Department of Health and Human Services in the performance of its duties in administering Medicaid under Titles XIX and XXI of the Social Security Act; or

(3) Notwithstanding the exemptions under subsections (1) and (2) of this section, contracts between the South Carolina Department of Health and Human Services and Medicaid managed care organizations must include provisions for biannual audits of Medicaid managed care organizations' pharmacy pricing and include limitations on any pharmacy benefit manager contract arrangements that bill the Medicaid Program for more than the total price paid to Pharmacies for actual claims.

B-42 South Dakota Regulatory Addendum to Pharmacy Participation Agreement

This South Dakota Addendum applies to the extent that Pharmacy provides covered drugs to covered persons of discount medical plans, health maintenance organizations, managed care organizations, health service corporations, insurers or carriers under South Dakota law (collectively and/or individually, "plan sponsor").

In the event of a direct conflict between this Addendum and the Agreement, the applicable provisions of this Addendum shall control if required. This Addendum may be modified from time to time pursuant to the Agreement.

Without limiting the generality of the foregoing, and notwithstanding anything in the Agreement to the contrary, Pharmacy agrees as follows:

To the extent Pharmacy services covered persons of a health carrier offering a managed care plan under South Dakota law, Pharmacy agrees:

In accordance with the Agreement, related attachments, and any applicable government program addenda to the Agreement, Pharmacy shall make health records available upon request so that PBM can process claims, perform necessary quality assurance or quality improvement programs, or comply with any lawful request for information from appropriate state authorities. S.D. Stat. § 58-17F-11(6).

Notwithstanding anything in the Agreement to the contrary, either party shall provide at least 60 days written notice to each other before terminating the Agreement without cause. If Pharmacy either gives or receives notice of termination without cause, Pharmacy agrees, upon PBM's request, to continue to provide covered drugs to covered persons and to follow all applicable requirements of the Agreement for the following time periods, whichever is applicable: (i) for a period of 90 days following the effective date of the termination; or (ii) for covered persons who have entered the second trimester of pregnancy at the time of termination, until the completion of postpartum care directly related to the delivery. S.D. Stat. § 58-17F-11(7).

Pharmacy acknowledges and agrees that plan sponsor retains the right to disapprove Pharmacy's participation status in plan sponsor's network. S.D. Stat. § 58-17F-12(2).

Pharmacy agrees that in the event of PBM's insolvency plan sponsor may require the assignment to plan sponsor of the provisions of the Agreement addressing Pharmacy's obligation to provide covered drugs. S.D. Stat. § 58-17F-12(7).

To the extent Pharmacy services covered persons of a discount medical plan under South Dakota law, Pharmacy agrees:

PBM's Pharmacy Participation Agreement for discount medical plans contains: (1) PBM's requirements concerning the services and products to be provided by Pharmacy at a discount; (2) Pharmacy's applicable discounted rates and (3) the requirement that Pharmacy will not charge covered persons more than the discounted rates. S.D. Stat. §§ 58-17E-27; 58-17E-28; 58-17E-29.

Time for disclosing proposed change in pharmacy audit terms (S.D. Stat. § 58-29F-3)

The pharmacy benefit manager shall disclose an amendment to the pharmacy audit terms in a contract between a Pharmacy and Prime at least 60 days prior to the effective date of the proposed change.

Requirements for conducting pharmacy audit (S.D. Stat. § 58-29F-4)

Unless otherwise prohibited by federal statutes or regulations, any entity conducting a pharmacy audit shall:

(1) Give a Pharmacy a minimum 14 days' written notice before conducting initial on-site audit;

(2) Conduct an audit that involves clinical or professional judgment in consultation with a licensed pharmacist; and

(3) Audit each Pharmacy under the same standards and parameters as other similarly situated Pharmacies.

Audit terms (S.D. Stat. § 58-29F-5)

Unless otherwise prohibited by federal statutes or regulations, for any entity conducting a pharmacy audit the following audit items apply:

(1) The period covered by the audit may not exceed 24 months from the date that the claim was submitted to or adjudicated by the entity, unless a longer period is required under state or federal law;

(2) If an entity uses random sampling as a method for selecting a set of claims for examination, the sample size shall be appropriate for a statistically reliable sample. Notwithstanding any other provision, the auditing entity shall provide the Pharmacy a masked list that provides a prescription number or date range that the auditing entity is seeking to audit;

(3) An on-site audit may not take place during the first five business days of the months of December and Jan. unless the Pharmacy consents;

(4) An auditor may not enter any portion of the pharmacy area where patient-specific information is available unless escorted, and to the extent possible shall remain out of sight and hearing range of the pharmacy patients;

(5) Any recoupment may not be deducted against future remittances until final completion of any appeals process and both parties have received the results of the final audit;

(6) A PBM may not require information to be written on a prescription unless the information is required to be written on the prescription by state or federal law. Recoupment may be assessed for items not written on the prescription if:

(a) Additional information is required in the Provider Manual; or

(b) The information is required by the Food and Drug Administration; or

(c) The information is required by the drug manufacturer's product safety program; and

(d) The information in subsections (a), (b) or (c) is not readily available for the auditor at the time of the audit;

(7) The auditing company or agent may not receive payment based on a percentage of the amount recovered. This section does not prevent the entity conducting the audit from charging or assessing the responsible party, directly or indirectly, based on amounts recouped if:

(a) The plan sponsor and the entity conducting the audit have a contract that explicitly states the percentage charge or assessment to the plan sponsor; and

(b) A commission to an agent or employee of the entity conducting the audit is not based, directly or indirectly, on amounts recouped.

Recoupment or chargeback criteria (S.D. Stat. § 58-29F-6)

For recoupment or chargeback, the following criteria apply:

(1) Audit parameters shall consider consumer-oriented parameters based on manufacturer listings;

(2) A Pharmacy's usual and customary price for compounded medications is considered the reimbursable cost unless the pricing methodology is outlined in the provider contract;

(3) A finding of overpayment or underpayment can only be based on the actual overpayment or underpayment and not a projection based on the number of patients served having a similar diagnosis or on the number of similar orders or refills for similar drugs;

(4) The entity conducting the audit may not use extrapolation in calculating the recoupment or penalties for audits unless required by state or federal law or regulation;

(5) Calculations of overpayments may not include dispensing fees unless:

(a) A prescription was not actually dispensed;

(b) The prescriber denied authorization;

(c) The prescription dispensed was a medication error by the Pharmacy; or

(d) The identified overpayment is solely based on an extra dispensing fee;

(6) An entity may not consider any clerical or recordkeeping error, such as a typographical error, scrivener's error or computer error regarding a required document or record as fraud. However, such errors may be subject to recoupment;

(7) In the case of errors that have no actual financial harm to the patient or plan, the PBM may not assess any chargebacks. Errors that are a result of the Pharmacy's failing to comply with a formal corrective action plan may be subject to recovery; and

(8) Interest may not accrue during the audit period for either party. The audit period begins with the notice of the audit and ends with the final audit report.

Validation of pharmacy record and delivery (S.D. Stat. § 58-29F-7)

To validate the pharmacy record and delivery, the Pharmacy may use authentic and verifiable statements or records including medication administration records of a nursing home, assisted living facility, hospital, physician or other authorized practitioner or additional audit documentation parameters located in the Provider Manual. Any legal prescription that meets the requirements in this chapter may be used to validate claims in connection with prescriptions, refills or changes in prescriptions, including medication administration records, faxes, ePrescriptions or documented telephone calls from the prescriber or the prescriber's agents.

Preliminary and final audit reports (S.D. Stat. § 58-29F-8)

A preliminary audit report shall be delivered to the Pharmacy within 60 days after the conclusion of the audit. A Pharmacy shall be allowed at least 45 days following receipt of the preliminary audit, to provide documentation to address any discrepancy found in the audit. A final audit report shall be delivered to the Pharmacy within 120 days after receipt of the preliminary audit report or final appeal, whichever is later. An entity shall remit any money due to a Pharmacy or pharmacist as a result of an underpayment of a claim within 45 days after the appeals process has been exhausted and the final audit report has been issued.

Appeals process (S.D. Stat. § 58-29F-9)

The entity conducting the audit shall establish a written appeals process which shall include appeals of preliminary reports and final reports.

Plan sponsor (S.D. Stat. § 58-29F-10)

If contractually required, an auditing entity shall provide a copy of the claims included in the audit to the plan sponsor, and any recouped money shall be returned to the plan sponsor.

Chapter not applicable to investigative audits (S.D. Stat. § 58-29F-11)

The provisions of this chapter do not apply to any investigative audit that involves fraud, willful misrepresentation or any audit completed by the state of South Dakota on health care programs operated by the state.

Civil action by Pharmacy (S.D. Stat. § 58-29F-12)

In addition to the remedies otherwise provided for in this chapter, in chapter 58-29E, or under general South Dakota law, any Pharmacy subject to an audit procedure may bring a civil action to enforce the provisions of this chapter and to seek damages from the pharmacy benefit manager and any person or organization representing the entity during the audit process for the violation of the provisions of this chapter.

B-43 Tennessee Regulatory Addendum to Pharmacy Participation Agreement

This Tennessee Addendum applies to the extent that Pharmacy provides covered drugs to covered persons of insurers, prepaid limited health service organizations, third-party prescription programs, health maintenance organizations and health care service corporations, under Tennessee law (collectively and/or individually, "plan sponsor").

In the event of a direct conflict between this Addendum and the Agreement, the applicable provisions of this Addendum shall control if required. This Addendum may be modified from time to time pursuant to the Agreement.

Without limiting the generality of the foregoing, and notwithstanding anything in the Agreement to the contrary, Pharmacy agrees as follows:

Pharmacy will in no event (including, but not limited to, nonpayment by PBM or any plan sponsor, PBM or any plan sponsor's insolvency, or breach of this Agreement) bill, charge, collect a deposit from, seek compensation, remuneration or reimbursement from, or have any recourse against, a covered person or other persons acting on their behalf. This provision does not prohibit the collection of copays or charges for noncovered services or items. Tenn. Code § 56-32-105(c).

Provided that sufficient payment has been received by PBM from plan sponsor and provided the applicable copay has been collected by Pharmacy, PBM will pay Pharmacy for covered drugs provided to covered persons in accordance with the payment rate information and timelines set forth in the Agreement. Tenn. Code § 63-10-103(1) and (2).

Any and all disputes, controversies, or claims (including without limitation tort claims, requests for provisional remedies or other interim relief and issues as to arbitrability of any matter) arising out of, in connection with or relating to this Agreement, or the breach hereof, that cannot be settled through negotiation shall be settled as set forth in the Provider Manual. Tenn. Code § 63-10-103(3).

Pharmacy must comply with PBM and plan sponsor's quality improvement activities including, but not limited to, the credentialing and quality assurance initiatives required by PBM, and any special quality management requirements and programs established by PBM or plan sponsors. PBM and plan sponsor shall have access to Pharmacy's records relating to claims and services to covered persons as set forth in the Agreement. Tenn. Admin. Code § 1200-8-33-.06(1)(i)(7).

To the extent covered drugs are provided to covered persons of a prepaid limited health service organization, the Agreement may be canceled upon issuance of an order by the Tennessee Department of Insurance pursuant to Tenn. Code § 56-51-129(c).

Maximum allowable cost for drug or medical product or device; appeal (TN ST § 56-7-3108; TN ADC 0780-01-95-.05)

(a) A PBM or covered entity shall establish a clearly defined process through which a pharmacy may contest the listed maximum allowable cost for a particular drug or medical product or device. If a pharmacy chooses to contest the listed maximum allowable cost for a particular drug or medical product or device, the pharmacy shall have the right to designate a pharmacy services administrative organization or other agent to file and handle its appeal of the maximum allowable cost of the drug or medical product or device.

(b) A pharmacy may base its appeal on one (1) or more of the following:

(1) The maximum allowable cost established for a particular drug or medical product or device is below the cost at which the drug or medical product or device is generally available for purchase by pharmacies in this state from national or regional wholesalers; or

(2) The PBM or covered entity has placed a drug on the list without properly determining that the requirements of § 56-7-3106 have been met.

(c) The pharmacy must file its appeal within seven (7) business days of its submission of the initial claim for reimbursement for the drug or medical product or device. The PBM or covered entity must make a final determination resolving the pharmacy's appeal within seven (7) business days of the PBM or covered entity's receipt of the appeal.

(d) If the final determination is a denial of the pharmacy's appeal, the PBM or covered entity must state the reason for the denial and provide the national drug code of an equivalent drug that is generally available for purchase by pharmacies in this state from national or regional wholesalers at a price which is equal to or less than the maximum allowable cost for that drug.

(e)(1) If a pharmacy's appeal is determined to be valid by the PBM or covered entity, the PBM or covered entity shall adjust the maximum allowable cost of the drug or medical product or device for the appealing pharmacy. The adjustment for the appealing pharmacy shall be effective from the date the pharmacy's appeal was filed, and the PBM or covered entity shall provide reimbursement to the appealing pharmacy and may require the appealing pharmacy to reverse and rebill the claim in question in order to receive the corrected reimbursement.

(2) Once an appealing pharmacy's appeal is determined to be valid by the PBM or covered entity, the PBM or covered entity shall adjust the maximum allowable cost of the drug or medical product or device to which the maximum allowable cost applies for all similar pharmacies in the network as determined by the PBM within three (3) business days for claims submitted in the next payment cycle.

(f) A PBM or covered entity shall make available on its secure web site information about the appeals process, including, but not limited to, a telephone number or process that a pharmacy may use to submit maximum allowable cost appeals.

Audits; recoupment of funds; appeals (Tenn. Code § 56-7-3103)

(a) When an audit of records of a pharmacist or Pharmacy is conducted by a covered entity, a PBM, the state or its political subdivisions or any other entity representing the same, it shall be conducted in the following manner:

(1) Written notice shall be given to the pharmacist or Pharmacy at least two weeks prior to conducting the initial on-site audit for each audit cycle;

(2) Any audit performed under this section that involves clinical or professional judgment shall be conducted in consultation with a pharmacist who has knowledge of the Tennessee Pharmacy Practice Act, compiled in title 63, chapter 10, parts 2—4;

(3) Any clerical or recordkeeping error identified during an audit, such as a typographical error, scrivener's error, omission or computer error, does not, in and of itself, constitute fraud or intentional misrepresentation and must not be the basis of a recoupment unless the error results in an actual overpayment to the Pharmacy or the wrong medication being dispensed to the patient. Notwithstanding any other law to the contrary, no such claim is subject to criminal penalties without proof of intent to commit fraud

(4) A pharmacist or Pharmacy may use the records of a hospital, physician or other authorized practitioner of the healing arts for drugs or medical supplies written or transmitted by any means of communication for purposes of validating pharmacy records with respect to orders or refills of a legend or narcotic drug;

(5) A finding of overpayment or underpayment may be a projection based on the number of patients served having a similar diagnosis or on the number of similar orders or refills for similar drugs; however, recoupment of claims must be based on the actual overpayment or underpayment, unless the projection for overpayment or underpayment is part of a settlement as agreed to by the pharmacist or Pharmacy;

(6) Each pharmacist or Pharmacy shall be audited under the standards and parameters as other similarly situated pharmacists or pharmacies audited by a covered entity, a pharmacy benefit manager, the state or its political subdivisions or any other entity representing the same;

(7) A pharmacist or Pharmacy must be allowed the length of time described in the pharmacist's or pharmacy's contract or Manual, whichever is applicable, which must not be less than 30 days, following receipt of the preliminary audit report in which to produce documentation to address any discrepancy found during an audit. A pharmacist or Pharmacy may correct a clerical or recordkeeping error by submitting an amended claim during the designated time frame if the prescription was dispensed according to the requirements of state and federal law. If the pharmacist's or Pharmacy's contract or Provider Manual does not specify the allowed length of time for the pharmacist or Pharmacy to address any discrepancy found in the audit following receipt of the preliminary report, then that pharmacist or Pharmacy must be allowed no less than 30 days following receipt of the preliminary audit report to respond and produce documentation;

(8) The period covered by an audit may not exceed two years from the date the claim was submitted to or adjudicated by a covered entity, a PBM, the state or its political subdivisions, or any other entity representing the same, except this subdivision (a)(8) shall not apply where a longer period is required by any federal rule or law;

(9) An audit shall not be initiated or scheduled during the first seven calendar days of any month due to the high volume of prescriptions filled during that time, unless otherwise consented to by the pharmacist or Pharmacy;

(10) The preliminary audit report must be delivered to the pharmacist or Pharmacy within 120 days after conclusion of the audit. A final audit report shall be delivered to the pharmacist or Pharmacy within six months after receipt of the preliminary audit report or final appeal, whichever is later;

(11) Notwithstanding any other law to the contrary, any audit of a pharmacist or Pharmacy shall not use the accounting practice of extrapolation in calculating recoupments or penalties for audits; and

(12) Any recoupment related to clerical or recordkeeping errors must not include the cost of the drug or dispensed product, except in cases of the following:

(A) Fraud or other intentional and willful misrepresentation;

(B) Dispensing in excess of the pharmacy benefits contract established by the plan sponsor; or

(C) Prescriptions not filled in accordance with the prescriber's order.

(b) Recoupments of any disputed funds shall only occur after final internal disposition of the audit, including the appeal process as set forth in subsection (c).

(c) Each PBM, as defined in § 56-7-3102, conducting an audit shall establish an appeals process under which a pharmacist or Pharmacy may appeal an unfavorable preliminary audit report to the pharmacy benefit manager on whose behalf the audit was conducted. The PBM conducting an audit shall provide to the pharmacist or Pharmacy, before or at the time of delivery of the preliminary audit report, a written explanation of the appeals process, including the name, address and telephone number of the person to whom an appeal should be addressed. If, following the appeal, it is determined that an unfavorable audit report or any portion of the audit report is unsubstantiated, the audit report or the portion shall be dismissed without the necessity of further proceedings.

(d) A pharmacy provider may use any prescription that meets the requirements of being a legal prescription as defined by applicable Tennessee law to validate claims submitted for reimbursement for dispensing of original and refill prescriptions, or changes made to prescriptions.

(e) Auditors are permitted to enter the prescription department when accompanied by or authorized by a member of the pharmacy staff. During the auditing process, auditors shall not disrupt the provision of services to the pharmacy's customers.

(f) A demand for recoupment, repayment or offset against future reimbursement for an overpayment on a claim for dispensing of an original or refill prescription shall not include the dispensing fee, unless the prescription that is the subject of the claim was not actually dispensed, was not valid, was fraudulent or was outside the contract. This subsection (f) shall not apply where a Pharmacy is requested, pursuant to a contractual provision or to § 56-7-2362(b) or § 56-32-138(b), to correct an error in a claim submitted in good faith.

(g) Audit information from an audit conducted by one PBM shall not be shared with or utilized by another PBM. This subsection (g) shall not apply to an investigative audit that is believed by the PBM to involve fraud or willful misrepresentation.

(h) Unless otherwise agreed to by contract, no audit finding or demand for recoupment, repayment or offset against future reimbursement shall be made for any claim for dispensing of an original or refill prescription for the reason of information missing from a prescription or for information not placed in a particular location on a prescription when the information or location of the information is not required or specified by federal or state law.

(i) In the event the actual quantity dispensed on a valid prescription for a covered beneficiary exceeds the allowable maximum days' supply of the product as defined in the applicable pharmacy benefit provider agreement, the amount allowed to be recouped, repaid or offset against future reimbursement shall be limited to an amount that is calculated based on the quantity of the product dispensed found to be in excess of the allowed days' supply quantity and using the cost of the product as reflected on the original claim.

(j) A pharmacy provider shall be allowed to dispense and shall be reimbursed for the full quantity of the smallest available commercially packaged product, including, but not limited to, eye drops, insulin, and topical products, which contains the total amount that is required to be dispensed to meet the days' supply ordered by the prescriber, even if the full quantity of the commercially prepared package exceeds the maximum days' supply allowed.

