PRIME THERAPEUTICS®

PRIME THERAPEUTICS

PROVIDER MANUAL

FOR PHARMACY PROVIDERS

Effective January 1, 2022

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INTRODUCTION TO PRIME THERAPEUTICS

INTRODUCTION

Prime Therapeutics LLC (Prime) provides pharmacy benefit management ("PBM") services for Benefit Sponsors, 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 in accordance with all applicable federal, state and local laws. Prime has adopted a compliance program and code of conduct. This includes 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 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 **www.PrimeTherapeutics.com**.

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

All capitalized terms that are otherwise not defined in this Manual refer to those defined in the Agreement.

Important: This Manual applies to all lines of business.

Failure to comply with Prime's terms and conditions, including, but not limited to, those described in this Manual, as revised, may result in placement on a corrective action plan, 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 MAILING ADDRESS

If you would like additional information, contact Prime at:

Prime Therapeutics
P.O. Box 64812
St. Paul, MN 55164-9403

PRIME'S CONTACT CENTER

800.821.4795

Prime's Contact Center has dedicated staff to assist Pharmacies. They can help with contract requests, processing questions and any comments and concerns you may have. Prime's representatives are available 24 hours a day, 7 days a week.

PRIME'S WEBSITE

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

- **Payer sheet**
- **Medicare Prescription Drug Coverage and Your Rights**
- **Formularies – Commercial**
- **Formularies – Medicare Part D**
- ***Prime Perspective* newsletters**
- **Compliance/Fraud, Waste and Abuse (FWA)**
- **Plan announcements**
- **Network request form**
- **Common billing errors**
- **Minimum Performance and Service Criteria for Medicare Part D**
- **Minimum Performance Criteria for LTC**
- **Medicare Part B vs. Part D coverage issues**
- **Pharmacy Audit Appeal form**
- **Prime Audit Advisor/Fax series**
- **Audit Guidelines**
- **FAQ: Claim Adjustments**
- **Long-Term Care and Home Infusion General Dispensing Requirements**
- **Home Infusion (HI) validation**
- **Long-term care (LTC) validation**
- **Medicaid program**
- **Vaccine program**
- **Check Inquiry form**
- **Maximum Allowable Cost (MAC) lists**
- **Instructions for viewing Network Reimbursement IDs (NRIDs) for adjudicated claims**
- **Dispensing Thresholds**
- **Provider Manual**
- **COVID-19 Testing and Vaccine Payer Sheets (as applicable**)

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 (PHI) 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 Fraud, Waste or Abuse anonymously by contacting Prime's 24-hour anonymous compliance hotline:

- Phone: **800.474.8651**
- Email: **reports@lighthouse-services.com**
- Mobile app: **App Store › Search for Anonymous Reporting (Lighthouse) › Download the app › Keyword "prime" › Select "save"**
- Third party vendor's website: **www.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
- Fraud, Waste and Abuse (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:

- Codes of conduct
- FWA programs
- 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 Program requirements. Pharmacies should communicate the plan and any means of enforcing the plan to all employees.

Refer to the Centers for Medicare & Medicaid Services (CMS) website, **CMS.gov**, for a complete list of compliance program requirements.

FRAUD, WASTE AND ABUSE (FWA)

"Fraud," "Waste" and "Abuse" or "FWA" means an inappropriate use of health care benefits or Benefit Plan in connection with the Pharmacy's delivery of, billing of, claiming of, 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, when an individual or organization unintentionally provides 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 NCPDP profile. Please complete the form via the NCPDP website. For your convenience, instructions for completing the NCPDP form are 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 Certification

On behalf of the Part D Benefit Sponsors Prime serves, Prime requires any staff providing Medicare Part D services to receive qualified Fraud, Waste and Abuse (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 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. Pharmacists 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 in the course of 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 pre-existing Patient-Prescribing Provider relationship or without a valid prescription drug order.