(k) The highest daily total dose which may be utilized by the patient pursuant to the prescriber's directions shall be used to make a determination of the days' supply. For prescriptions having a titrated dose schedule, the schedule shall be used to determine the days' supply.

(l) Subsections (d)-(k) shall not apply to any investigative audit that involves allegations of fraud or willful misrepresentation.

Reimbursement; reference price updates (Tenn. Code § 56-7-3104)

(a) Reimbursement by a PBM under a contract to a pharmacist or Pharmacy for prescription drugs and other products and supplies that is calculated according to a formula that uses a nationally recognized reference in the pricing calculation shall use the most current nationally recognized reference price or amount in the actual or constructive possession of the PBM or its agent.

(b) For purposes of compliance with this section, PBMs shall be required to update the nationally recognized reference prices or amounts used for calculation of reimbursement for prescription drugs and other products and supplies no less than every three business days.

B-44 Texas Regulatory Addendum to Pharmacy Participation Agreement

This Texas Addendum applies to the extent that Pharmacy provides covered drugs to covered persons of insurers, preferred provider plan carriers, exclusive provider benefit plan issuers, health maintenance

organizations and managed care entities under Texas law (collectively and/or individually, "plan sponsor").

In the event of a direct conflict between this Addendum and the Agreement, the applicable provisions of this Addendum shall control if required. This Addendum may be modified from time to time pursuant to the Agreement.

Without limiting the generality of the foregoing, Pharmacy agrees as follows:

Upon request by any reasonable and verifiable means, Pharmacy is entitled to all information necessary to determine that Pharmacy is being compensated in accordance with the Agreement. Pharmacy may request a description and copy of the coding guidelines, including any underlying bundling, recoding or other payment methodology and fee schedules applicable to payment for specific services that Pharmacy will receive under the Agreement. PBM may provide the required information by any reasonable method. PBM shall provide the information not later than 30 days after the date PBM receives the request. The information shall include a level of detail sufficient to enable a reasonable person with experience and competence in claim processing to determine the payment to be made

according to the terms of the Agreement for covered drugs that are rendered to covered persons. PBM will provide notice of changes to information that will result in a change of payment to Pharmacy not later than 90 days before the date the changes take effect and shall not make retroactive revisions to the coding guidelines and fee schedules. The Agreement may be terminated by Pharmacy on or before 30 days after the date Pharmacy receives information requested in this paragraph without penalty or discrimination in participation in other health care products or plans. Upon receipt of information described in this paragraph, Pharmacy may only: (1) use or disclose the information for the purpose of practice management, billing activities and other business operations and (2) disclose the information to a governmental agency involved in the regulation of health care or insurance. PBM shall, on Pharmacy's request, provide the name, edition and model version of the software that PBM uses to determine bundling and unbundling of claims, if applicable. This provision may not be waived, voided or nullified by contract. Tex. Ins. Code §§ 843.321, 1301.136; 28 Tex. Admin. Code §§ 3.3703(20), 11.901(c)(6).

If Pharmacy voluntarily terminates its participation under the Agreement, Pharmacy shall provide reasonable advance notice to each covered person under Pharmacy's care. PBM shall provide assistance to Pharmacy in ensuring that the notice requirements are met. Tex. Ins. Code §§ 843.309, 1301.160; 28

Tex. Admin. Code § 3.3703(18). If PBM terminates the Agreement, reasonable advance notice shall be given by PBM or plan sponsor, as applicable, to covered persons currently being treated by Pharmacy as permitted by law. Tex. Ins. Code §§ 843.308, 843.309; 28 Tex. Admin. Code § 11.901(c)(7).

Notwithstanding anything to the contrary in the Agreement, Pharmacy shall not be required to hold harmless plan sponsor or otherwise assume tort liability resulting from plan sponsor's acts or omissions. Tex. Ins. Code §§ 843.310, 1301.065; 28 Tex. Admin. Code §§ 3.3703(9), 3.9204(h), 11.901(a).

Neither PBM nor plan sponsor shall engage in any retaliatory action against Pharmacy, including terminating Pharmacy's participation under the Agreement or refusing to renew the Agreement, because Pharmacy has reasonably filed a complaint against plan sponsor on behalf of a covered person or appealed a decision by plan sponsor. Tex. Ins. Code §§ 843.281, 1301.066; 28 Tex. Admin. Code § 11.901(b)(1).

Pharmacy shall post in its place of business a notice to covered persons on the process for resolving complaints with plan sponsors. The notice must include the Texas Department of Insurance's toll-free telephone number for filing a complaint. Tex. Ins. Code § 843.283; 28 Tex. Admin. Code §§ 3.9204(k), 11.901(b)(4).

Notwithstanding anything to the contrary in the Agreement, PBM and plan sponsor shall adhere to all applicable statutes and rules in Texas regarding the prompt payment of claims and submission of clean claims, including those set forth in Tex. Ins. Code, Title 6, Subtitle C, Chapter 843, Subchapter J, Title 8, Subtitle D, Chapter 1301, Subchapters C and C-1, and Texas Admin. Code, Title 28, Sections 21.2801 to 21.2820. Tex. Ins. Code § 1301.107; 28 Tex. Admin. Code §§ 3.3703(11), 11.901(b)(6).

PBM shall provide Pharmacy written reasons for the termination of the Agreement at least 90 days prior to the effective date of the termination. Within 30 days following receipt of the written termination notice, Pharmacy may request a review by PBM or plan sponsor's advisory review panel. Within 60 days of Pharmacy's request and before the effective date of the termination, Pharmacy shall be entitled to a review of the proposed termination by the advisory review panel, except in a case in which there is imminent harm to patient health or an action by a state pharmacy board, or other licensing board or governmental agency, that effectively impairs Pharmacy's ability to practice, or in a case of fraud or malfeasance. The advisory review panel shall be composed of physicians and providers, including at least one representative in Pharmacy's specialty or a similar specialty, if available, appointed to serve on the standing quality assurance committee or utilization review committee of plan sponsor or PBM, as applicable. Within that same 60-day period, the advisory review panel must make its formal recommendation and PBM shall communicate the decision regarding termination to Pharmacy. The decision of the advisory panel must be considered but is not binding on plan sponsor or PBM. PBM or plan sponsor, as applicable, shall provide Pharmacy, on request, a copy of the recommendation of the advisory review panel and the determination of plan sponsor or PBM. On Pharmacy's request, Pharmacy is entitled to an expedited review process. Tex. Ins. Code §§ 843.306, 843.307, 1301.057; 28 Tex. Admin.Code §§ 3.3703(19), 3.3706, 3.9204(e), (g), 11.901(d).

Pharmacy agrees that Pharmacy may bill covered persons based only on the discounted rate and provisions set forth in the Agreement. Tex. Ins. Code § 1301.060; 28 Tex. Admin. Code § 3.3703(10).

Pharmacy agrees that in no event including, but not limited to, nonpayment by plan sponsor or PBM, insolvency of plan sponsor or PBM, or breach of the Agreement, shall Pharmacy bill, charge, collect a deposit from, seek compensation, remuneration or reimbursement from, or have any recourse against a covered person or a person, other than plan sponsor or PBM, acting on their behalf for covered drugs provided pursuant to the Agreement. This provision shall not prohibit collection of supplemental charges or copays made in accordance with the terms of the benefit plan. Pharmacy further agrees that this provision shall survive termination of the Agreement regardless of the cause giving rise to the termination and shall be construed to be for the benefit of covered persons. This provision supersedes any oral or written contrary agreement now existing or hereafter entered into between Pharmacy and covered persons or persons acting on their behalf. Any modification, addition, or deletion to the provisions of this clause shall be effective on a date no earlier than 15 days after the Texas Insurance Commissioner has received written notice of such proposed changes. Tex. Ins. Code §§ 843.361, 1272.055; 28 Tex. Admin. Code §§ 3.9204(i), 11.901(a)(1), 11.2604(b)(7).

Termination of the Agreement, unless based on medical competence or professional behavior, does not release plan sponsor from the obligation to continue reimbursing Pharmacy for providing medically necessary covered drugs at the time of termination to covered persons who have special circumstances in accordance with the dictates of medical prudence. Examples of covered persons who may have special circumstances include a covered person with a disability, acute condition, life-threatening illness, or who is past 24 weeks of pregnancy. plan sponsor shall provide continued reimbursement at rates no less than the rates set forth in the Agreement for the covered persons' care in exchange for continuity of ongoing treatment. For purposes of this provision, "special circumstance" means a condition such that Pharmacy reasonably believes that discontinuing care by Pharmacy could cause harm to the covered persons. Pharmacy shall identify in writing a special circumstance warranting continued service and must request that a covered person be permitted to continue treatment under Pharmacy's care and agree not to seek payment from the covered person of any amount for which the covered person would not be responsible

if the Pharmacy continued to participate under the Agreement. Disputes regarding the necessity for continued treatment by Pharmacy shall be resolved directly between Pharmacy and PBM and/or plan sponsor, as applicable. This provision does not extend the obligation of plan sponsor or PBM to reimburse Pharmacy for ongoing treatment of a covered person after: (1) 90 days of the effective date of termination or (2) if the covered person has been diagnosed with a terminal illness at the time of termination, the expiration of the nine-month period after the effective date of the termination. However, the obligation of plan sponsor to reimburse Pharmacy for services provided to a covered person who is past 24 weeks of pregnancy at the time of termination, extends through delivery of the child, immediate postpartum care and a follow-up checkup within the six-week period after delivery. Tex. Ins. Code §§ 843.362, 1272.302; 28 Tex. Admin. Code §§ 3.3703(12), 3.9204(f), 11.901(a)(3).

Pharmacy shall be entitled to a waiver of the requirement that claims be electronically submitted under the Agreement in any of the following circumstances:

No method is available for the submission of claims in electronic form. This exception applies to situations in which the federal standards for electronic submissions (45 CFR, Parts 160 and 162) do not support all of the information necessary to process the claim.

The operation of small provider practices. This exception applies to those providers with fewer than 10 full-time-equivalent employees, consistent with 42 CFR § 424.32(d)(1)(vii).

Demonstrable undue hardship, including fiscal or operational hardship. Any other special circumstances that would justify a waiver.

Pharmacy's request for a waiver must be in writing and must include documentation supporting the issuance of a waiver. Upon receipt of a request for a waiver, PBM shall, within 14 calendar days, issue or deny a waiver in writing to Pharmacy. An issued waiver will contain any restrictions, conditions or limitations related to the waiver. A denial shall include the reasons therefore and provide notice of Pharmacy's right to appeal the waiver determination (including the denial or placement of any restrictions, conditions, or limitations) to the Texas Department of Insurance within 14 calendar days of receipt. PBM shall not refuse to contract or renew the Agreement with Pharmacy because Pharmacy has requested a waiver or appealed a waiver determination.

Notwithstanding anything to the contrary in the Agreement, PBM shall not limit the mode of electronic transmission that Pharmacy may use to submit information to PBM electronically. PBM shall provide Pharmacy 90 calendar day's written notice before requiring Pharmacy to electronically submit any additional claims or equivalent encounter information, referral certifications, or any authorization or eligibility transactions not already required under this Agreement.

In the event of a systems failure or catastrophic event (as defined in 28 Tex. Admin. Code § 21.2803) that substantially interferes with Pharmacy's business operations, Pharmacy may submit non-electronic claims to PBM beginning on the date of the systems failure or catastrophic event and for the number of calendar days during which the substantial interference occurs. Pharmacy must provide written notice to PBM within five calendar days of the systems failure or catastrophic event of Pharmacy's intent to submit non-electronic claims.

28 Tex. Admin. Code § 11.901(b)(10), 21.3701.

Nothing in the Agreement shall be construed to extend statutory or regulatory time frames set forth by Texas law or to waive Pharmacy's right to recover reasonable attorney's fees and court costs where provided for by statute. 28 Tex. Admin. Code § 21.2817.

Pharmacy agrees to comply with all applicable requirements of Insurance Code § 1661.005 and refund any overpayment received from a covered person within 30 days after Pharmacy determines that an overpayment has been made. Tex. Ins. Code§ 1661.005; 28 Tex. Admin. Code § 3.3703(25).

Appeal from Maximum Allowable Cost Price Determination (TX INS § 1369.357)

(a) A health benefit plan issuer or PBM must provide in the contract with each pharmacist or pharmacy a procedure for the pharmacist or pharmacy to appeal a maximum allowable cost price of a drug on or before the 10th day after the date a pharmacy benefit claim for the drug is made.

(b) The health benefit plan issuer or PBM shall respond to an appeal described by Subsection (a) in a documented communication not later than the 10th day after the date the appeal is received by the health benefit plan issuer or PBM.

(c) If the appeal is successful, the health benefit plan issuer or PBM shall:

(1) adjust the maximum allowable cost price that is the subject of the appeal effective on the day after the date the appeal is decided;

(2) apply the adjusted maximum allowable cost price to all similarly situated pharmacists and pharmacies as determined by the health benefit plan issuer or PBM; and

(3) allow the pharmacist or pharmacy that succeeded in the appeal to reverse and rebill the pharmacy benefit claim giving rise to the appeal.

(d) If the appeal is not successful, the health benefit plan issuer or PBM shall disclose to the pharmacist or pharmacy:

(1) each reason the appeal is denied; and

(2) the national drug code number from the national or regional wholesalers from which the drug is generally available for purchase by pharmacists and pharmacies in this state at the maximum allowable cost price that is the subject of the appeal.

Audit of pharmacist or Pharmacy: Notice; General provisions (TX INS § 1369.254)

(a) Except as provided by subsection (d), a health benefit plan issuer or Prime that performs an on-site audit under this subchapter of a pharmacist or pharmacy shall provide the pharmacist or Pharmacy reasonable notice of the audit and accommodate the pharmacist's or pharmacy's schedule to the greatest extent possible. The notice required under this subsection must be in writing and must be sent by a means that allows tracking of delivery to the pharmacist or Pharmacy not later than 14 days before the date on which the on-site audit is scheduled to occur.

(b) Not later than seven days after the date a pharmacist or Pharmacy receives notice under subsection (a), the pharmacist or Pharmacy may request that an on-site audit be rescheduled to a mutually convenient date. The request must be reasonably granted.

(c) Unless the pharmacist or Pharmacy consents in writing, a health benefit plan issuer or PBM may not schedule or have an on-site audit conducted:

(1) Except as provided by subsection (d), before 14 days after the date the pharmacist or Pharmacy receives notice under subsection (a), if applicable;

(2) More than twice annually in connection with a particular payer; or

(3) During the first five calendar days of January and December.

(d) A health benefit plan issuer or Prime is not required to provide notice before conducting an audit if, after reviewing claims data, written or oral statements of pharmacy staff, wholesalers, or others, or other investigative information, including patient referrals, anonymous reports or postings on Internet websites, the plan issuer or Prime suspects the pharmacist or Pharmacy subject to the audit committed fraud or made an intentional misrepresentation related to the pharmacy business. The pharmacist or Pharmacy may not request that the audit be rescheduled under subsection (b).

(e) A pharmacist or Pharmacy may be required to submit documents in response to a desk audit not earlier than 20 days after the date the health benefit plan issuer or PBM requests the documents.

(f) A contract between a pharmacist or Pharmacy and a health benefit plan issuer or PBM must state detailed audit procedures. If a health benefit plan issuer or PBM proposes a change to the audit procedures for an on-site audit or a desk audit, the plan issuer or Prime must notify the pharmacist or Pharmacy in writing of a change in an audit procedure not later than 60 days before the effective date of the change.

(g) The list of the claims subject to an on-site audit must be provided in the notice under subsection (a) to the pharmacist or Pharmacy and must identify the claims only by the prescription numbers or a date range for prescriptions subject to the audit. The last two digits of the prescription numbers provided may be omitted.

(h) If the health benefit plan issuer or PBM in an on-site audit or a desk audit applies random sampling procedures to select claims for audit, the sample size may not be greater than 300 individual prescription claims.

Completion of audit (Tex. Ins. Code § 1369.255)

An audit of a claim under Section 1369.254 must be completed on or before the one-year anniversary of the date the claim is received by the health benefit plan issuer or PBM.

Audit requiring professional judgment (Tex. Ins. Code § 1369.256)

A health benefit plan issuer or PBM that conducts an on-site audit or a desk audit involving a pharmacist's clinical or professional judgment must conduct the audit in consultation with a licensed pharmacist.

Access to pharmacy area (Tex. Ins. Code § 1369.257)

A health benefit plan issuer or PBM that conducts an on-site audit may not enter the pharmacy area unless escorted by an individual authorized by the pharmacist or Pharmacy.

Validation using certain records authorized (Tex. Ins. Code § 1369.258)

A pharmacist or Pharmacy that is being audited may:

(1) Validate a prescription, refill of a prescription or change in a prescription with a prescription that complies with applicable federal laws and regulations and state laws and rules adopted under Section 554.051, Occupations Code; and

(2) Validate the delivery of a prescription with a written record of a hospital, physician or other authorized practitioner of the healing arts.

Audit discrepancies; wholesale invoices (Tex. Ins. Code § 1369.2581)

(a) A health benefit plan issuer or PBM that audits wholesale invoices during an audit of a pharmacist or Pharmacy may not audit the pharmacy claims of another health benefit plan or PBM.

(b) A health benefit plan issuer or PBM shall reverse a finding of a discrepancy if:

(1) The National Drug Code for the dispensed drug is in a quantity that is a subunit or multiple of the drug purchased by the pharmacist or Pharmacy as supported by a wholesale invoice;

(2) The pharmacist or Pharmacy dispensed the correct quantity of the drug according to the prescription; and

(3) The drug dispensed by the pharmacist or Pharmacy shares all but the last two digits of the National Drug Code of the drug reflected on the supplier invoice.

(c) A health benefit plan issuer or PBM must accept as evidence to support the validity of a pharmacy claim related to a dispensed drug:

(1) Subject to validation, including validation by pharmacy purchase order and payment of a supplier invoice, copies of supplier invoices in the pharmacist's or Pharmacy's possession, including:

(A) Supplier invoices issued before the date the drug was dispensed and not earlier than 60 days before the first day of the audit period; and

(B) Invoices and any supporting documents from any supplier authorized by federal or state law to transfer ownership of the drug acquired by the pharmacist or Pharmacy; and

(2) Reports required by any state board or agency.

(d) A health benefit plan issuer or Prime must provide, not later than five business days after the date of a request by the pharmacist or Pharmacy, any supporting documents the pharmacist's or Pharmacy's suppliers provided to the health benefit plan issuer or PBM.

Calculation of recoupment; use of extrapolation prohibited (Tex. Ins. Code § 1369.259)

(a) A health benefit plan issuer or Prime may not calculate the amount of a recoupment based on:

(1) An absence of documentation the pharmacist or Pharmacy is not required by applicable federal laws and regulations and state laws and rules to maintain; or

(2) An error that does not result in actual financial harm to the patient or enrollee, the health benefit plan issuer or PBM.

(b) A health benefit plan issuer or PBM may not require extrapolation audits as a condition of participation in a contract, network, or program for a pharmacist or Pharmacy.

(c) A health benefit plan issuer or PBM may not use extrapolation to complete an on-site audit or a desk audit of a pharmacist or Pharmacy. Notwithstanding subsection (a)(2), the amount of a recoupment must be based on the actual overpayment or underpayment and may not be based on an extrapolation.

(d) A health benefit plan issuer or PBM may not include a dispensing fee amount in the calculation of an overpayment unless:

(1) The fee was a duplicate charge;

(2) The prescription for which the fee was charged;

(A) Was not dispensed; or

(B) Was dispensed:

(i) Without the prescriber's authorization;

(ii) To the wrong patient; or

(iii) With the wrong instructions; or

(3) The wrong drug was dispensed.

Clerical or recordkeeping error; fraud allegation (Tex. Ins. Code § 1369.260)

(a) An unintentional clerical or recordkeeping error, such as a typographical error, scrivener's error or computer error, found during an on-site audit or a desk audit:

(1) Is not prima facie evidence of fraud or intentional misrepresentation; and

(2) May not be the basis of a recoupment unless the error results in actual financial harm to a patient or enrollee, health benefit plan issuer, or

(b) If the health benefit plan issuer or PBM alleges that the pharmacist or Pharmacy committed fraud or intentional misrepresentation described by subsection (a), the health benefit plan issuer or PBM must state the allegation in the final audit report required by Section 1369.264.

(c) After an audit is initiated, a pharmacist or Pharmacy may resubmit a claim described by subsection (a) if the deadline for submission of a claim under Section 843.337 or 1301.102 has not expired.

Access to previous audit reports; Uniform audit standards (Tex. Ins. Code § 1369.261)

(a) Except as provided by subsection (b), a health benefit plan issuer or PBM may have access to an audit report of a pharmacist or Pharmacy only if the report was prepared in connection with an audit conducted by the health benefit plan issuer or PBM

(b) A health benefit plan issuer or PBM may have access to audit reports other than the reports described by subsection (a) if, after reviewing claims data, written or oral statements of pharmacy staff, wholesalers, or others, or other investigative information, including patient referrals, anonymous reports or postings on internet websites, the plan issuer or the PBM suspects the audited pharmacist or Pharmacy committed fraud or made an intentional misrepresentation related to the pharmacy business.

(c) An auditor must conduct an on-site audit or a desk audit of similarly situated pharmacists or Pharmacies under the same audit standards.

Compensation of auditor (Tex. Ins. Code § 1369.262)

An individual performing an on-site audit or a desk audit may not directly or indirectly receive compensation based on a percentage of the amount recovered as a result of the audit.

Conclusion of audit; summary; preliminary audit report (Tex. Ins. Code § 1369.263)

(a) At the conclusion of an on-site audit or a desk audit, the health benefit plan issuer or PBM shall:

(1) Provide to the pharmacist or Pharmacy a summary of the audit findings; and

(2) Allow the pharmacist or Pharmacy to respond to questions and alleged discrepancies, if any, and comment on and clarify the findings.

(b) Not later than 60 days after the date the audit is concluded, the health benefit plan issuer or PBM shall send by a means that allows tracking of delivery to the pharmacist or Pharmacy a preliminary audit report stating the results of the audit and a list identifying documentation, if any, required to resolve discrepancies, if any, found as a result of the audit.

(c) The pharmacist or Pharmacy may, by providing documentation or otherwise, challenge a result or remedy a discrepancy stated in the preliminary audit report not later than 30 days after the date the pharmacist or Pharmacy receives the report.

(d) The pharmacist or Pharmacy may request an extension to provide documentation supporting a challenge. The request shall be reasonably granted. A health benefit plan issuer or PBM that grants an extension is not subject to the deadline to send the final audit report under Section 1369.264.

Final audit report (Tex. Ins. Code § 1369.264)

Not later than 120 days after the date the pharmacist or Pharmacy receives a preliminary audit report under Section 1369.263, the health benefit plan issuer or PBM shall send by a means that allows tracking of delivery to the pharmacist or Pharmacy a final audit report that states:

(1) The audit results after review of the documentation submitted by the pharmacist or Pharmacy in response to the preliminary audit report; and

(2) The audit results, including a description of all alleged discrepancies and explanations for and the amount of recoupments claimed after consideration of the pharmacist's or Pharmacy's response to the preliminary audit report.

Certain audits exempt from deadlines (Tex. Ins. Code § 1369.265)

A health benefit plan issuer or PBM is not subject to the deadlines for sending a report under Sections 1369.263 and 1369.264 if, after reviewing claims data, written or oral statements of pharmacy staff, wholesalers, or others, or other investigative information, including patient referrals, anonymous reports, or postings on internet websites, the plan issuer or PBM suspects the audited pharmacist or Pharmacy committed fraud or made an intentional misrepresentation related to the pharmacy business. if, after reviewing claims data, written or oral statements of pharmacy staff, wholesalers, or others, or other investigative information, including patient referrals, anonymous reports, or postings on internet websites, the plan issuer or PBM suspects the audited pharmacist or Pharmacy committed fraud or made an intentional misrepresentation related to the pharmacy business.

Recoupment and interest charged after audit (Tex. Ins. Code § 1369.266)

(a) If an audit under this subchapter is conducted, the health benefit plan issuer or PBM:

(1) May recoup from the pharmacist or Pharmacy an amount based only on a final audit report; and

(2) May not accrue or assess interest on an amount due until the date the pharmacist or Pharmacy receives the final audit report under Section 1369.264.

(b) The limitations on recoupment and interest accrual or assessment under subsection (a) do not apply to a health benefit plan issuer or PBM that, after reviewing claims data, written or oral statements of pharmacy staff, wholesalers, or others, or other investigative information, including patient referrals, anonymous reports or postings on internet websites, suspects the audited pharmacist or Pharmacy committed fraud or made an intentional misrepresentation related to the pharmacy business.

B-45 Utah Regulatory Addendum to Pharmacy Participation Agreement

This Utah Addendum applies to the extent that Pharmacy provides covered drugs to covered persons of health maintenance organizations, managed care organizations, insurers or carriers under Utah law (collectively and/or individually, "plan sponsor").

In the event of a direct conflict between this Addendum and the Agreement, the applicable provisions of this Addendum shall control if required. This Addendum may be modified from time to time pursuant to the Agreement.

Without limiting the generality of the foregoing, Pharmacy agrees as follows:

During the first two years of the Agreement, PBM may terminate the Agreement with or without cause upon providing Pharmacy with the requisite amount of notice provided in the Agreement, but in no case shall it be less than 60 days. Utah Code § 31A-45-304(2)(a).

PBM may terminate Pharmacy for cause as provided in the Agreement provided that prior to terminating for cause, PBM shall:

Inform Pharmacy of its intent to terminate and the grounds for doing so; and

Upon Pharmacy's request, PBM shall meet with Pharmacy to discuss the reasons for termination. Utah Code § 31A-45-304(2)(b), (c).

Notwithstanding the above, if PBM has a reasonable basis to believe that Pharmacy has engaged in fraudulent conduct or poses a significant risk to patient care or safety, PBM may immediately suspend Pharmacy from further performance under the Agreement, provided that Pharmacy shall be made aware of and allowed to access PBM's internal appeals process before termination may become final. Utah Code § 31A-45-304(c), (d).

PBM and Pharmacy agree to resolve all disputes, controversies and claims in the manner set forth in the Agreement and any related attachments, with the exception that, if arbitration is initiated, the arbitrator shall be jointly selected by the parties, the cost of which shall be jointly shared, and each party shall bear its own additional expenses. Utah Code §§ 31A-45-304(2)(d); 31A-45-303; 31A-8-407; 31A-46-303(6).

If plan sponsor or PBM fails to pay for covered drugs as set forth in the Agreement, covered persons shall not be liable to Pharmacy for any sums owed by plan sponsor or PBM. Utah Code §§ 31A-8-407(1)(a)(i); 31A-45-303.

Pharmacy acknowledges and agrees that if plan sponsor or PBM becomes insolvent, the rehabilitator or liquidator may require Pharmacy to:

Continue to provide covered drugs until the earlier of (a) 90 days after the date of the filing of a petition for rehabilitation or liquidation or (b) the date the term of the Agreement ends; and

Reduce the fees that Pharmacy is otherwise entitled to receive from plan sponsor or PBM under the Agreement during the time period described in the paragraph immediately above, provided that the rehabilitator or liquidator may not reduce a fee to less than 75% of the regular fee set forth in the Agreement and provided that covered persons shall continue to pay the same copays, deductibles and other payments for services as before the petition for reorganization or liquidation. Pharmacy shall accept the reduced payment as payment in full and relinquish the right to collect additional amounts from covered persons. Utah Code §§ 31A-8-407; 31A-45-303(1)(c).

Insurer and pharmacy benefit management services — Registration — Maximum allowable cost — Audit restrictions (UT ST § 31A-46-303)

(2) A PBM shall not use maximum allowable cost as a basis for reimbursement to a pharmacy unless:

(a) the drug is listed as "A" or "B" rated in the most recent version of the United States Food and Drug Administration's approved drug products with therapeutic equivalent evaluations, also known as the "Orange Book," or has an "NR" or "NA" rating or similar rating by a nationally recognized reference; and

(b) the drug is:

(i) generally available for purchase in this state from a national or regional wholesaler; and

(ii) not obsolete.

(3) The maximum allowable cost may be determined using comparable and current data on drug prices obtained from multiple nationally recognized, comprehensive data sources, including wholesalers, drug file vendors, and pharmaceutical manufacturers for drugs that are available for purchase by pharmacies in the state.

(4) For every drug for which the PBM uses maximum allowable cost to reimburse a contracted pharmacy, the PBM shall:

(a) include in the contract with the pharmacy information identifying the national drug pricing compendia and other data sources used to obtain the drug price data;

(b) review and make necessary adjustments to the maximum allowable cost, using the most recent data sources identified in Subsection (4)(a), at least once per week;

(c) provide a process for the contracted pharmacy to appeal the maximum allowable cost in accordance with Subsection (5); and

(d) include in each contract with a contracted pharmacy a process to obtain an update to the pharmacy product pricing files used to reimburse the pharmacy in a format that is readily available and accessible.

(5)(a) The right to appeal in Subsection (4)(c) shall be:

(i) limited to 21 days following the initial claim adjudication; and

(ii) investigated and resolved by the PBM within 14 business days.

(b) If an appeal is denied, the PBM shall provide the contracted pharmacy with the reason for the denial and the identification of the national drug code of the drug that may be purchased by the pharmacy at a price at or below the price determined by the PBM.

(6) The contract with each pharmacy shall contain a dispute resolution mechanism in the event either party breaches the terms or conditions of the contract.

(7) This section does not apply to a PBM when the PBM is providing pharmacy benefit management services on behalf of the Medicaid program.

Utah Code § 31A-46-303(5).

Pharmacy benefit management services — Auditing of pharmacy records — Appeals (Utah Code § 58-17b-622)

(2)(a) Except as provided in subsection (2)(b), this section applies to:

(i) A contract for the audit of a Pharmacy entered into, amended or renewed on or after July 1, 2012; and

(ii) An entity that conducts an audit of the pharmacy records of a Pharmacy licensed under this chapter.

(b) This section does not apply to an audit of pharmacy records:

(i) For a federally funded prescription drug program, including:

(A) The state Medicaid Program;

(B) The Medicare Part D Program;

(C) A Department of Defense prescription drug program; and

(D) A Veterans Affairs prescription drug program; or

(ii) When fraud or other intentional and willful misrepresentation is alleged and the pharmacy audit entity has evidence that the pharmacy's actions reasonably indicate fraud or intentional and willful misrepresentation.

(3)(a) An audit that involves clinical or professional judgment shall be conducted by or in consultation with a pharmacist who is employed by or working with the auditing entity and who is licensed in the state or another state.

(b) If an audit is conducted on-site at a Pharmacy, the entity conducting the audit:

(i) Shall give the Pharmacy 10 days' advance written notice of:

(A) The audit; and

(B) The range of prescription numbers or a date range included in the audit; and

(ii) May not audit a Pharmacy during the first five business days of the month, unless the Pharmacy agrees to the timing of the audit.

(c) An entity may not audit claims:

(i) Submitted more than 18 months prior to the audit, unless:

(A) Required by federal law; or

(B) The originating prescription is dated in the preceding six months; or

(ii) That exceed 200 selected prescription claims.

(4)(a) An entity may not:

(i) Include dispensing fees in the calculations of overpayments unless the prescription is considered a misfill;

(ii) Recoup funds for prescription clerical or recordkeeping errors, including typographical errors, scrivener's errors and computer errors on a required document or record unless the audit entity is alleging fraud or other intentional or willful misrepresentation and the audit entity has evidence that the Pharmacy's actions reasonably indicate fraud or intentional and willful misrepresentation;

(iii) Recoup funds for refills dispensed in accordance with Section 58-17b-608.1, unless the health benefit plan does not cover the prescription drug dispensed by the Pharmacy;

(iv) Collect any funds, charg-backs or penalties until the audit and all appeals are final, unless the audit entity is alleging fraud or other intentional or willful misrepresentation and the audit entity has evidence that the Pharmacy's actions reasonably indicate fraud or intentional and willful misrepresentation; or

(v) Recoup funds or collect any funds, chargebacks or penalties from a Pharmacy in response to a request for audit unless the Pharmacy confirms to the entity the date on which the Pharmacy received the request for audit.

(b) Auditors shall only have access to previous audit reports on a particular Pharmacy if the previous audit was conducted by the same entity except as required for compliance with state or federal law.

(5) A Pharmacy subject to an audit:

(a) May use one or more of the following to validate a claim for a prescription, refill or change in a prescription:

(i) Electronic or physical copies of records of a health care facility, or a health care provider with prescribing authority;

(ii) Any prescription that complies with state law;

(iii) The Pharmacy's own physical or electronic records; or

(iv) The physical or electronic records, or valid copies of the physical or electronic records, of a practitioner or health care facility as defined in Section 26B-2-201; and

(b) May not be required to provide the following records to validate a claim for a prescription, refill or change in a prescription:

(i) If the prescription was handwritten, the physical handwritten version of the prescription; or

(ii) A note from the practitioner regarding the patient or the prescription that is not otherwise required for a prescription under state or federal law.

(6)(a)(i) An entity that audits a Pharmacy shall establish:

(A) A maximum time for the Pharmacy to submit records or other documents to the entity following receipt of an audit request for records or documents; and

(B) A maximum time for the entity to provide the Pharmacy with a preliminary audit report following submission of records under subsection (6)(a)(i)(A).

(ii) The time limits established under subsections (6)(a)(i)(A) and (B):

(A) shall be identical; and

(B) May not be less than seven days or more than 60 days.

(iii) An entity that audits may not, after the audit completion date, request additional records or other documents from the Pharmacy to complete the preliminary audit report described in subsection (6)(b).

(b) An entity that audits a Pharmacy shall provide the Pharmacy with a preliminary audit report, delivered to the Pharmacy or its corporate office of record, within the time limit established under subsection (6)(a)(i)(B).

(c)(i) Except as provided in subsection (6)(c)(ii), a Pharmacy has 30 days following receipt of the preliminary audit report to respond to questions, provide additional documentation and comment on and clarify findings of the audit.

(ii) An entity may grant a reasonable extension under subsection (6)(c)(i) upon request by the Pharmacy.

(iii) Receipt of the report under subsection (6)(c)(i) shall be determined by:

(A) Postmark or other evidence of the date of mailing; or

(B) The date of transmission if the report is transmitted electronically.

(iv) If a dispute exists between the records of the auditing entity and the Pharmacy, the records maintained by the Pharmacy shall be presumed valid for the purpose of the audit.

(7) If an audit results in the dispute or denial of a claim, the entity conducting the audit shall allow:

(a) The Pharmacy to resubmit a claim using any commercially reasonable method, including fax, mail or electronic claims submission provided that the period of time when a claim may be resubmitted has not expired under the rules of the plan sponsor; and

(b) The health benefit plan or other entity that finances or reimburses the cost of health care services or pharmaceutical products to rerun the claim if the health benefit plan or other entity chooses to rerun the claim at no cost to the Pharmacy.

(8)(a) Within 60 days after the completion of the appeals process under subsection (9), a final audit report shall be delivered to the Pharmacy or its corporate office of record.

(b) The final audit report shall include a disclosure of any money recovered by the entity that conducted the audit.

(9)(a) An entity that audits a Pharmacy shall establish a written appeals process for appealing a preliminary audit report and a final audit report and shall provide the Pharmacy with notice of the written appeals process.

(b) If the PBM's contract or Provider Manual contains the information required by this subsection (9), the requirement for notice is met.

B-46 Vermont Regulatory Addendum to Pharmacy Participation Agreement

This Vermont Addendum applies to the extent that Pharmacy provides covered drugs to covered persons of discount medical plans, health maintenance organizations, managed care organizations, health service corporations, insurers or carriers under Vermont law (collectively and/or individually, "plan sponsor").

In the event of a direct conflict between this Addendum and the Agreement, the applicable provisions of this Addendum shall control if required. This Addendum may be modified from time to time pursuant to the Agreement.

Without limiting the generality of the foregoing, Pharmacy agrees as follows:

To the extent Pharmacy provides services to covered persons of a managed care organization under Vermont law, Pharmacy agrees:

Pharmacy's requirements and responsibilities with respect to administrative policies and programs, including, but not limited to, payment terms, utilization review, quality assessment and improvement programs, chronic care programs, credentialing, grievance procedures, data reporting requirements, confidentiality requirements and any applicable provisions required by federal or state law are set forth in the Agreement, the pharmacy Manual and any related attachments. Pharmacy shall be allowed to participate in PBM's quality management program, dispute resolution process and utilization management program to the extent required by law. Pharmacy shall notify PBM of any changes that would impact Pharmacy's credentialing status or ongoing availability to covered persons. Vt. Admin. Code 4-5-3:5(5.3)(E).

Pharmacy agrees to take those steps necessary, as directed by PBM, to ensure the availability and confidentiality of the health records necessary to monitor and evaluate the quality of care and to conduct medical and other health care evaluations and audits to determine, on a concurrent or retrospective basis, the necessity and appropriateness of care provided to covered persons. Pharmacy shall make its health records available as required by law to appropriate state and federal authorities involved in assessing the quality of care or investigating the grievances or complaints of covered persons and shall comply with the applicable state and federal laws related to the confidentiality of medical or health records. Vt. Admin. Code 4-5-3:5(5.3)(F).

Pharmacy agrees that in no event, including nonpayment by plan sponsor or PBM, insolvency of plan sponsor or PBM, or breach of the Agreement, shall Pharmacy bill, charge, collect a deposit from, seek compensation, remuneration or reimbursement from, or have any recourse against a covered person or a person (other than plan sponsor) acting on behalf of the covered person for covered drugs provided pursuant to this Agreement. This provision does not prohibit Pharmacy from collecting coinsurance, deductibles and copays, as specifically provided in covered person's certificate of coverage, or fees for uncovered services delivered on a fee-for-service basis to covered persons. This provision does prohibit Pharmacy from requesting payment from a covered person for any services that have been confirmed by independent external review obtained through the Department of Banking, Insurance, Securities and Health Care Administration pursuant to Vermont law to be medically unnecessary, experimental, investigational or a medically inappropriate off-label use of a drug. Vt. Admin. Code 4-5-3:5(5.3)(I).

In the event plan sponsor and/or PBM becomes insolvent or otherwise ceases operations, covered drugs to covered persons will continue through the period for which a premium has been paid to plan sponsor on behalf of the covered person or until the covered person's discharge from an inpatient facility, whichever period is greater. Covered drugs to a covered person confined in an inpatient facility on the date of insolvency or other cessation of operations will continue until the covered person's continued confinement in the facility is no longer medically necessary. Vt. Admin. Code 4-5-3:5(5.3)(J).

The provisions of subsections “c” and “d” above shall be construed in favor of the covered person; shall survive termination of the Agreement regardless of the reason for termination, including the insolvency of plan sponsor and/or PBM, and shall supersede any oral or written contrary agreement between Pharmacy and a covered person or a covered person’s representative if the contrary agreement is inconsistent with the “hold harmless” and continuation of covered services provisions required in those paragraphs. Vt. Admin. Code 4-5-3:5(5.3)(K).

Notwithstanding anything in the Agreement to the contrary, either party shall provide at least 60 days written notice to each other before terminating the Agreement without cause. Such notices shall not issue unless and until negotiations have concluded and a final decision on termination has been reached. Within five working days of the date that Pharmacy either gives or receives final notice of termination, either for or without cause, Pharmacy shall supply PBM with a list of its patients that are covered persons of affected plan sponsors. Vt. Admin. Code 4-5-3:5(5.3)(L).