  Patient-Prescribing Provider Relationship Definition: There are three (3) ways a Patient-Prescribing Provider relationship can be established:

  - There is a pre-existing 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; or
  - 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; or
    - Any other communication technology that allows the Prescribing Provider to meet the applicable standard of care
- **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 Prescribing Provider's Drug Enforcement Administration (DEA) number or prescription pad** — Prescription pads may be stolen from Prescribing Providers 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 non-existent 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 non-covered 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
  - Inappropriate use of product selection codes (PSC) (also known as dispense as written [DAW] codes), submission clarification codes (SCC) and dynamic Prior Authorizations (PAs)
  - Billing an 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 a greater vial size than what is necessary to supply the ordered dose
- Waiving Copays — The Pharmacy does not collect the copay due from the 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 make 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 without the Prescribing Provider's permission to increase the quantity or number of refills.
- **Dispensing expired or adulterated prescription drugs** — The Pharmacy dispenses drugs that are expired or have not been stored or handled according to the manufacturer or FDA 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.
- **TrOOP manipulation** — Manipulation of true out-of-pocket (TrOOP) costs by the Pharmacy, including to either push a Covered Person through the coverage gap so the Covered Person can reach catastrophic coverage before being eligible, or to keep a Covered Person in the coverage gap so that catastrophic coverage is never realized
- **Failure to offer negotiated prices** — The Pharmacy's failure 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 dispensing 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

NOTICE TO CALIFORNIA PHARMACIES

This serves as notice to Pharmacies in California about rights under 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

Pharmacy has certain rights as a Pharmacy under Cal. Health and Safety Code §1371.39.

SECTION 3: CLAIMS PROCESSING

GENERAL INFORMATION

Online Claims Submission

The Pharmacy must electronically submit all claims to Prime for all Prescription Drug Services provided to a Covered Person. This includes situations where no Pharmacy Payment from Prime 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" or "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 hours a day, 7 days a week.

Claim Formats

- POS claims must be submitted in the current NCPDP format or current industry version.
- 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 at **NCPDPOnline.org**.

For a complete list of required and situational processing requirements, refer to the Payer sheets located on **Prime's website**.

The Pharmacy must refer to 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.

In order for Prime to assist Pharmacies with claims adjudication, please email your unique processing codes, condor codes, and/or input codes: **PharmacyOps@PrimeTherapeutics.com**.

Medicare Reference Materials

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

- **Medicare Prescription Drug Coverage and Your Rights Standardized Pharmacy Notice Instruction**
- **Medicare Prescription Drug Coverage and Your Rights**
- **Medicare Part B vs. D Coverage Issues**
- **Minimum Performance and Service Criteria for Medicare Part D**
- **Minimum Performance and Service Criteria for LTC**

Collection of Copay/Cost Share

The Pharmacy must collect from the Covered Person Payor Copayments, 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 non-covered services, unless otherwise prohibited by applicable law. The Pharmacy cannot waive, discount, reduce or increase the Copayment 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, non-payment by a Benefit Sponsor Payor for Prescription Drug Services rendered to Covered Persons by Pharmacy, insolvency of a Benefit Sponsor Payor, or breach by Prime of any term or condition of the Agreement, will 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.

ELIGIBILITY

Covered Person Identification Card

Prime is not obligated to pay the Pharmacy for services provided to an individual who, at the time services are provided, is not eligible to receive benefits for the services provided. The Pharmacy must verify a Covered Person's eligibility and must require a Covered Person to present a Covered Person Identification Card prior to providing a Prescription Drug Service.

The Covered Person Identification Card does not ensure a Covered Person's eligibility. If a Covered Person does not have a Covered Person Identification 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 identification card or call Prime's Contact Center at **800.821.4795** to obtain accurate information 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 should 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.

In accordance with 45 CFR § 155.430, 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 from a Covered Person payment for Prescription Drug Services. 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.

Controlled Substance Prescription Dispensing Considerations

Pharmacies may not use or accept form or pre-filled prescriptions to dispense controlled substances. Pharmacies may only dispense Schedule II 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 at **800.821.4795** to verify the multiple-birth eligibility flag has been set.

Medicare E1 Eligibility Query

The E1 Eligibility Query is a real-time transaction submitted by the Pharmacy 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 Identification Card.