In the event the Agreement is terminated without cause by either party or PBM elects not to renew the Agreement without cause, Pharmacy agrees to continue to provide covered drugs and abide by the payment rates, quality-of-care standards and protocols under the Agreement, and to provide the necessary clinical information to PBM and/or plan sponsor, as follows:

xi. For covered persons with life-threatening, disabling or degenerative conditions, Pharmacy shall continue to provide covered drugs for 60 days from the date of termination or non-renewal or until accepted by a contracted provider, whichever is shorter; and

xii. For covered persons in their second or third trimester of pregnancy, Pharmacy shall continue to provide covered drugs until the completion of postpartum care. Vt. Admin. Code 4-5-3:5(5.1)(G).

To the extent Pharmacy services covered persons of an HMO under Vermont law, Pharmacy agrees:

Pharmacy agrees that in no event, including nonpayment by plan sponsor or PBM, insolvency of plan sponsor or PBM, or breach of the Agreement, shall Pharmacy bill, charge, collect a deposit from, seek compensation, remuneration or reimbursement from or have any recourse against a covered person or a person (other than plan sponsor) acting on behalf of the covered person for covered drugs provided pursuant to this Agreement. 8 Vt. Stat. § 5102b(d).

In the event of plan sponsor’s insolvency, Pharmacy shall continue to provide covered drugs to covered persons after plan sponsor’s insolvency during the period for which premium payment has been made and until covered persons’ discharge from inpatient facilities, whichever comes first. 8 Vt. Stat. § 5102b(f).

Pharmacy benefit managers; required practices with respect to pharmacies (VT ST T. 18 § 3631)

(c) For each drug for which a PBM establishes a maximum allowable cost in order to determine the reimbursement rate, the PBM shall do all of the following:

(1) Make available, in a format that is readily accessible and understandable by a pharmacist, the actual maximum allowable cost for each drug and the source used to determine the maximum allowable cost, which shall not be dependent upon individual beneficiary identification or benefit stage.

(2) Update the maximum allowable cost at least once every seven (7) calendar days. In order to be subject to maximum allowable cost, a drug must be widely available for purchase by all pharmacies in the State, without limitations, from national or regional wholesalers and must not be obsolete or temporarily unavailable.

(3) Establish or maintain a reasonable administrative appeals process to allow a dispensing pharmacy provider to contest a listed maximum allowable cost.

(4)(A) Respond in writing to any appealing pharmacy provider within ten (10) calendar days after receipt of an appeal, provided that, except as provided in subdivision (B) of this subdivision (4), a dispensing pharmacy provider shall file any appeal within ten (10) calendar days from the date its claim for reimbursement is adjudicated.

(B) A PBM shall allow a dispensing pharmacy provider to appeal after the 10-calendar-day appeal period set forth in subdivision (A) of this subdivision (4) if the prescription claim is subject to an audit initiated by the PBM or its auditing agent.

(5) For a denied appeal, provide the reason for the denial and identify the national drug code and a Vermont-licensed wholesaler of an equivalent drug product that may be purchased by contracted pharmacies at or below the maximum allowable cost.

(6) For an appeal in which the appealing pharmacy is successful:

(A make the change in the maximum allowable cost within thirty (30) business days after the redetermination; and

(B) allow the appealing pharmacy or pharmacist to reverse and rebill the claim in question.

Pharmacy rights during an audit (18 Vt. Stat § 3802)

Notwithstanding any provision of law to the contrary, whenever a health insurer, a third-party payer, or an entity representing a responsible party conducts an audit of the records of a Pharmacy, the Pharmacy shall have a right to all of the following:

(1) To have an audit involving clinical or professional judgment be conducted by a pharmacist licensed to practice pharmacy in one or more states, who has at least a familiarity with Vermont pharmacy statutes and rules and who is employed by or working with an auditing entity.

(2) If an audit is to be conducted on-site at a Pharmacy, the entity conducting the audit:

(A) Shall give the Pharmacy at least 14 days' advance written notice of the audit and the specific prescriptions to be included in the audit;

(B) Shall not audit a Pharmacy on Mondays or on weeks containing a federal holiday, unless the Pharmacy agrees to alternative timing for the audit; and

(C) Shall not audit claims that:

(i) Were submitted to the auditing entity more than 18 months prior to the date of the audit, unless:

(I) Required by federal law; or

(II) The originating prescription was dated within the 24-month period preceding the date of the audit; or

(ii) Exceed 200 selected prescription claims.

(3) If any audit is to be conducted remotely, the entity conducting the audit:

(A) Shall give the Pharmacy at least seven business days following the pharmacy's confirmation of receipt of the notice of the audit to respond to the audit; and

(B) Shall not audit claims that:

(i) Were submitted to the pharmacy benefit manager more than three months prior to the date of the audit or on a date earlier than that for which the Pharmacy could electronically retransmit a corrected claim; or

(ii) Exceed five selected prescription claims.

(4) To have auditors enter the prescription department only when accompanied by or authorized by a member of the pharmacy staff, and not to have auditors disrupt the provision of services to the Pharmacy's customers.

(5) Not to have clerical or recordkeeping errors, including typographical errors, scrivener's errors and computer errors, on a required document or record deemed fraudulent in the absence of any financial harm or other evidence; provided that this subdivision shall not be construed to prohibit recoupment of actual fraudulent payments.

(6) If required under the terms of the contract, to have the auditing entity provide to the Pharmacy, upon request, all records related to the audit in an electronic or digital media format.

(7) In order to validate a pharmacy record with respect to a prescription or refill, to have the properly documented records of a hospital or of any person authorized by law to prescribe medication transmitted by any means of communication.

(8) To use any prescription that meets the requirements to be a legal prescription under Vermont law, including prescriber notations such as "as directed" and "as needed" which require the professional judgment of the pharmacist to determine that the dose dispensed is within normal guidelines, to validate claims submitted for reimbursement for dispensing of original and refill prescriptions, or changes made to prescriptions.

(9) To dispense and receive reimbursement for the full quantity of the smallest commonly available commercially packaged product, including eye drops, insulin and topical products, that contains the total amount required to be dispensed to meet the days' supply ordered by the prescriber, even if the full quantity of the commercially prepared package exceeds the maximum days' supply allowed.

(10) To determine the days' supply using the highest daily total dose that may be utilized by the patient pursuant to the prescriber's directions, and for prescriptions with a titrated dose schedule, to use the schedule to determine the days' supply.

(11) To be subject to recoupment only following the correction of a claim and to have recoupment limited to amounts paid in excess of amounts payable under the corrected claim.

(12) Not to have a demand for recoupment, repayment or offset against future reimbursement for overpayment of a claim for dispensing of an original or refill prescription include the dispensing fee, unless the prescription that is the subject of the claim was not actually dispensed, was not valid, was fraudulent or was outside the provisions of the contract; provided that this subdivision shall not apply if a Pharmacy is required to correct an error in a claim submitted in good faith.

(13) Unless otherwise agreed to by contract, not to have an audit finding or demand for recoupment, repayment or offset against future reimbursement made for any claim for dispensing of an original or refill prescription due to information missing from a prescription or to information not placed in a particular location when the information or location is not required or specified by state or federal law. The Pharmacy shall be allowed 30 days to document and correct the missing information.

(14) In the event the actual quantity dispensed on a valid prescription for a covered beneficiary exceeded the allowable maximum days' supply of the product as defined in the contract, to have the amount to be recouped, repaid or offset against future reimbursement limited to an amount calculated based on the quantity of the product dispensed found to be in excess of the allowed days' supply quantity and using the cost of the product as reflected on the original claim.

(15) Not to have the accounting practice of extrapolation used in calculating any recoupment or penalty, unless otherwise required by federal law or by federal health plans.

(16) Except for cases of federal Food and Drug Administration regulation or drug manufacturer safety programs, to be free of recoupments based on either:

(A) Documentation requirements in addition to or in excess of State Board of Pharmacy documentation creation or maintenance requirements; or

(B) A requirement that a Pharmacy or pharmacist perform a professional duty in addition to or in excess of State Board of Pharmacy professional duty requirements.

(17) Except for Medicare claims, to be subject to reversals of approval for drug, prescriber or patient eligibility upon adjudication of a claim only in cases in which the Pharmacy obtained the adjudication by fraud or misrepresentation of claim elements.

(18) To be audited under the same standards and parameters as other similarly situated Pharmacies audited by the same entity.

(19) To have the preliminary audit report delivered to the Pharmacy within 30 days following the Pharmacy's preliminary response.

(20) To have at least 30 days following receipt of the preliminary audit report to produce documentation to address any discrepancy found during the audit.

(21) To have a final audit report delivered to the Pharmacy within 30 days after the end of the appeals period, as required by section 3803 of this title.

(22) Except for audits initiated to address an identified problem, to be subject to no more than one audit per calendar year, unless fraud or misrepresentation is reasonably suspected.

(23) Not to have audit information from an audit conducted by one auditing entity shared with or utilized by another auditing entity, except as required by state or federal law.

(24) To have all payment data related to audited claims, including:

(A) Payment amount;

(B) Any direct and indirect remuneration (DIR) or generic effective rate (GER) fees assessed or other financial offsets;

(C) Date of electronic payment or check date and number;

(D) The specific contracted reimbursement basis for each claim, including its basis, such as maximum allowable cost (MAC), wholesale acquisition cost (WAC), average wholesale price (AWP) or average manufacturer price (AMP); and

(E) The respective values used to calculate each claim payment.

Appeals (18 Vt. Stat § 3803)

(a) An entity that audits a Pharmacy shall provide the Pharmacy with a preliminary audit report, which shall be delivered to the Pharmacy or to its corporate office of record within 60 days following completion of the audit.

(b) A Pharmacy shall have 30 days following receipt of the preliminary audit report in which to respond to questions, provide additional documentation and comment on and clarify audit findings. Receipt of the report shall be based on the date postmarked on the envelope or the date of a computer transmission, if transferred electronically.

(c) If an audit results in the dispute or denial of a claim, the entity conducting the audit shall allow the Pharmacy to resubmit the claim using any commercially reasonable method, including U.S. mail, facsimile or electronic claims submission, as long as the period of time during which a claim may be resubmitted has not expired.

(d) Within 120 days after the completion of the appeals process established by this section, a final audit report shall be delivered to the Pharmacy or to its corporate office of record. The final audit report shall include a disclosure of any funds recovered by the entity that conducted the audit.

(e) An entity that audits a Pharmacy shall have in place a written appeals process by which a Pharmacy may appeal the preliminary audit report and the final audit report, and shall provide the Pharmacy with notice of the appeals process.

(f) A Pharmacy shall be entitled to request a mediator agreed upon by both parties to resolve any disagreements; such request shall not be deemed to waive any existing rights of appeal.

Pharmacy audit recoupments (18 Vt. Stat § 3804)

(a) Recoupment of any disputed funds shall occur only after the final internal disposition of an audit, including the appeals process set forth in section 3803 of this title.

(b) An entity conducting an audit may not:

(1) Include dispensing fees in calculations of overpayments unless the prescription is determined to have been dispensed in error;

(2) Recoup funds for clerical or recordkeeping errors, including typographical errors, scriveners' errors and computer errors on a required document or record unless the error resulted in overpayment or the entity conducting the audit has evidence that the Pharmacy's actions reasonably indicate fraud or other intentional or willful misrepresentation;

(3) Collect any funds, charg-backs or penalties until the audit and all appeals are final, unless the entity conducting the audit is alleging fraud or other intentional or willful misrepresentation;

(4) Recoup an amount in excess of the actual overpayment.

(c) Recoupment on an audit shall be refunded to the responsible party as contractually agreed upon by the parties.

(d) The entity conducting the audit may charge or assess the responsible party, directly or indirectly, based on amounts recouped if both of the following conditions are met:

(1) The responsible party and the entity conducting the audit have entered into a contract that explicitly states the percentage charge or assessment to the responsible party; and

(2) A commission or other payment to an agent or employee of the entity conducting the audit is not based, directly or indirectly, on amounts recouped.

Applicability (18 Vt. Stat § 3805)

The provisions of this chapter shall not apply to any audit or investigation undertaken by any state agency, including the Office of the Attorney General or the Agency of Human Services, to a fiscal agent of the state, or to any audit, review or investigation that involves alleged Medicaid fraud, Medicaid waste, Medicaid abuse, insurance fraud, or criminal fraud or misrepresentation.

B-47 Virginia Regulatory Addendum to Pharmacy Participation Agreement

This Virginia Addendum applies to the extent that Pharmacy provides covered drugs to covered persons of a health maintenance organization, health plan or carrier licensed under Virginia law (collectively and/or individually, "plan sponsor").

In the event of a direct conflict between this Addendum and the Pharmacy Participation Agreement ("Agreement"), the applicable provisions of this Addendum shall control if required. This Addendum may be modified from time to time pursuant to the Agreement.

Without limiting the generality of the foregoing, Pharmacy agrees as follows:

In the processing of any payment of claims for covered drugs rendered by Pharmacy under the Agreement and in performing under the Agreement, the parties shall adhere to and comply with the minimum fair business standards required under Va. Code § 38.2-3407.15(B). See also Va. Code § 38.2- 4319 and 4214, which includes the following:

Claims shall be paid within 40 days of receipt of the claim, except where the obligation to pay the claim is not reasonably clear due to the existence of a reasonable basis supported by specific information available for review by Pharmacy that:

i. The claim is determined not to be a clean claim due to a good faith determination or dispute regarding (i) the manner in which the claim form was completed or submitted, (ii) the eligibility of a person for coverage, (iii) the responsibility of another carrier for all or part of the claim, (iv) the amount of the claim or the amount currently due under the claim, (v) the benefits covered, or (vi) the manner in which services were accessed or provided; or

ii. The claim was submitted fraudulently. Va. Code § 38.2-3407.15(B)(1).

Pharmacy benefit manager (PBM) shall maintain a written or electronic record of the date of receipt of a claim. Pharmacy shall be entitled to inspect such record on request and to rely on that record or on any other admissible evidence as proof of the fact of receipt of the claim, including, without limitation, electronic or facsimile confirmation of receipt of a claim. Va. Code § 38.2-3407.15(B)(1).

PBM shall, within 30 days of receipt of a claim, request electronically or in writing from Pharmacy the information and documentation that PBM believes will be required to process and pay the claim or to determine if the claim is a clean claim. Upon receipt of the additional information requested under this subsection, claims shall be paid in compliance with this section. PBM shall not refuse to pay a claim for covered drugs rendered pursuant to this Agreement if PBM fails to notify or attempt to notify Pharmacy of the matters identified above in a timely manner, unless such failure was caused in material part by Pharmacy; however, nothing herein shall preclude PBM from imposing a retroactive denial of payment of such a claim if permitted by the Agreement unless such retroactive denial of payment of the claim would violate subsection (h) set forth below. Nothing in this subsection shall require PBM to pay a claim that is not a clean claim. Va. Code § 38.2-3407.15(B)(2).

Any interest owing or accruing on a claim under § 38.2-3407.1 or § 38.2-4306.1 of Title 38.2 of the Virginia Code, under the Agreement, or under any other applicable law, shall be paid without necessity of demand at the time the claim is paid or within 60 days thereafter, if not sooner. Va. Code § 38.2-3407.15(B) (3).

PBM and/or plan sponsor, as applicable, shall establish and implement reasonable policies to permit Pharmacy (i) to confirm in advance during normal business hours by free telephone or electronic means if available whether the health care services to be provided are medically necessary and a covered benefit and (ii) to determine the plan sponsor's requirements applicable to Pharmacy (or to the type of health care services that Pharmacy has contracted to deliver under this Agreement) for (a) pre-certification or authorization of coverage decisions, (b) retroactive reconsideration of a certification or authorization of coverage decision or retroactive denial of a previously paid claim, (c) pharmacy-specific payment and reimbursement methodology, coding levels and methodology, downcoding, and bundling of claims and (d) other pharmacy-specific applicable claims processing and payment matters necessary to meet the terms and conditions of the Agreement, including determining whether a claim is a clean claim. PBM does not routinely, as a matter of policy, bundle or downcode claims submitted by Pharmacy. If, however, PBM routinely, as a matter of policy, bundles or downcodes claims submitted by Pharmacy, PBM shall clearly disclose that practice in each Pharmacy contract. Furthermore, PBM shall either (i) disclose in its Pharmacy contracts or on its website the specific bundling and downcoding policies that PBM reasonably expects to be applied to Pharmacy or Pharmacy's services on a routine basis as a matter of policy or (ii) disclose in each Pharmacy contract a telephone or facsimile number or email address that Pharmacy can use to request the specific bundling and downcoding policies that PBM reasonably expects to be applied to that Pharmacy or pharmacy's services on a routine basis as a matter of policy. If such request is made by or on behalf of Pharmacy, PBM shall provide the requesting Pharmacy with such policies within 10 business days following the date the request is received. Va. Code § 38.2-3407.15(B)(4)(a).

PBM shall make available to Pharmacy, within 10 business days of receipt of a request, copies of or reasonable electronic access to all such policies that are applicable to Pharmacy or to the particular health care services identified by Pharmacy. In the event the provision of the entire policy would violate any copyright law, PBM may instead comply with this subsection by delivering to Pharmacy a timely, clear explanation of the policy as it applies to Pharmacy and to any health care services identified by Pharmacy. Va. Code § 38.2-3407.15(B)(4)(b).

PBM and/or plan sponsor shall pay a claim if PBM and/or plan sponsor has previously authorized the health care service or has advised Pharmacy or covered person in advance of the provision of health care services that the health care services are medically necessary and a covered benefit, unless:

iii. The documentation for the claim clearly fails to support the claim as originally authorized; or

iv. The refusal is because (i) another plan sponsor is responsible for the payment, (ii) Pharmacy has already been paid for the health care services identified on the claim, (iii) the claim was submitted fraudulently or the authorization was based, in whole or material part, on erroneous information provided to PBM or plan sponsor by Pharmacy, covered person or other person not related to PBM or plan sponsor, as applicable, or (iv) the person receiving the health care services was not a covered person eligible to receive them on the date of service and PBM and/or plan sponsor did not know and, with the exercise of reasonable care, could not have known of the person's eligibility status. Va. Code § 38.2-3407.15(B)(5).

Neither PBM nor plan sponsor may impose any retroactive denial of a previously paid claim unless PBM or plan sponsor has provided the reason for the retroactive denial and (i) the original claim was submitted fraudulently, (ii) the original claim payment was incorrect because Pharmacy was already paid for the services identified on the claim or the health care services identified on the claim were not delivered by Pharmacy, or (iii) the time that has elapsed since the date of the payment of the original challenged claim does not exceed the lesser of (a) 12 months or (b) the number of days within which PBM and/or plan sponsor requires, under the Agreement, that a claim be submitted by Pharmacy following the date on which a health care service is provided. PBM or plan sponsor shall notify Pharmacy at least 30 days in advance of any retroactive denial of a claim. Va. Code § 38.2-3407.15(B)(7).

Neither PBM nor plan sponsor may impose any retroactive denial of payment or in any other way seek recovery or refund of a previously paid claim unless PBM or plan sponsor specifies, in writing, the specific claim or claims for which the retroactive denial is to be imposed or the recovery or refund is sought and also provides a written explanation of why the claim is being retroactively adjusted.
Va. Code § 38.2-3407.15(B)(8).

This Agreement shall include, at the time it is presented to Pharmacy for execution, (i) the fee schedule, reimbursement policy or statement as to the manner in which claims will be calculated and paid, which is applicable to Pharmacy or to the range of health care services reasonably expected to be delivered by Pharmacy on a routine basis and (ii) all material addenda, schedules and exhibits thereto and any policies [including those referred to in subsection (e) above] applicable to Pharmacy or to the range of health care services reasonably expected to be delivered by Pharmacy under the Agreement. Va. Code § 38.2-3407.15(B)(9).

No amendment to the Agreement or to any addenda, schedule, exhibit or policy thereto (or new addenda, schedule, exhibit or policy) applicable to Pharmacy (or to the range of health care services reasonably expected to be delivered by Pharmacy) shall be effective as to Pharmacy, unless Pharmacy has been provided with the applicable portion of the proposed amendment (or the proposed new addenda, schedule, exhibit or policy) at least 60 calendar days before the proposed effective date and Pharmacy has failed to notify PBM in writing within 30 calendar days of receipt of the documentation of pharmacy's intention to terminate the Agreement at the earliest date thereafter permitted under the Agreement. Va. Code § 38.2-3407.15(B)(10).

In the event that PBM's or plan sponsor's provision of a policy required to be provided under subsection (j) or (k) above would violate any applicable copyright law, PBM or plan sponsor may instead comply with this subsection by providing a clear, written explanation of the policy as it applies to the Pharmacy. Va. Code § 38.2-3407.15(B)(11).

PBM and/or plan sponsor, as applicable, has established in writing its claim payment dispute mechanism and shall make this information available to Pharmacy upon request. Va. Code § 38.2-3407.15(B)(12).

To the extent that the Agreement requires Pharmacy to submit claims electronically, Pharmacy shall be entitled to electronic payment of clean claims, as defined in subsection A of Section 38.3-3407.15, Va. Code Ann., if the claims are submitted in the form required by PBM, in compliance with 45 CFR Part 142, as amended, if Pharmacy agrees to accept claims details for such payments electronically, in compliance with 45 CFR Part 142, as amended, and if Pharmacy has provided accurate electronic funds transfer information to PBM. Va. Code § 38.2-3407.9:03.

This section applies only with respect to MAC list owned and/or controlled by PBM.

To the extent Pharmacy provides services to covered persons of an HMO, Pharmacy agrees to the following:

Pharmacy hereby agrees that in no event, including, but not limited to, nonpayment by plan sponsor or PBM or the insolvency of plan sponsor or PBM, or breach of the Agreement, shall Pharmacy bill, charge, collect a deposit from, seek compensation, remuneration or reimbursement from or have any recourse against any covered person other than the plan sponsor for covered drugs provided pursuant to this Agreement. This provision shall not prohibit collection of any applicable copays or deductibles billed in accordance with the terms of plan sponsor's subscriber agreement. Pharmacy further agrees that (i) this provision shall survive the termination of the Agreement regardless of the cause giving rise to such termination and shall be construed to be for the benefit of plan sponsor's covered persons and that (ii) this provision supersedes any oral or written agreement to the contrary now existing or hereafter entered into between Pharmacy and covered persons or persons acting on such covered person's behalf. Va. Code § 38.2-5805(C)(4), (9), and (10); Va. Code § 38.2-4301(C)(2).

If Pharmacy terminates this Agreement, Pharmacy shall give PBM and plan sponsor at least 60 days' advance written notice of termination. Va. Code § 38.2-5805(C)(1), (7).

Neither Pharmacy nor its agent, trustee or assignee thereof may maintain any action at law against a covered person to collect sums owed by plan sponsor or PBM. Va. Code § 38.2-5805(C)(2), (5).

Carrier and intermediary contracts with pharmacy providers; disclosure and updating of maximum allowable cost of drugs; limit on termination or nonrenewal (VA ST § 38.2-3407.15:3)

B. Any contract between a carrier and its intermediary, pursuant to which the intermediary has the right or obligation to establish a maximum allowable cost, and any provider contract between a carrier and a participating pharmacy provider or its contracting agent, pursuant to which the carrier has the right or obligation to establish a maximum allowable cost, shall contain specific provisions that require the intermediary or carrier to:

1. Update, not less frequently than once every seven (7) days, the maximum allowable cost list, unless there has been no change to the maximum allowable cost of any drug on the list since the last update;
2. Verify, not less frequently than once every seven (7) days, that the drugs on the maximum allowable cost list are available to participating pharmacy providers from at least one regional or national pharmacy wholesaler and that the amount for each drug is not obsolete and promptly revise the maximum allowable cost if necessary to comply with this subsection;
3. Provide a process for each participating pharmacy provider to readily access the maximum allowable cost list specific to that provider; and
4. Prohibit the intermediary or carrier from terminating or failing to renew its contractual relationship with a participating pharmacy provider for invoking its rights under any contractual provision required by this section.

C. Any contract between a carrier and its intermediary, pursuant to which the intermediary has the right or obligation to establish a maximum allowable cost, and any provider contract between a carrier and a participating pharmacy provider or its contracting agent, pursuant to which the carrier has the right or obligation to establish a maximum allowable cost, shall contain specific provisions that require the intermediary or carrier to provide a process for an appeal, investigation, and resolution of disputes regarding maximum allowable cost drug pricing that includes:

1. A time period of fourteen (14) days from the date of initial claim adjudication for the participating pharmacy provider to file its dispute request;
2. A requirement that the dispute request be investigated and resolved within fourteen (14) days of its initiation by the participating pharmacy provider;
3. A telephone number at which the participating pharmacy provider may contact the carrier or its intermediary to speak to a person responsible for processing dispute requests;
4. A requirement that a carrier or its intermediary, if a dispute request is denied, provide (i) a reason for the denial, and (ii) the national drug code of the drug under dispute that the carrier or its intermediary contends may be purchased by the participating pharmacy provider for an amount that is equal to or less than the maximum allowable cost; and
5. A requirement that a carrier or its intermediary, if a dispute is successful, update the maximum allowable cost for the drug under dispute within five days of the determination of the dispute.

Carrier contracts with pharmacy providers; required provisions; limit on termination or nonrenewal (Va. Code § 38.2-3407.15:1)

B. Any contract between a carrier and its intermediary, pursuant to which the intermediary has the right or obligation to conduct audits of participating pharmacy providers, and any provider contract between a carrier and a participating pharmacy provider or its contracting agent, pursuant to which the carrier has the right or obligation to conduct audits of participating pharmacy providers, shall contain specific provisions that prohibit the carrier or intermediary, in the absence of fraud, from recouping amounts calculated from or arising out of any of the following:

1. Probability sampling, extrapolation, or other mathematical or statistical methods that allegedly project an error;
2. Clerical errors by the participating pharmacy provider;
3. An act or omission of the participating pharmacy provider that was not specifically prohibited or required by the provider contract when the claim was adjudicated unless the act or omission was a violation of applicable law or regulation;
4. The refusal of a carrier or its intermediary to consider, during an audit or audit appeal, a pharmacy record in electronic form to validate a claim;
5. Dispensing fees or interest on the claim, except in the event of an overpayment, if the prescription was dispensed in accordance with applicable law or regulation;
6. Any claim authorized and dispensed more than 24 months prior to the date of the audit unless the claim is adjusted at the direction of the commission, except that this time period shall be tolled while the denial of the claim is being appealed;
7. An alleged breach of auditing requirements if they are not the same as the requirements that the carrier or intermediary applies to other participating pharmacy providers in the same setting;
8. The refusal of the carrier or its intermediary to consider during an audit or audit appeal a pharmacy record, a prescriber or patient verification or a prescriber record to validate a claim; or
9. The alleged failure of the participating pharmacy provider to supply during an audit or audit appeal a pharmacy record not specifically identified in the provider contract.

C. Any (i) contract between a carrier and its intermediary pursuant to which the intermediary has the right or obligation to conduct audits of participating pharmacy providers and (ii) provider contract between a carrier and a participating pharmacy provider or its contracting agent pursuant to which the carrier has the right or obligation to conduct audits of participating pharmacy providers shall contain the following terms and provisions relating to audits, which shall apply in the absence of fraud:

1. The initial on-site audit shall give the Pharmacy written notice at least 14 days before conducting the initial audit for each audit cycle and shall disclose the specific prescription numbers to be included in the audit. The carrier or intermediary may mask the last two digits of such numbers. A Pharmacy shall have at least 72 hours after receiving the written notice of an on-site audit to request a five business-day extension of the proposed audit date. A Pharmacy making such a request shall be granted at least five additional business days and shall cooperate with the auditor to establish an alternative date.
2. Unless otherwise consented to by the Pharmacy, an on-site audit shall not be initiated or scheduled during the first five calendar days of any month, or on a Monday and shall not involve the auditing of more than one location of the Pharmacy at any particular time.
3. No on-site audit of a particular pharmacy location on behalf of a particular carrier shall occur more than once in a 12-month period.

4. Each Pharmacy shall be audited under the same standards and parameters as every other similarly situated Pharmacy. Any documentation and records required by an auditor during an audit shall be of the same type as the documentation and records required for all other similarly situated Pharmacies.
5. Any audit issues that involve clinical or professional judgment shall be conducted by a pharmacist who has available for consultation a pharmacist licensed by the commonwealth.
6. Each audit shall be conducted by a field agent who possesses the requisite knowledge and experience in pharmacy practice.
7. Audits shall be conducted in the Commonwealth in compliance with federal and state laws, rules and regulations, including regulations adopted by the Board of Pharmacy.
8. Prescriptions shall be considered valid prescriptions if they are compliant with the then-current Board of Pharmacy rules and regulations and have been successfully adjudicated upon a clean claim submission. Carrier restrictions shall be addressed during the claims adjudication process either through the rejection of the clean claim or a rejection of the clean claim with direction to obtain a prior authorization and shall not be the basis for a retrospective recoupment of a paid claim.
9. Electronic records, including electronic beneficiary signature logs, electronic tracking of prescriptions, electronic prescriber prescription transmissions and imagery of hard copy prescriptions, electronically scanned store and patient records maintained at or accessible to the offices of an audited pharmacy's central operations, and any other reasonably clear and accurate electronic documentation shall be acceptable for auditing under the same terms, conditions and validation and for the same purposes as their paper analogs. Point of sale electronic register data shall qualify as proof of delivery to the patient, provided that the auditor can validate the receipt on the basis of the patient data included.
10. A Pharmacy may use the historical records of a hospital, physician or other authorized practitioner of the healing arts for drugs or medicinal supplies written and transmitted by any documented means of communication for purposes of validating the pharmacy record with respect to orders or refills of a legend or narcotic drug.
11. Validation and documentation at the time of dispensing of appropriate days' supply and drug dosing shall be based on manufacturer guidelines and definitions or, in the case of topical products or titrated products, based on the professional judgment of the pharmacist in communication with the patient or prescriber.
12. A pharmacy's usual and customary price for compounded medications is considered the reimbursable cost unless the pricing methodology is published in the provider contract and signed by both parties or their agents.
13. A carrier or its intermediary shall not make chargebacks or seek recoupment from a Pharmacy, or assess or collect penalties from a Pharmacy, until the time period for filing an appeal to an initial audit report has passed or until the appeals process has been exhausted, whichever is later. If the identified discrepancy for a single audit exceeds $25,000, future payments in excess of that amount may be withheld pending adjudication of an appeal.
14. The preliminary audit report shall (i) be delivered to the Pharmacy or its pharmacy corporate office within 60 calendar days, with reasonable extensions allowed, after conclusion of the audit and (ii) contain claim level information for any discrepancy found and total dollar amount of claims subject to recovery.
15. A Pharmacy shall be allowed at least 60 calendar days following receipt of the preliminary audit report in which to produce documentation to address any discrepancy found during an audit or to file an appeal.

16. A final audit report containing claim-level information for any discrepancy found and total dollar amount of claims subject to recovery shall be delivered to the Pharmacy or its pharmacy corporate office (i) within 90 calendar days after the audited Pharmacy's receipt of the preliminary audit report, if the audited Pharmacy does not file an appeal or offers no documentation to address a discrepancy found during an audit or (ii) within 60 calendar days after the auditing entity receives the audited Pharmacy's appeal or documentation to address a discrepancy.
17. A carrier or its intermediary shall not recover from the Pharmacy Payment of claims that is identified through the audit process to be the responsibility of another payer.
18. No recoupment of amounts paid to a Pharmacy for any claim shall be made solely on the basis of a prescriber's or patient's lack of response to a request made by a carrier or its intermediary.
19. A carrier or its intermediary shall issue its initial audit findings in conformity with the laws of the Commonwealth.
20. A carrier or its intermediary shall not retroactively deny a claim (i) more than one year after the date of payment of the claim if the reason for denial would be patient ineligibility or (ii) at any time if the carrier or its intermediary verified the patient's eligibility at the time of dispensing and provided an authentication number to the Pharmacy.

D. Any contract between a carrier and its intermediary, pursuant to which the intermediary has the right or obligation to conduct audits of participating pharmacy providers, and any provider contract between a carrier and a participating pharmacy provider or its contracting agent, pursuant to which the carrier has the right or obligation to conduct audits of participating pharmacy providers, shall contain specific provisions that prohibit the carrier or intermediary, in the absence of fraud by the participating pharmacy provider, from terminating or failing to renew the contractual relationship with a participating pharmacy provider for invoking its rights under any contractual provision required to be contained in the contract pursuant to subsections B or C above.

VA § 38.2-3407.15:8.

1. A carrier shall pay any claim within 40 days of receipt of the claim, except where the obligation of the carrier to pay a claim is not reasonably clear due to the existence of a reasonable basis supported by specific information available for review by the person submitting the claim that:

a. The claim is determined by the carrier not to be a clean claim due to a good faith determination or dispute regarding (i) the manner in which the claim form was completed or submitted, (ii) the eligibility of a person for coverage, (iii) the responsibility of another carrier for all or part of the claim, (iv) the amount of the claim or the amount currently due under the claim, (v) the benefits covered or (vi) the manner in which services were accessed or provided; or

b. The claim was submitted fraudulently.
Each carrier shall maintain a written or electronic record of the date of receipt of a claim. The person submitting the claim shall be entitled to inspect such record on request and to rely on that record or on any other admissible evidence as proof of the fact of receipt of the claim, including, without limitation, electronic or facsimile confirmation of receipt of a claim.

2. A carrier shall, within 30 days after receipt of a claim, notify the person submitting the claim of any defect or impropriety that prevents the carrier from deeming the claim a clean claim and request the information that will be required to process and pay the claim. Upon receipt of the additional information necessary to make the original claim a clean claim, a carrier shall make the payment of the claim in compliance with this section. No carrier may refuse to pay a claim for health care services rendered pursuant to a provider contract which are covered benefits if the carrier fails timely to notify or attempt to notify the person submitting the claim of the matters identified above, unless such failure was caused in material part by the person submitting the claims; however, nothing herein shall preclude such a carrier from imposing a retroactive denial of payment of such a claim if permitted by the provider contract unless such retroactive denial of payment of the claim would violate subdivision 8. Beginning no later than January 1, 2026, all notifications and information required under this subdivision shall be delivered electronically.
3. Any interest owing or accruing on a claim under § 38.2-3407.1 or 38.2-4306.1, under any provider contract or under any other applicable law, shall, if not sooner paid or required to be paid, be paid, without necessity of demand, at the time the claim is paid or within 60 days thereafter.
4. A carrier shall notify the provider in the provider contract if the carrier, or entity completing a transaction on behalf of the carrier, uses a payment method that imposes a transaction or processing fee or similar charge on the provider and shall offer the provider an alternative payment method in which the carrier, or entity completing a transaction on behalf of the carrier, does not impose such a fee or similar charge. If the provider elects to accept the alternative payment method and has provided all required information to the carrier to enroll in such alternative method, the carrier shall pay the claim using such alternative payment method.
5. a. Every carrier shall establish and implement reasonable policies to permit any provider with which there is a provider contract (i) to confirm in advance during normal business hours by free telephone or electronic means if available whether the health care services to be provided are medically necessary and a covered benefit and (ii) to determine the carrier's requirements applicable to the provider (or to the type of health care services which the provider has contracted to deliver under the provider contract) for (a) pre-certification or authorization of coverage decisions, (b) retroactive reconsideration of a certification or authorization of coverage decision or retroactive denial of a previously paid claim, (c) provider-specific payment and reimbursement methodology, coding levels and methodology, downcoding, and bundling of claims, and (d) other provider-specific, applicable claims processing and payment matters necessary to meet the terms and conditions of the provider contract, including determining whether a claim is a clean claim. If a carrier routinely, as a matter of policy, bundles or downcodes claims submitted by a provider, the carrier shall clearly disclose that practice in each provider contract. Further, such carrier shall either (1) disclose in its provider contracts or on its website the specific bundling and downcoding policies that the carrier reasonably expects to be applied to the provider or provider's services on a routine basis as a matter of policy or (2) disclose in each provider contract a telephone or facsimile number or email address that a provider can use to request the specific bundling and downcoding policies that the carrier reasonably expects to be applied to that provider or provider's services on a routine basis as a matter of policy. If such request is made by or on behalf of a provider, a carrier shall provide the requesting provider with such policies within 10 business days following the date the request is received.

b. Every carrier shall make available to such providers, within 10 business days of receipt of a request, copies of or reasonable electronic access to all such policies which are applicable to the particular provider or to particular health care services identified by the provider. In the event the provision of the entire policy would violate any applicable copyright law, the carrier may instead comply with this subsection by timely delivering to the provider a clear explanation of the policy as it applies to the provider and to any health care services identified by the provider.

6. Every carrier shall pay a claim if the carrier has previously authorized the health care service or has advised the provider or enrollee in advance of the provision of health care services that the health care services are medically necessary and a covered benefit, unless:

   a. The documentation for the claim provided by the person submitting the claim clearly fails to support the claim as originally authorized;

   b. The carrier's refusal is because (i) another payor is responsible for the payment, (ii) the provider has already been paid for the health care services identified on the claim, (iii) the claim was submitted fraudulently or the authorization was based, in whole or material part, on erroneous information provided to the carrier by the provider, enrollee, or other person not related to the carrier, or (iv) the person receiving the health care services was not eligible to receive them on the date of service and the carrier did not know, and with the exercise of reasonable care could not have known, of the person's eligibility status; or

   c. During the post-service claims process, it is determined that the claim was submitted fraudulently.

7. In the case of an invasive or surgical procedure, if the carrier has previously authorized a health care service as medically necessary and during the procedure the health care provider discovers clinical evidence prompting the provider to perform a less or more extensive or complicated procedure than was previously authorized, then the carrier shall pay the claim, provided that the additional procedures were (i) not investigative in nature, but medically necessary as a covered service under the covered person's benefit plan; (ii) appropriately coded consistent with the procedure actually performed; and (iii) compliant with a carrier's post-service claims process, including required timing for submission to carrier.

8. No carrier shall impose any retroactive denial of a previously paid claim or in any other way seek recovery or refund of a previously paid claim unless the carrier specifies in writing the specific claim or claims for which the retroactive denial is to be imposed or the recovery or refund is sought, the carrier has provided a written explanation of why the claim is being retroactively adjusted, and (i) the original claim was submitted fraudulently, (ii) the original claim payment was incorrect because the provider was already paid for the health care services identified on the claim or the health care services identified on the claim were not delivered by the provider, or (iii) the time which has elapsed since the date of the payment of the original challenged claim does not exceed 12 months. Notwithstanding the provisions of clause (iii), a provider and a carrier may agree in writing that recoupment of overpayments by withholding or offsetting against future payments may occur after such 12-month limit for the imposition of the retroactive denial. A carrier shall notify a provider at least 30 days in advance of any retroactive denial or recovery or refund of a previously paid claim.

   Beginning no later than January 1, 2026, all written communications, explanations, notifications, and related provider responses applicable to this subdivision shall be delivered electronically. The electronic method and location for delivery shall be agreed upon by the carrier and provider and included in the provider contract.

9. No provider contract shall fail to include or attach at the time it is presented to the provider for execution (i) the fee schedule, reimbursement policy or statement as to the manner in which claims will be calculated and paid that is applicable to the provider or to the range of health care services reasonably expected to be delivered by that type of provider on a routine basis and (ii) all material addenda, schedules and exhibits thereto and any policies (including those referred to in subdivision 5) applicable to the provider or to the range of health care services reasonably expected to be delivered by that type of provider under the provider contract.

Appendix B: Regulatory addendums (continued)

10. No amendment to any provider contract or to any addenda, schedule, exhibit or policy thereto (or new addenda, schedule, exhibit or policy) applicable to the provider (or to the range of health care services reasonably expected to be delivered by that type of provider) shall be effective as to the provider, unless the provider has been provided with the applicable portion of the proposed amendment (or of the proposed new addenda, schedule, exhibit or policy) at least 60 calendar days before the effective date and the provider has failed to notify the carrier within 30 calendar days of receipt of the documentation of the provider's intention to terminate the provider contract at the earliest date thereafter permitted under the provider contract.
11. In the event that the carrier's provision of a policy required to be provided under subdivision 9 or 10 would violate any applicable copyright law, the carrier may instead comply with this section by providing a clear, written explanation of the policy as it applies to the provider.
12. All carriers shall establish, in writing, their claims payment dispute mechanism and shall make this information available to providers. If a carrier's claim denial is overturned following completion of a dispute review, the carrier shall, on the day the decision to overturn is made, consider the claims impacted by such decision as clean claims. All applicable laws related to the payment of a clean claim shall apply to the payments due.
13. Every carrier shall include in its provider contracts a provision that prohibits a provider from discriminating against any enrollee solely due to the enrollee's status as a litigant in pending litigation or a potential litigant due to being involved in a motor vehicle accident. Nothing in this subdivision shall require a health care provider to treat an enrollee who has threatened to make or has made a professional liability claim against the provider or the provider's employer, agents, or employees or has threatened to file or has filed a complaint with a regulatory agency or board against the provider or the provider's employer, agents, or employees.
14. Beginning July 1, 2025, every carrier shall make available through electronic means a way for providers to determine whether an enrollee is covered by a health plan that is subject to the Commission's jurisdiction.

B-48 Washington Regulatory Addendum to Pharmacy Participation Agreement

In the event any provision of this Addendum conflicts with the terms of the Pharmacy Participation Agreement ("Agreement) (including documents incorporated by reference therein), the terms of this Addendum shall control to the extent of the conflict with respect to benefit plans subject to applicable Washington law or regulation.

To the extent that Pharmacy provides pharmacy services to covered persons of a health carrier, health carrier service contractor, health maintenance organization or other insurer licensed under Washington law (collectively and/or individually, "plan sponsor"), Pharmacy agrees to comply with any requirements for participation as a Pharmacy in Washington as required by applicable law.

Without limiting the generality of the foregoing and notwithstanding anything to the contrary in the Agreement, Pharmacy agrees as follows:

Pharmacy hereby agrees that in no event, including, but not limited to, nonpayment by pharmacy benefit manager (PBM) or plan sponsor, PBM or plan sponsor's insolvency or breach of this Agreement shall Pharmacy bill, charge, collect a deposit from, seek compensation, remuneration, or reimbursement from or have any recourse against, a covered person or other persons acting on their behalf, other than plan sponsor, for services provided pursuant to the Agreement. This provision shall not prohibit collection of deductibles, copays, coinsurance and/or noncovered services, which have not otherwise been paid by a primary or secondary carrier in accordance with regulatory standards for coordination of benefits, from covered persons in accordance with the terms of the covered person's benefit plan. WAC § 284-170-421(3)(a).

Pharmacy agrees, in the event of insolvency of PBM or plan sponsor, to continue to provide the services promised in the Agreement to covered persons for the duration of the period for which premiums on behalf of the covered person were paid or until the covered person's discharge from inpatient facilities (if applicable), whichever time is greater.

RCW §§ 48.44.055(2); 48.46.245(2); WAC § 284-170-421(3)(b).

Nothing in the Agreement shall be construed to modify the rights and benefits contained in the covered person's benefit plan. WAC § 284-170-421(3)(c).

Pharmacy may not bill the covered person for covered services (except for deductibles, copays or coinsurance) where payment is denied because Pharmacy has failed to comply with the terms or conditions of the Agreement. WAC § 284-170-421(3)(d).

Pharmacy further agrees that (i) sections 1–4 above shall survive termination of the Agreement, regardless of the cause giving rise to termination, and shall be construed for the benefit of covered persons and (ii) these sections supersede any oral or written contrary agreement now existing or hereafter entered into between Pharmacy and covered persons or persons acting on their behalf. WAC § 284-170-421(3)(e).

To the extent permitted by the Agreement, if Pharmacy contracts with other providers or facilities who agree to provide covered services to covered persons with the expectation of receiving payment directly or indirectly from PBM or plan sponsor, such providers or facilities must agree to abide by the provisions of sections 1–5 above. WAC § 284-170-421(3)(f).

Pharmacies willfully collecting or attempting to collect an amount from a covered person, knowing that collection to be in violation of the Agreement, constitutes a Class C felony under RCW § 48.80.030(5). WAC § 284-170-421(4).

Pharmacy's responsibilities with respect to applicable administrative programs, including, but not limited to, payment, utilization review, quality assessment and improvement programs, credentialing, grievance, appeal and adverse benefit determination procedures, data reporting requirements, pharmacy benefit substitution processes, confidentiality requirements and any applicable federal or state requirements are specified in the Agreement and/or Provider Manual. WAC § 284-170-421(5).

PBM shall provide reasonable notice of no fewer than 60 days of changes that affect pharmacy compensation or health care service delivery under the Agreement, unless changes to federal or state law or regulations make such advance notice impossible, in which case notice will be provided as soon as possible. Subject to any termination and continuity of care provisions in the Agreement and Section 12 below, Pharmacy may terminate this Agreement without penalty if it does not agree with the changes. Material amendments, as defined in RCW § 48.39.005, to the Agreement may be rejected by Pharmacy without affecting the terms of the existing Agreement. No amendments to the Agreement will be made retroactive without the express written consent of Pharmacy. WAC § 284-170-421(6).

No health carrier subject to the jurisdiction of the state of Washington may in any way preclude or discourage their providers from informing patients of the care they require, including various

treatment options, and whether, in their view, such care is consistent with medical necessity, medical appropriateness or otherwise covered by the patient's service agreement with the health carrier. No health carrier may prohibit, discourage or penalize a provider otherwise practicing in compliance with the law from advocating on behalf of a patient with a health carrier. Nothing in this section shall be construed to authorize providers to bind health carriers to pay for any service. Furthermore, no health carrier may preclude or discourage patients or those paying for their coverage from discussing the comparative merits of different health carriers with their providers. This prohibition specifically includes prohibiting or limiting providers participating in those discussions, even if critical of a carrier. WAC § 284-170-421(7).

Pharmacy shall make records available to appropriate state and federal authorities involved in assessing the quality of care or investigating complaints, grievances, appeals or review of any adverse benefit determinations of covered persons subject to applicable state and federal laws related to the confidentiality of medical or health records; and will cooperate with audit reviews of encounter data in relation to the administration of risk adjustment and reinsurance programs. WAC § 284-170-421(8).

The parties shall provide at least 60 days' written notice to each other before terminating the Agreement without cause. WAC § 284-170-421(9).

Pharmacy shall provide services under the Agreement to covered persons without regard to the covered persons' enrollment in a plan as a private purchaser of a plan or as a participant in publicly financed programs of health care services. This requirement does not apply to circumstances when the Pharmacy should not render services due to limitations arising from lack of training, experience, skill or licensing restrictions. WAC § 284-170-421(11).

PBM will not penalize Pharmacy when Pharmacy, in good faith, reports to state or federal authorities any practice by a plan sponsor that jeopardizes the health or welfare of a covered person or that may violate state or federal law. WAC § 284-170-421(12).

Pharmacy is entitled to a fair dispute resolution mechanism. In addition to the dispute resolution process set forth in the Agreement, Pharmacy shall contact PBM at the address listed in the "Notice" provision of the Agreement for the procedures for processing and resolving disputes. WAC § 284-170-421(13). In all events, the following shall apply:

With respect to billing disputes, PBM shall render a decision within 60 days of receipt of a written complaint from Pharmacy. WAC § 284-170-440(5).

In all events, Pharmacy shall have no fewer than 30 days after the action giving rise to a dispute to complain and initiate the dispute resolution process. WAC § 284-170-440(3).

Except as otherwise permitted in RCW § 48.46.243(2), in the event PBM or plan sponsor fails to pay for services as provided in the Agreement, the covered person shall not be liable to the Pharmacy for sums owed by PBM or plan sponsor. Pharmacy and its agents, trustees or assignees may not maintain any action against a covered person to collect sums owed by PBM and/or plan sponsor. RCW § 48.46.243.

For amounts due Pharmacy under the Agreement:

Pharmacy shall be paid in accordance with the following minimum standards:

i. 95% of monthly volume of a plan sponsor's clean claims shall be paid within 30 days of receipt by PBM; and

ii. 95% of the monthly volume of a plan sponsor's claims shall be paid or denied within 60 days of receipt by PBM, except as agreed to in writing by the parties on a claim-by-claim basis. WAC § 284-170-431(2)(a).

The receipt date of a claim is the date PBM receives either written or electronic notice of the claim. PBM has established a reasonable method for confirming receipt of claims and responding to Pharmacy inquiries about claims via the online adjudication system and Pharmacy Help Desk. WAC §§ 284-170- 431(b), (c).

Plan sponsor or PBM, as applicable, shall pay interest on undenied and unpaid clean claims more than 61 days old until plan sponsor or PBM, as applicable, meets the standards established in this section. Interest shall be assessed at the rate of 1% per month and shall be calculated monthly as simple interest prorated for any portion of a month. Interest shall be added to the amount of the unpaid claim without the necessity of the Pharmacy submitting an additional claim. Any interest paid under this section shall not be applied to a covered person's deductible, copay, coinsurance or any similar obligation of a covered person. WAC § 284-170-431(2)(d).

A "clean claim" means a claim that has no defect or impropriety, including any lack of required substantiating documentation or particular circumstances that require special treatment that prevents timely payments from being made on the claim under this section. WAC § 284-170-431(3).

Denial of a claim, including the specific reason why the claim was denied, will be communicated to Pharmacy. If the denial is based upon medical necessity or similar grounds, PBM or plan sponsor, as appropriate, will provide Pharmacy with the supporting basis for the decision. WAC § 284-170-431(4).

The standards set forth in this section do not apply to claims about which there is a substantial evidence of fraud or misrepresentation by Pharmacy or covered persons, or instances where PBM has not been granted reasonable access to information under the Pharmacy's control; or where failure to comply is occasioned by any act of God, bankruptcy, act of a governmental authority responding to an act of God or other emergency, or the result of a strike, lockout or other labor dispute. WAC §§ 284-170-431(6), (7).

Pharmacy may make a pharmacy prior authorization request. If an authorization number is required to be transmitted on a claim for covered drugs, PBM shall provide the authorization number to Pharmacy after approval of the prior authorization request and upon receipt of a claim for that authorized medication. WAC § 284-170-470(5).

Emergency fills by Pharmacy will be authorized and the claim payment for the emergency fill will be approved when (a) Pharmacy cannot reach the applicable prior authorization department (e.g., plan sponsor or PBM, as applicable) by phone because it is outside of that department's business hours or (b) Pharmacy reaches the applicable prior authorization department but the prescriber cannot be reached for full consultation. WAC § 284-170-470(7).

The above provisions shall not apply in the event of an act of God, bankruptcy, act of a governmental authority responding to an act of God or other emergency or as the result of a strike, lockout or other labor dispute. WAC § 284-170-470(9).

To the extent permitted by the Agreement, in the event Pharmacy subcontracts with providers in connection with the Agreement, Pharmacy shall require that its subcontracts comply with the provisions set forth in this Addendum. WAC § 284-170-401.

The PBM's audit of records shall be limited to covered persons and shall be limited to the extent necessary to perform the audit. To the extent required by law, Pharmacy shall have the right to audit claim denials. WAC § 284-170-460.

Predetermination of reimbursement costs — Appeals — Review by commissioner (RCW § 48.200.280)

(2) A PBM:

(a) May not place a drug on a list unless there are at least two therapeutically equivalent multiple source drugs, or at least one generic drug available from only one manufacturer, generally available for purchase by network Pharmacies from national or regional wholesalers;

(b) Shall ensure that all drugs on a list are readily available for purchase by Pharmacies in this state from national or regional wholesalers that serve Pharmacies in Washington;

(c) Shall ensure that all drugs on a list are not obsolete;

(d) Shall make available to each network Pharmacy at the beginning of the term of a contract, and upon renewal of a contract, the sources utilized to determine the predetermined reimbursement costs for multisource generic drugs of the PBM;

(e) Shall make a list available to a network Pharmacy upon request in a format that is readily accessible to and usable by the network Pharmacy;

(f) Shall update each list maintained by the PBM every seven business days and make the updated lists, including all changes in the price of drugs, available to network Pharmacies in a readily accessible and usable format;

(g) Shall ensure that dispensing fees are not included in the calculation of the predetermined reimbursement costs for multisource generic drugs;

(h) May not cause or knowingly permit the use of any advertisement, promotion, solicitation, representation, proposal or offer that is untrue, deceptive or misleading;

(i) May not charge a Pharmacy a fee related to the adjudication of a claim, credentialing, participation, certification, accreditation or enrollment in a network including, but not limited to, a fee for the receipt and processing of a pharmacy claim, for the development or management of claims processing services in a PBM network or for participating in a PBM network;

(j) May not require accreditation standards inconsistent with or more stringent than accreditation standards established by a national accreditation organization;

(k) May not reimburse a Pharmacy in the state an amount less than the amount the PBM reimburses an affiliate for providing the same pharmacy services; and

(l) May not directly or indirectly retroactively deny or reduce a claim or aggregate of claims after the claim or aggregate of claims has been adjudicated, unless:

(i) The original claim was submitted fraudulently; or

(ii) The denial or reduction is the result of a pharmacy audit conducted in accordance with RCW 48.200.220.

(3) A PBM must establish a process by which a network Pharmacy may appeal its reimbursement for a drug subject to predetermined reimbursement costs for multisource generic drugs. A network Pharmacy may appeal a predetermined reimbursement cost for a multisource generic drug if the reimbursement for the drug is less than the net amount that the network Pharmacy paid to the supplier of the drug. An appeal requested under this section must be completed within 30 calendar days of the Pharmacy submitting the appeal. If after 30 days the network Pharmacy has not received the decision on the appeal from the PBM, the appeal is considered denied.

The PBM shall uphold the appeal of a Pharmacy with fewer than 15 retail outlets within the state of Washington under its corporate umbrella if the Pharmacy or pharmacist can demonstrate that it is unable to purchase a therapeutically equivalent interchangeable product from a supplier doing business in Washington at the PBM's list price.

(4) A PBM must provide, as part of the appeals process established under subsection (3) of this section:

(a) A telephone number at which a network Pharmacy may contact the PBM and speak with an individual who is responsible for processing appeals; and

(b) If the appeal is denied, the reason for the denial and the National Drug Code of a drug that has been purchased by other network Pharmacies located in Washington at a price that is equal to or less than the predetermined reimbursement cost for the multisource generic drug. A Pharmacy with 15 or more retail outlets within the state of Washington under its corporate umbrella may submit information to the commissioner about an appeal under subsection (3) of this section for purposes of information collection and analysis.

(5)(a) If an appeal is upheld under this section, the PBM shall make a reasonable adjustment on a date no later than one day after the date of determination.

(b) If the request for an adjustment has come from a critical access Pharmacy, as defined by the state health care authority by rule for purposes related to the prescription drug purchasing consortium established under RCW 70.14.060, the adjustment approved under (a) of this subsection shall apply only to critical access Pharmacies.

(6) Beginning July 1, 2017, if a network pharmacy appeal to the PBM is denied, or if the network Pharmacy is unsatisfied with the outcome of the appeal, the Pharmacy or pharmacist may dispute the decision and request review by the commissioner within 30 calendar days of receiving the decision.

(a) All relevant information from the parties may be presented to the commissioner, and the commissioner may enter an order directing the PBM to make an adjustment to the disputed claim, deny the pharmacy appeal or take other actions deemed fair and equitable. An appeal requested under this section must be completed within 30 calendar days of the request.

(b) Upon resolution of the dispute, the commissioner shall provide a copy of the decision to both parties within seven calendar days.

(c) The commissioner may authorize the office of administrative hearings, as provided in chapter 34.12 RCW, to conduct appeals under this subsection.

(d) A PBM may not retaliate against a Pharmacy for pursuing an appeal under this subsection.

(e) This subsection applies only to a Pharmacy with fewer than 15 retail outlets within the state of Washington under its corporate umbrella.

(7) These requirements do not apply to the Washington state medical assistance program.

Auditing of claims — Requirements — Prohibited practices (RCW § 48.200.220)

An entity that audits claims or an independent third party that contracts with an entity to audit claims:

(1) Must establish, in writing, a procedure for a Pharmacy to appeal the entity's findings with respect to a claim and must provide a Pharmacy with a notice regarding the procedure, in writing or electronically, prior to conducting an audit of the Pharmacy's claims;

(2) May not conduct an audit of a claim more than 24 months after the date the claim was adjudicated by the entity;

(3) Must give at least 15 days' advance written notice of an on-site audit to the Pharmacy or corporate headquarters of the Pharmacy;

(4) May not conduct an on-site audit during the first five days of any month without the Pharmacy's consent;

(5) Must conduct the audit in consultation with a pharmacist who is licensed by this or another state if the audit involves clinical or professional judgement;

(6) May not conduct an on-site audit of more than 250 unique prescriptions of a Pharmacy in any 12-month period, except in cases of alleged fraud;

(7) May not conduct more than one on-site audit of a Pharmacy in any 12-month period;

(8) Must audit each Pharmacy under the same standards and parameters that the entity uses to audit other similarly situated Pharmacies;

(9) Must pay any outstanding claims of a Pharmacy no more than 45 days after the earlier of the date all appeals are concluded or the date a final report is issued under RCW 48.200.260(3);

(10) May not include dispensing fees or interest in the amount of any overpayment assessed on a claim unless the overpaid claim was for a prescription that was not filled correctly;

(11) May not recoup costs associated with:

(a) Clerical errors; or

(b) Other errors that do not result in financial harm to the entity or a consumer; and

(12) May not charge a Pharmacy for a denied or disputed claim until the audit and the appeals procedure established under subsection (1) of this section are final.

Basis of finding of claim (RCW § 48.200.230)

An entity's finding that a claim was incorrectly presented or paid must be based on identified transactions and not based on probability sampling, extrapolation or other means that project an error using the number of patients served who have a similar diagnosis or the number of similar prescriptions or refills for similar drugs.

Contract with third party — Prohibited practices (RCW § 48.200.240)

An entity that contracts with an independent third party to conduct audits may not:

(1) Agree to compensate the independent third party based on a percentage of the amount of overpayments recovered; or

(2) Disclose information obtained during an audit except to an entity, the Pharmacy subject to the audit or the holder of the policy or certificate of insurance that paid the claim.

Evidence of validation of claim (RCW § 48.200.250)

For purposes of RCW 48.200.210 through 48.200.270, an entity, or an independent third party that contracts with an entity to conduct audits, must allow as evidence of validation of a claim:

(1) An electronic or physical copy of a valid prescription if the prescribed drug was within 14 days of the dispensing date:

(a) Picked up by the patient or the patient's designee;

(b) Delivered by the Pharmacy to the patient; or

(c) Sent by the Pharmacy to the patient using the United States Postal Service or other common carrier;

(2) Point-of-sale electronic register data showing purchase of the prescribed drug, medical supply or service by the patient or the patient's designee; or

(3) Electronic records, including electronic beneficiary signature logs, electronically scanned and stored patient records maintained at or accessible to the audited Pharmacy's central operations, and any other reasonably clear and accurate electronic documentation that corresponds to a claim.

Preliminary audit report — Dispute or denial of claim — Final audit report — Recoupment of disputed funds (RCW § 48.200.260)

(1)(a) After conducting an audit, an entity must provide the Pharmacy that is the subject of the audit with a preliminary report of the audit. The preliminary report must be received by the Pharmacy no later than 45 days after the date on which the audit was completed and must be sent:

(i) By mail or common carrier with a return receipt requested; or

(ii) Electronically with electronic receipt confirmation.

(b) An entity shall provide a Pharmacy receiving a preliminary report under this subsection no fewer than 45 days after receiving the report to contest the report or any findings in the report in accordance with the appeals procedure established under RCW 48.200.220(1) and must allow the submission of additional documentation in support of the claim. The entity shall consider a reasonable request for an extension of time to submit documentation to contest the report or any findings in the report.

(2) If an audit results in the dispute or denial of a claim, the entity conducting the audit shall allow the Pharmacy to resubmit the claim using any commercially reasonable method, including facsimile, mail or email.

(3) An entity must provide a Pharmacy that is the subject of an audit with a final report of the audit no later than 60 days after the later of the date the preliminary report was received or the date the Pharmacy contested the report using the appeals procedure established under RCW 48.200.220(1). The final report must include a final accounting of all moneys to be recovered by the entity.

(4) Recoupment of disputed funds from a Pharmacy by the entity or repayment of funds to the entity by a Pharmacy, unless otherwise agreed to by the entity and the Pharmacy, shall occur after the audit and the appeals procedure established under RCW 48.200.220(1) are final. If the identified discrepancy for an individual audit exceeds $40,000, any future payments to the Pharmacy may be withheld by the entity until the audit and the appeals procedure established under RCW 48.200.220(1) are final.

Application (RCW § 48.200.270)

RCW 48.200.210 through 48.200.270 do not:

(1) Preclude an auditing entity from instituting an action for fraud against a Pharmacy;

(2) Apply to an audit of pharmacy records when fraud or other intentional and willful misrepresentation is indicated by physical review, review of claims data or statements or other investigative methods; or

(3) Apply to a state agency that is conducting audits or a person that has contracted with a state agency to conduct audits of pharmacy records for prescription drugs paid for by the state medical assistance program.

B-49 West Virginia Regulatory Addendum to Pharmacy Participation Agreement

This West Virginia Addendum applies to the extent that Pharmacy provides covered drugs to covered persons of insurers, carriers, health maintenance organizations, hospital and medical service

corporations and prepaid limited health service organizations under West Virginia law (collectively and/or individually, “plan sponsor”).

In the event of a direct conflict between this Addendum and the Agreement, the applicable provisions of this Addendum shall control if required. This Addendum may be modified from time to time pursuant to the Agreement.

Without limiting the generality of the foregoing, and notwithstanding anything in the Agreement to the contrary, Pharmacy agrees as follows:

Pharmacy shall render to covered persons any service as it may be entitled to under the terms and conditions of the Benefit Plan and shall submit only such charges to PBM as are set forth in the fee schedule of the Agreement, and any related attachments. W.Va. Code § 33-24-7.

In the event plan sponsor or PBM fails to pay fees for services rendered to covered persons by Pharmacy, the covered persons shall not be liable to Pharmacy. Pharmacy shall not collect or attempt to collect from covered persons any money for covered drugs. Neither Pharmacy nor its representative may maintain any action at law against covered persons to collect money owed to Pharmacy by plan sponsor or PBM. This provision shall not be construed to apply to the amount of any deductible or copay. W.Va. Code §§ 33-25A-7a, 33-25D-10.

Pharmacy shall provide 60-day advance written notice to PBM and the West Virginia Commissioner of Insurance before canceling the Agreement for any reason. Nonpayment for goods or services rendered by Pharmacy to covered persons is not a valid reason for avoiding the 60-day advance notice of cancellation. W.Va. Code §§ 33-25A-7a, 33-25D-10.

PBM shall adhere to the following standards in the processing and payment of claims:

PBM shall either deny, pay or require plan sponsor to pay a clean claim, as defined in W.Va. Code § 33- 45-1, within 40 days of receipt if submitted manually or within 30 days if submitted electronically, except when: (a) another party is responsible for the claim; (b) PBM is coordinating benefits within another plan sponsor; (c) Pharmacy has already been paid for the claim; (d) the claim was submitted fraudulently; or (e) there was a material misrepresentation in the claim.

PBM shall maintain a written or electronic record of the date of receipt of a claim. Pharmacy shall be entitled to inspect the record on request and to rely on that record or any other relevant evidence as proof of the fact of receipt of the claim. If PBM fails to maintain an electronic or written record of the date a claim is received, the claim shall be considered received three business days after the claim was submitted based upon the written or electronic record of the date of submittal by Pharmacy.

Within 30 days after receipt of a claim, PBM shall request electronically or in writing from Pharmacy any information or documentation that PBM believes will be required to process and pay the claim or to determine if the claim is a clean claim. PBM shall use all reasonable efforts to ask for all desired information in one request, and shall if necessary, within 15 days of receipt of the information from the first request, only seek or require additional information one additional time if such additional information could not have been reasonably identified at the time of the original request or to specifically identify a material failure to provide the information requested in the initial request. Upon receipt of the information requested which PBM reasonably believes will be required to adjudicate the claim or to determine if the claim is a clean claim, PBM shall either deny, pay or require plan sponsor to pay the claim within 30 days. PBM or plan sponsor may not refuse to pay a claim for covered drugs if PBM fails to timely notify Pharmacy within 30 days of receipt of the claim of the additional information requested unless such failure was caused in material part by Pharmacy. Provided, that nothing herein precludes PBM from imposing a retroactive denial of such claim where otherwise permitted by the Agreement unless such retroactive denial would violate subparagraph (h) of this paragraph 4.

Interest shall accrue at a rate of 10% per annum after the claims payment period set forth in subparagraph (a) above. At the time the claim is paid, or within 30 days thereafter, plan sponsor shall pay interest owing, without necessity of demand. The interest payment shall be accompanied by an explanation of the assessment on each claim of interest paid.

PBM shall establish and implement reasonable policies to permit Pharmacy to promptly confirm in advance during normal business hours whether the health care services to be provided are covered drugs and to determine requirements applicable to Pharmacy for: (i) precertification or authorization of coverage decisions; (ii) retroactive reconsideration of a certification or authorization of coverage decision or retroactive denial of a previously paid claim; (iii) specific payment and reimbursement methodology; and (iv) claims processing and payment matters necessary to meet the terms and conditions of the Agreement, including determining whether a claim is a clean claim.

PBM shall make available to Pharmacy within 20 business days of receipt of a request, reasonable access either electronically or otherwise, to all policies that are applicable to Pharmacy.

plan sponsor or PBM shall pay a clean claim if PBM or plan sponsor has previously authorized the services or has advised Pharmacy or the covered person in advance of the provision of the services that the services are covered drugs unless the documentation for the claim provided by Pharmacy clearly fails to support the claim as originally authorized or unless the refusal is because:

i. Another party is responsible for the payment;

ii. Pharmacy has already been paid for the services;

iii. The claim was submitted fraudulently, or the authorization was based in whole or material part on erroneous information provided to PBM or plan sponsor by Pharmacy or another person not related to PBM or plan sponsor;

iv. The person receiving the services was not a covered person on the date of service and neither PBM nor plan sponsor knew or with the exercise of reasonable care could have known, of the person's eligibility status;

v. There is a dispute regarding the amount of charges submitted; or

vi. The services were not covered drugs and neither PBM nor plan sponsor knew or with the exercise of reasonable care could have known, at the time of the certification that the services were not covered.

A previously paid claim may be retroactively denied only if:

vii. The claim was submitted fraudulently;

viii. The claim contained material misrepresentations;

ix. The claim payment was incorrect because Pharmacy was already paid on the claim or the services were not delivered by Pharmacy; or

x. Pharmacy was not entitled to reimbursement;

xi. The service was not a covered drug; or

xii. The person to whom the service was rendered was not a covered person.

Upon receipt of notice of a retroactive denial, Pharmacy shall notify PBM within 40 days of its intent to pay or demand written explanation of the reasons for the denial.

Upon receipt of explanation for retroactive denial, Pharmacy shall reimburse PBM within 30 days for allowing an offset against future payments or provide written notice of dispute.

Disputes shall be resolved between the parties within 30 days of receipt of notice of dispute.

Upon resolution of dispute, Pharmacy shall pay any amount due or provide written authorization for an offset against future payments.

PBM may retroactively deny a claim for the reasons set forth in section subparagraph (h)(iii)-(vi) above within one year from the date the claim was originally paid. There shall be no time limit for retroactively denying a claim for the reasons set forth in subparagraph (h)(i)-(ii) above.

Pharmacy acknowledges that at the time the Agreement was presented to Pharmacy for execution it included or was accompanied by (i) a fee schedule, reimbursement policy and statement as to the

manner in which claims will be calculated and paid and the range of services reasonably expected to be delivered by Pharmacy; and (ii) all referenced addenda, schedules and exhibits.

An amendment to the Agreement that relates to payment or the delivery of care by Pharmacy shall not be effective as to Pharmacy unless Pharmacy has been provided with the proposed amendment and has failed to notify PBM within 20 business days of receipt of Pharmacy's intent to terminate the Agreement at the earliest date thereafter permitted under the Agreement.

PBM shall complete its initial credentialing process and accept or reject Pharmacy within four months after submission of Pharmacy's completed application. This time frame may be extended for an additional three months because of delays in primary source verification. PBM shall make available to Pharmacy a list of all information required to be included in the application. If Pharmacy is permitted by PBM to provide services during the credentialing period, Pharmacy shall be paid for the services pursuant to the terms and conditions of the Agreement if Pharmacy's application is approved.

If provision of any policy required to be provided by PBM to Pharmacy under this section 4 would violate any applicable copyright law, PBM may instead provide a clear explanation of the policy as it applies to Pharmacy.

PBM and plan sponsor shall not be violation of any requirement of this section if its failure to comply is cause in material part by Pharmacy or if PBM's or plan sponsor's compliance is rendered impossible due to matters beyond its control, such as an act of God, insurrection, strike, fire or power outages, which are not caused in material part by PBM or plan sponsor.

W.Va. Code § 33-45-2.

Pharmacy agrees to participate in and adhere to all quality improvement activities of PBM or plan sponsor and will allow PBM and plan sponsor access to Pharmacy records as required by law. W.Va. Admin. Code § 114-53-5(5.4).

PBM and plan sponsor allow open covered person communication regarding appropriate treatment alternatives and will not penalize Pharmacy for discussion of medically necessary or appropriate care for covered persons. W.Va. Admin. Code § 114-53-5(5.4).

Notwithstanding anything to the contrary in the Agreement, to the extent Pharmacy provides covered drugs to covered persons of a discount medical plan organization under West Virginia law, the Agreement shall contain: (1) PBM's requirements concerning the services and products to be provided by Pharmacy at a discount; and (2) Pharmacy's applicable discounted rates. Pharmacy agrees that Pharmacy will not charge covered persons more than the discounted rates. W.Va. Code §§ 33-15E-10, 33-15E-13.

Procedures for conducting pharmacy audits (W.Va. Code § 33-51-4)

(a) An entity conducting a pharmacy audit shall conform to the following rules:

(1) Except as otherwise provided by federal or state law, an auditing entity conducting a pharmacy audit may have access to a Pharmacy's previous audit report only if the report was prepared by the auditing entity.

(2) Information collected during a pharmacy audit is confidential by law, except that the auditing entity conducting the pharmacy audit may share the information with the pharmacy benefit manager and with the covered entity for which a pharmacy audit is being conducted and with any regulatory agencies and law-enforcement agencies as required by law.

(3) The auditing entity conducting a pharmacy audit may not compensate an employee or contractor with which an auditing entity contracts to conduct a pharmacy audit solely based on the amount claimed or the actual amount recouped by the pharmacy being audited.

(4) The auditing entity shall provide the Pharmacy being audited with at least 14 calendar days' prior written notice before conducting a pharmacy audit unless both parties agree otherwise. If a delay of the audit is requested by the Pharmacy, the Pharmacy shall provide notice to the pharmacy benefit manager within 72 hours of receiving notice of the audit.

(5) The auditing entity may not initiate or schedule a pharmacy audit without the express consent of the Pharmacy during the first five business days of any month for any Pharmacy that averages in excess of 600 prescriptions filled per week.

(6) The auditing entity shall accept paper or electronic signature logs that document the delivery of prescription or nonproprietary drugs and pharmacist services to a health plan beneficiary or the beneficiary's caregiver or guardian.

(7) Prior to leaving the Pharmacy after the on-site portion of the pharmacy audit, the auditing entity shall provide to the representative of the Pharmacy a complete list of pharmacy records reviewed.

(8) A pharmacy audit that involves clinical judgment shall be conducted by, or in consultation with, a pharmacist.

(9) A pharmacy audit may not cover:

(A) A period of more than 24 months after the date a claim was submitted by the Pharmacy to the pharmacy benefit manager or covered entity unless a longer period is required by law; or

(B) More than 250 prescriptions: provided that a refill does not constitute a separate prescription for the purposes of this subparagraph.

(10) The auditing entity may not use extrapolation to calculate penalties or amounts to be charged back or recouped unless otherwise required by federal requirements or federal plans.

(11) The auditing entity may not include dispensing fees in the calculation of overpayments unless a prescription is considered a misfill. As used in this subdivision, "misfill" means a prescription that was not dispensed, a prescription error, a prescription where the prescriber denied the authorization request or a prescription where an extra dispensing fee was charged.

(12) The auditing entity conducting a pharmacy audit or person acting on behalf of the auditing entity may not seek any fee, chargebacks, recoupment or other adjustment for a dispensed product, or any portion of a dispensed product, unless one of the following has occurred:

(A) Fraud or other intentional and willful misrepresentation as evidenced by a review of the claims data, statements, physical review or other investigative methods;

(B) Dispensing in excess of the benefit design, as established by the plan sponsor;

(C) Prescriptions not filled in accordance with the prescriber's order; or

(D) Actual overpayment to the Pharmacy.

(13) Any fee, chargebacks, recoupment or other adjustment is limited to the actual financial harm associated with the dispensed product, or portion of the dispensed product, or the actual underpayment or overpayment as set forth in the criteria in subdivision (12) of this subsection.

(14) A Pharmacy may do any of the following when a pharmacy audit is performed:

(A) A Pharmacy may use authentic and verifiable statements or records, including, but not limited to, medication administration records of a nursing home, assisted living facility, hospital or health care provider with prescriptive authority, to validate the pharmacy record and delivery; and

(B) A Pharmacy may use any valid prescription, including, but not limited to, medication administration records, facsimiles, electronic prescriptions, electronically stored images of prescriptions, electronically created annotations or documented telephone calls from the prescribing health care provider or practitioner's agent to validate claims in connection with prescriptions or changes in prescriptions or refills of prescription or nonproprietary drugs. Documentation of an oral prescription order that has been verified by the prescribing health care provider shall meet the provisions of this subparagraph for the initial audit review.

(b) An auditing entity shall provide the Pharmacy with a written report of the pharmacy audit and comply with the following requirements:

(1) A preliminary pharmacy audit report shall be delivered to the Pharmacy or its corporate parent within 60 calendar days after the completion of the pharmacy audit. The preliminary report shall include contact information for the auditing entity that conducted the pharmacy audit and an appropriate and accessible point of contact, including telephone number, facsimile number, email address, and auditing firm name and address so that audit results, procedures and any discrepancies can be reviewed. The preliminary pharmacy audit report shall include, but not be limited to, claim level information for any discrepancy found and total dollar amounts of claims subject to recovery.

(2) A Pharmacy is allowed at least 30 calendar days following receipt of the preliminary audit report to respond to the findings of the preliminary report.

(3) A final pharmacy audit report shall be delivered to the Pharmacy or its corporate parent no later than 90 calendar days after completion of the pharmacy audit. The final pharmacy audit report shall include any response provided to the auditing entity by the Pharmacy or corporate parent and shall consider and address such responses.

(4) The final audit report may be delivered electronically.

(5) A Pharmacy may not be subject to a chargeback or recoupment for a clerical or recordkeeping error in a required document or record, including a typographical or computer error, unless the error resulted in overpayment to the Pharmacy.

(6) An auditing entity conducting a pharmacy audit or person acting on behalf of the entity may not make a chargeback or recoupment or collect penalties from a Pharmacy until the time to file an appeal of a final pharmacy audit report has passed or the appeals process has been exhausted, whichever is later.

(7) If an identified discrepancy in a pharmacy audit exceeds $25,000, future payments to the Pharmacy in excess of that amount may be withheld pending adjudication of an appeal.

(8) No interest accrues for any party during the audit period, beginning with the notice of the pharmacy audit and ending with the conclusion of the appeals process.

(9) Except for Medicare claims, approval of drug, prescriber or patient eligibility upon adjudication of a claim may not be reversed unless the Pharmacy or pharmacist obtained adjudication by fraud or misrepresentation of claims elements.

Appeals process (W.Va. Code § 33-51-5)

A Pharmacy may appeal a final audit report in accordance with the procedures established by the entity conducting the pharmacy audit.

Appendix B: Regulatory addendums (continued)

Limitations (W.Va. Code § 33-51-6)

(a) The provisions of this article do not apply to an investigative audit of pharmacy records when:

(1) Fraud, waste, abuse or other intentional misconduct is indicated by physical review or review of claims data or statements; or

(2) Other investigative methods indicate a Pharmacy is or has been engaged in criminal wrongdoing, fraud or other intentional or willful misrepresentation.

(b) This article does not supersede any audit requirements established by federal law.

B-50 Wisconsin Regulatory Addendum to Pharmacy Participation Agreement

This Wisconsin Addendum applies to the extent that Pharmacy provides covered drugs to covered persons of a limited-service health organization, preferred provider plan, defined network plan, health maintenance organization or insurer licensed under Wisconsin law (collectively and/or individually, "plan sponsor").

In the event of a direct conflict between this Addendum and the Agreement, the applicable provisions of this Addendum shall control if required. This Addendum may be modified from time to time pursuant to the Agreement.

Without limiting the generality of the foregoing, Pharmacy agrees as follows:

If Pharmacy's participation under the Agreement terminates for reasons other than misconduct on the part of Pharmacy or Pharmacy's cessation of practice in the applicable geographic service area,

Pharmacy agrees to continue to provide care to covered persons undergoing a course of treatment for the shorter of the following time periods:

For the remainder of the course of treatment or for 90 days after pharmacy's participation under the Agreement terminates, whichever is shorter; or

If the covered person is a woman in the second or third trimester of pregnancy when pharmacy's participation under the Agreement terminates, until the completion of postpartum care for the woman and infant.

Wis. Stat. § 609.24(1)(c).

Pharmacy agrees to accept as reimbursement for services provided under this continuity of care provision the contracted rate set forth in the Agreement. Wis. Stat. § 609.24(1)(e)

When providing services under this continuity of care provision, Pharmacy shall be subject to the hold harmless requirements of Wis. Stat. Ann. § 609.91. Wis. Stat. § 609.24(3).

Pharmacy shall post a notification of termination and of covered persons' rights to continuity of care under Wis. Stat. Ann. § 609.24 in each of its Pharmacies subject to the Agreement the greater of 30 days prior to the termination or 15 days following PBM's receipt of Pharmacy's termination notice. Wis. Stat. § 609.24(4); Wis. Admin. Code Ins. § 9.35(1m).

Pharmacy acknowledges that attached hereto as "Appendix 1" is a summary notice of the statutory limitations and requirements of the hold-harmless provisions of Wis. Stat. Ann. §§ 609.91 to 609.935 and 609.97(1) to which Pharmacy agrees to adhere. Wis. Stat. § 609.94.

Pharmacy benefit managers (Wis. Stat. 632.865(2))

(2) Pricing transparency. (a) The PBM shall agree in each contract or renewal to do all of the following:

1. Update maximum allowable cost pricing information for prescribed drugs or devices at least every seven (7) business days and provide a means by which contracted pharmacies may promptly review pricing updates in a format that is readily available and accessible.
2. Reimburse pharmacists and pharmacies for prescribed drugs or devices subject to maximum allowable cost information that has been updated at least every seven (7) business days.
3. Eliminate prescribed drugs or devices from the maximum allowable cost information or modify maximum allowable cost in a timely fashion consistent with availability of prescribed drugs or devices and pricing changes in the marketplace.

(b) A PBM shall include in each contract with a pharmacy a process to appeal, investigate, and resolve disputes regarding maximum allowable cost pricing that includes all of the following:

1. A 21-day limit on the right to appeal following the initial claim.
2. A requirement that the appeal be investigated and resolved within 21 days after the date of the appeal.

3. A dedicated telephone number at which the pharmacy may contact the PBM to speak to a person responsible for processing appeals.
4. A requirement that a PBM provide a reason for any appeal denial and the national drug code published in a directory by the federal food and drug administration of a prescribed drug or device that may be purchased by retail network pharmacies at a price at or below the maximum allowable cost.
5. A requirement that a PBM make a pricing adjustment no later than one day after the date of the final determination of the appeal.

Pharmacy benefit managers (Wis. Stat. 632.865(6))

Procedures.

An entity conducting an on-site or desk audit of pharmacist or pharmacy records shall do all of the following:

1. If the audit is an audit on the premises of the pharmacist or Pharmacy, notify the pharmacist or Pharmacy in writing of the audit at least two weeks before conducting the audit.
2. Refrain from auditing a pharmacist or Pharmacy within the first five business days of a month unless the pharmacist or Pharmacy consents to an audit during that time.
3. If the audit involves clinical or professional judgment, conduct the audit by or in consultation with a pharmacist licensed in any state.
4. Limit the audit review to no more than 250 separate prescriptions. For purposes of this subdivision, a refill of a prescription is not a separate prescription.
5. Limit the audit review to claims submitted no more than two years before the date of the audit, unless required otherwise by state or federal law.
6. Allow the pharmacist or Pharmacy to use authentic and verifiable records of a hospital, physician or other health care provider to validate the pharmacist's or Pharmacy's records relating to delivery of a prescription drug and use any valid prescription that complies with requirements of the pharmacy examining board to validate claims in connection with a prescription, refill of a prescription or change in prescription.
7. Allow the Pharmacy or pharmacist to document the delivery of a prescription drug or pharmacist services to an enrollee under a health benefit plan using either paper or electronic signature logs.
8. Before leaving the Pharmacy after concluding the on-site portion of an audit, provide to the representative of the Pharmacy or the pharmacist a complete list of the pharmacy records reviewed.

Results of audit

An entity that has conducted an audit of a pharmacist or Pharmacy shall do all of the following:

1. Deliver to the pharmacist or Pharmacy a preliminary report of the audit within 60 days after the date the auditor departs from an on-site audit or the Pharmacy or pharmacist submits paperwork for a desk audit. A preliminary report under this subdivision shall include claim-level information for any discrepancy reported, the estimated total amount of claims subject to recovery and contact information for the entity or person that completed the audit so the pharmacist or Pharmacy subject to the audit may review audit results, procedures and discrepancies.
2. Allow a pharmacist or Pharmacy that is the subject of an audit to provide documentation to address any discrepancy found in the audit within 30 days after the date the pharmacist or Pharmacy receives the preliminary report.

3. Deliver to the pharmacist or Pharmacy a final audit report, which may be delivered electronically, within 90 days of the date the pharmacist or Pharmacy receives the preliminary report or the date of the final appeal of the audit, whichever is later. The final audit report under this subdivision shall include any response provided to the auditor by the Pharmacy or pharmacist and consider and address the Pharmacy's or pharmacist's response.
4. Refrain from assessing a recoupment or other penalty on a pharmacist or Pharmacy until the appeal process is exhausted and the final report under subd. 3. is delivered to the pharmacist or Pharmacy.
5. Refrain from accruing or charging interest between the time the notice of the audit is given under par. (b)1. and the final report under subd. 3. has been delivered.
6. Exclude dispensing fees from calculations of overpayments.
7. Establish and follow a written appeals process that allows a Pharmacy or pharmacist to appeal the final report of an audit and allow the Pharmacy or pharmacist as part of the appeal process to arrange for, at the cost of the Pharmacy or pharmacist, an independent audit.
8. Refrain from subjecting the Pharmacy or pharmacist to a recoupment or recovery for a clerical or recordkeeping error in a required document or record, including a typographical or computer error, unless the error resulted in an overpayment to the Pharmacy or pharmacist.

Confidentiality of audit

Information obtained in an audit under this subsection is confidential and may not be shared unless the information is required to be shared under state or federal law and except that the audit may be shared with the entity on whose behalf the audit is performed. An entity conducting an audit may have access to the previous audit reports on a particular Pharmacy only if the audit is conducted by the same entity.

Cooperation with audit

If Prime is conducting an audit that is complying with this subsection in auditing a Pharmacy or pharmacist, the Pharmacy or pharmacist that is the subject of the audit may not interfere with or refuse to participate in the audit.

Payment of auditors

A pharmacy benefit manager or entity conducting an audit may not pay an auditor employed by or contracted with the pharmacy benefit manager or entity based on a percentage of the amount recovered in an audit.

Applicability

1. This subsection does not apply to an investigative audit that is initiated as a result of a credible allegation of fraud or willful misrepresentation or criminal wrongdoing.
2. If an entity conducts an audit to which a federal law applies that is in conflict with all or part of this subsection, the entity shall comply with this subsection only to the extent that it does not conflict with federal law.

Wisconsin Notice "1"

THIS NOTICE DESCRIBES HOLD-HARMLESS PROVISIONS WHICH AFFECT YOUR ABILITY TO SEEK RECOURSE AGAINST HEALTH MAINTENANCE ORGANIZATION INSURER ENROLLEES FOR PAYMENT FOR SERVICES

Section 609.94, Wis. Stat. requires each health maintenance organization insurer ("HMO insurer"), to provide a summary notice to all of its participating providers of the statutory limitations and requirements in §§ 609.91 to 609.935, and § 609.97 (1), Wis. Stat.

Summary

Under Wisconsin law, a health care provider may not hold HMO insurer enrollees or policyholders ("enrollees") liable for costs covered under an HMO insurer policy if the provider is subject to statutory provisions which "hold harmless" the enrollees. For most health care providers application of the statutory hold-harmless is "mandatory" or it applies unless the provider elects to "opt-out." A provider permitted to "opt-out" must file timely notice with the Wisconsin Office of the Commissioner of Insurance ("OCI").

Some types of provider care are subject to the hold-harmless statutes only if the provider voluntarily "opts-in." An HMO insurer may partially satisfy its regulatory capital and surplus requirements if health care providers elect to remain subject to the statutory hold-harmless provisions.

This notice is only a summary of the law. Every effort has been made to accurately describe the law. However, if this summary is inconsistent with a provision of the law or incomplete, the law will control.

Filings for exemption with OCI must be on the prescribed form in order to be effective.

Hold harmless

A health care provider who is subject to the statutory hold-harmless provisions is prohibited from seeking to recover health care costs from an enrollee. The provider may not bill, charge, collect a deposit from, seek remuneration or compensation from, file or threaten to file with a credit reporting agency or have any recourse against an enrollee or any person acting on the enrollee's behalf, for health care costs for which the enrollee is not liable. The prohibition on recovery does not affect the liability of an enrollee for any deductibles or copays, or for premiums owed under the policy or certificate issued by the HMO insurer.

A. Mandatory for hold harmless.

An enrollee of an HMO insurer is not liable to a health care provider for health care costs that are covered under a policy issued by that HMO insurer if any of the following are met:

Care is provided by a provider who is an affiliate of the HMO insurer, owns at least 5% of the voting securities of the HMO insurer, is directly or indirectly involved with the HMO insurer through direct or indirect selection of or representation by one or more board members, or is an Individual Practice

Association ("IPA") and is represented, or an affiliate is represented, by one of at least three HMO insurer board members who directly or indirectly represent one or more IPAs or affiliates of IPAs.

Care is provided by a provider under a contract with or through membership in an organization identified in 1.

To the extent the charge exceeds the amount the HMO insurer has contractually agreed to pay the provider for that health care service.

The care is provided to an enrolled medical assistance recipient under a Department of Health and Family Services prepaid health care policy.

The care is required to be provided under the requirements of s. Ins. 9.35 Wis. Adm. Code.

B. "Opt-out" hold harmless.

If the conditions described in A do not apply, the provider will be subject to the statutory hold harmless unless the provider files timely election with OCI to be exempt if the health care meets any of the following:

Provided by a hospital or an IPA.

A physician service, or other provider services, equipment, supplies, or drugs that are ancillary or incidental to such services and are provided under a contract with the HMO insurer or are provided by a provider selected by the HMO insurer.

Provided by a provider, other than a hospital, under a contract with or through membership in an IPA that has not elected to be exempt. Note that only the IPA may file election to exempt care provided by its member providers from the statutory hold harmless. (See Exemptions and Elections, No. 4.)

C. "Opt-in" hold harmless.

If a provider of health care is not subject to the conditions described in A or B, the provider may elect to be subject to the statutory hold-harmless provisions by filing a notification with OCI stating that the provider elects to be subject with respect to any specific HMO insurer. A provider may terminate such a notice of election by stating the termination date in that notice or in a separate notification.

Conditions not affecting immunity

An enrollee's immunity under the statutory hold harmless is not affected by any of the following:

Any agreement entered into by a provider, an HMO insurer or any other person, whether oral or written, purporting to hold the enrollee liable for costs (except a notice of election or termination permitted under the statute).

A breach of or default on any agreement by the HMO insurer, an IPA or any other person to compensate the provider for health care costs for which the enrollee is not liable.

The insolvency of the HMO insurer or any person contracting with the HMO insurer, or the commencement of insolvency, delinquency or bankruptcy proceedings involving the HMO insurer or other persons which would affect compensation for health care costs for which an enrollee is not liable under the statutory hold harmless.

The inability of the provider or other person who is owed compensation to obtain compensation for health care costs for which the enrollee is not liable.

Failure by the HMO insurer to provide notice to providers of the statutory hold-harmless provisions.
Any other conditions or agreement existing at any time.

Exemptions and elections

Hospitals, IPAs and providers of physician services who may "opt-out" may elect to be exempt from the statutory hold harmless and prohibition on recovery of health care costs under the following conditions and with the following notifications:

If the hospital, IPA or other provider has a written contract with the HMO insurer, the provider must within 30 days after entering into that contract provide a notice to OCI of the provider's election to be exempt from the statutory hold-harmless and recovery limitations for care under the contract.

If the hospital, IPA or other provider does not have a contract with an HMO insurer, the provider must notify OCI that it intends to be exempt with respect to a specific HMO insurer and must provide that notice for the period Jan. 1, 1990, to December 21, 1990, at least 60 days before the health care costs are incurred; and must provide that notice for health care costs incurred on and after Jan. 1, 1991, at least 90 days in advance.

A provider who submits a notice of election to be exempt may terminate that election by stating a termination date in the notice or by submitting a separate termination notice to OCI.

The election by an IPA to be exempt from the statutory provisions, or the failure of an IPA to so elect, applies to costs of health care provided by any provider, other than a hospital, under contract with or through membership in the IPA. Such a provider, other than a hospital, may not exercise an election separately from the IPA. Similarly, an election by a clinic to be exempt from the statutory limitations and restrictions or the failure of the clinic to elect to be exempt applies to costs of health care provided by any provider through the clinic. An individual provider may not exercise an election to be exempt separate from the clinic.

The statutory hold-harmless "opt-out" provision applies to physician services only if the services are provided under a contract with the HMO insurer or if the physician is a selected provider for the HMO insurer, unless the services are provided by a physician for a hospital, IPA or clinic which is subject to the statutory hold-harmless "opt-out" provision.

Notices

All notices of election and termination must be in writing and in accordance with rules promulgated by the Commissioner of Insurance. All notices of election or termination filed with OCI are not affected by the renaming, reorganization, merger, consolidation or change in control of the provider, HMO insurer or other person. However, OCI may promulgate rules requiring an informational filing if any of these events occur.

Notices to the Office of the Commissioner of Insurance must be written, on the prescribed form, and received at the Office's current address:

P. O. Box 7873, Madison, WI 53707-7873

HMO insurer capital and security surplus

Each HMO insurer is required to meet minimum capital and surplus standard ("compulsory surplus requirements"). These standards are higher if the HMO insurer has fewer than 90% of its liabilities covered by the statutory hold harmless. Specifically, beginning Jan. 1, 1992, the compulsory surplus requirement shall be at least the greater of $750,000 or 6% of the premiums earned by the HMO insurer in the last 12 months if its covered liabilities are less than 90%, or 3% of the premiums earned by the HMO insurer in the last 12 months if its covered liabilities are 90% or more. In addition to capital and surplus, an HMO insurer must also maintain a security surplus in the amount set by the Commissioner of Insurance.

Financial information

An HMO insurer is required to file financial statements with OCI. You may request financial statements from the HMO insurer. OCI also maintains files of HMO insurer financial statements that can be inspected by the public.

Source: WISCONSIN ADMINISTRATIVE CODE COMMISSIONER OF INSURANCE

CHAPTER INS 9. DEFINED NETWORK PLANS

SUBCHAPTER III. MARKET CONDUCT STANDARDS FOR DEFINED NETWORKPLANS, PREFERRED PROVIDER PLANS AND LLIMITED SERVICE HEALTH ORGANIZATIONS

APPENDIX C NOTICE

2013 WI ADC Ch. Ins. 9, effective 2-28-2013

B-51 Wyoming Regulatory Addendum to Pharmacy Participation Agreement

This Wyoming Addendum applies to the extent that Pharmacy provides covered drugs to covered persons of health maintenance organizations, managed care organizations, health service corporations, insurers or carriers under Wyoming law (collectively and/or individually, "plan sponsor").

In the event of a direct conflict between this Addendum and the Agreement, the applicable provisions of this Addendum shall control if required. This Addendum may be modified from time to time pursuant to the Agreement.

Without limiting the generality of the foregoing, Pharmacy agrees as follows:

To the extent Pharmacy provides covered drugs to covered persons of a health maintenance organization under Wyoming law, Pharmacy agrees:

In the event plan sponsor fails to pay for covered drugs as set forth in the Agreement, covered persons shall not be liable to Pharmacy for any sums owed by plan sponsor. Pharmacy shall not collect or attempt to collect from covered persons sums owed by plan sponsor. Pharmacy and its agents, trustees or assignees shall not maintain an action at law against covered persons to collect sums owed by plan sponsor. Wyo. Stat. § 26-34-114(o), (q).

In the event of plan sponsor's insolvency, Pharmacy agrees to continue to provide covered drugs to covered persons after plan sponsor's insolvency during the period for which premium payment has been made and until covered persons' discharge from inpatient facilities. Wyo. Stat. § 26-34-114(r)(ii).

Notwithstanding anything in the Agreement to the contrary, Pharmacy shall give PBM at least 60 days' advance notice prior to termination of the Agreement. Wyo. Stat. § 26-34-114(s).

Maximum allowable cost; offering information and alternatives (WY ST § 26-52-104)

(d) A PBM shall:

(i) Make available to each network provider at the beginning of the term of the network provider's contract, and upon renewal of the contract, the sources utilized to determine the maximum allowable cost pricing;

(ii) Provide a telephone number, email address and website at which a network pharmacy or the pharmacy's designee who holds a contract with the PBM may contact an employee of a pharmacy benefit manager to discuss the pharmacy's appeal;

(iii) Provide a process for network providers to readily access the maximum allowable cost applicable to that provider;

(iv) Review and update applicable maximum allowable cost price information at least once every seven (7) business days to reflect any modification of maximum allowable cost pricing; and

(v) Ensure that dispensing fees are not included in the calculation of maximum allowable cost.

(e) A PBM shall establish a process by which a contracted pharmacy, or the pharmacy's designee who holds a contract with the PBM, can appeal the provider's reimbursement for a drug subject to maximum allowable cost pricing. A contracted pharmacy, or the pharmacy's designee who holds a contract with the PBM, shall have up to ten (10) business days after dispensing a drug subject to a maximum allowable cost in which to appeal the amount of the maximum allowable cost. A PBM shall respond to the appeal within ten (10) business days after the contracted pharmacy or the pharmacy's designee who holds a contract with the PBM makes the appeal.

(f) If a maximum allowable cost appeal is denied, the PBM shall provide to the appealing pharmacy, or the pharmacy's designee who holds a contract with the PBM, the reason for the denial and the national drug code number for the drug that is available for purchase by similarly situated pharmacies in the state and the names of national or regional wholesalers that have the product available for purchase at a price that is at or below the maximum allowable cost.

(g) If an appeal is upheld, the PBM shall make an adjustment to the applicable maximum allowable cost no later than one (1) day after the date of the determination and make the adjustment applicable to all similarly situated network pharmacy providers, as determined by the insurer or PBM. The PBM shall allow the appealing pharmacy to reverse and rebill the claim which was the subject of the appeal.

Pharmacy benefit manager audits (Wyo. Stat. § 26-52-103)

(a) Any pharmacy benefit manager or person acting on behalf of a pharmacy benefit manager who conducts an audit of a Pharmacy shall follow the following procedures:

(i) Provide written notice to the Pharmacy not less than 10 business days before conducting any on-site, initial audit

Conduct any audit requiring clinical or professional judgment through or in consultation with a licensed pharmacist;

(iii) Limit the period covered by the audit to not more than two years from the date that an audited claim was adjudicated;

(iv) Allow verifiable statements or records, including medication administration records of a nursing home, assisted living facility, hospital, physician or other authorized practitioner, to validate the pharmacy record;

(v) Allow legal prescriptions, including medication administration records, faxes, electronic prescriptions or documented telephone calls from the prescriber or the prescriber's agent, to validate claims in connection with prescriptions, refills or changes in prescriptions;

(vi) Apply the same standards and parameters to each audited Pharmacy as are applied to other similarly situated Pharmacies in a Pharmacy Network contract in this state;

(vii) Not conduct any audit provided for in this section during the first seven calendar days of any month without the consent of t he audited Pharmacy; and

(viii) Establish a written appeals process and provide a copy to every audited Pharmacy.

(b) Prime or person acting on behalf of Prime who conducts an audit of a Pharmacy also shall comply with the following requirements:

(i) Any finding of overpayment or underpayment shall be based on the actual overpayment or underpayment and not on a projection based on the number of patients served having a similar diagnosis or on the number of similar orders or refills for similar drugs;

(ii) Any finding of an overpayment shall not include the dispensing fee amount unless:

(A) A prescription was not received by the patient or the patient's designee;

(B) The prescriber denied authorization;

(C) The prescription dispensed was a medication error by the Pharmacy; or

(D) The identified overpayment is based solely on an extra dispensing fee.

(iii) No audit shall use extrapolation in calculating the recoupments or penalties for audits, unless required by state or federal contracts;

(iv) No payment for the performance of an audit shall be based on a percentage of the amount recovered;

(v) Interest shall not accrue during the audit period;

(vi) No audit shall consider any clerical or recordkeeping error, such as a typographical error, scrivener's error or computer error regarding a required document or record, as fraud. These errors may be subject to recoupment. No recovery shall be assessed for errors causing no financial harm to the patient or plan. Errors that are the result of a Pharmacy failing to comply with a formal corrective action plan may be subject to recovery. Any recoupment shall be based on the actual overpayment of a claim;

(vii) A preliminary audit report shall be delivered to the audited Pharmacy within 120 days after the conclusion of the audit;

(viii) A Pharmacy shall be allowed at least 30 days following receipt of the preliminary audit report to provide documentation addressing any audit finding, and a reasonable extension of time shall be granted upon request;

(ix) A final audit report shall be delivered to the Pharmacy not more than 120 days after the preliminary audit report is received by the Pharmacy or submission of final internal appeal, whichever is later;

(x) Recoupment of any disputed funds or repayment of funds to the pharmacy benefit manager or insurer by the Pharmacy, if permitted pursuant to contracts, shall occur, to the extent demonstrated or documented in the pharmacy audit findings, after final internal disposition of the audit including the appeals process. If the identified discrepancy for an individual audit exceeds $15,000, any future payments to the Pharmacy may be withheld pending finalization of the audit;

(xi) No chargebacks, recoupment or other penalties may be assessed until the appeal process has been exhausted and the final report issued.

(c) Subsections (a) and (b) of this section shall not apply to:

(i) Audits in which suspected fraudulent activity or other intentional or willful misrepresentation is evidenced by a physical review, review of claims data, statements or other investigative methods; or

(ii) Audits of claims paid for by federally funded programs.

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