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

Pharmacies should not submit an E1 for pharmaceutical manufacturer copay assistance coupon programs as they are not considered Prescription Drug Services.

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 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 copayments.

Section 1902(n)(3)(B) of the Social Security Act, as modified by Section 4714 of the Balanced Budget Act of 1997, states that all Medicare and Medicare Advantage providers may not balance bill QMB individuals for Medicare cost-sharing under any circumstances.

A value of 51 will be sent in the Benefit Stage Qualifier field (NCPDP field 393-MV) to notify the Pharmacy that this claim is submitted under the Part D BIN/PCN, but the claim is NOT paid for by the Part D benefit plan. It is paid for by the Part B benefit.

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 who inappropriately balance bill the QMB individuals are subject to sanctions and possible termination of participation in one or more Networks or termination of the Agreement.

Best Available Evidence (BAE)

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. If the claims system does not show the correct LIS status for the Covered Person, Medicare requires the Pharmacy to accept 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 at **800.445.7085**.
- 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 (3) 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 (1) business day for an immediate need.

Hospice Best Available Evidence (BAE)

A Covered Person's hospice provider pays for the medications for their 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 and ask for a Hospice Prior Authorization (PA). If Prime does not have dual system authentication of hospice admission, Prime asks the hospice 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 one of the following facts:
  - The date the revocation is to be effective
  - The Notice of Medicare Coverage from the hospice
  - The Notice of Medicare Non-Coverage (NOMNC); or
  - 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 and POS messaging.

Bank Identification Number (BIN) and Processor Control Number (PCN)

A BIN and 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 (NPI)

- **Pharmacy 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" will be displayed with message "PrescrTyp1NPI Required." The Pharmacy may, through use of a Submission Clarification Code (SCC), attest that the Prescribing Provider NPI number supplied at POS is or will soon be a valid NPI. The Pharmacy must submit the Prescribing Provider NPI 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 to their DEA registration for the drug being dispensed. Prime will communicate with the Pharmacy via a claim rejection if the submitted NPI is associated to an inactive or invalid DEA without the correct prescriptive authority. If Prime communicates that the associated DEA is inactive and invalid, the Pharmacy can enter a Submission

Clarification Code (SCC) in field 420-DK to attest that they have verified the Prescribing Provider has appropriate prescriptive authority.

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.

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: 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: 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 varies 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., greater than 30 days or greater 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. For this subset, the smallest unit exceeds the maximum benefit days' supply and there is subjectivity in calculating the days' supply (such as topical products). In this case, the Pharmacy must submit the maximum days' supply allowed under the Covered Person's Benefit Plan.

Example: Covered Person's benefit allows up to a 30-day supply. One unbreakable unit may last 40 days, depending upon the amount used, but a course of therapy should be limited to 28 days (e.g., clobetasol shampoo). 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 (NDC)

When the Pharmacy submits a claim for a Prescription Drug Service, the Pharmacy must submit the NDC number for the original package size from which the Prescription Drug Service was dispensed. The quantity of the Prescription Drug Service dispensed must comply with the dispensing limitations obtained through the online POS system.

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

NDC Codes

Pharmacies are required to use standard NDC codes.

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.

If a Pharmacy claim is not adjudicated online within 90 days of the prescription fill date for commercial/Health Insurance Marketplace (HIM) Benefit Plans and 180 days for Medicare Part D Benefit Plans, the claim will reject as too old to process.

All requests to open a window for resubmission must be received from the Pharmacy by submitting their request in writing to **PharmacyOps@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:

- Written
- Telephone
- Electronic
- Facsimile (fax)
- Pharmacy

All claims submissions must indicate the prescription origin code in order to facilitate CMS reporting and tracking of ePrescribe 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 drug manufacturers to provide outpatient drugs to eligible health care entities at significantly reduced prices.

Duplicate discounts are prohibited under Prime's agreements with manufacturers and 42 U.S.C. 256b(a)(5) (A)(i), and drugs purchased at a discounted 340B price are not eligible for drug rebates. Pharmacies must comply with Prime's claims processing requirements for 340B claims by submitting "20" in the NCPDP Submission Clarification Code (420-DK) field and "08" in the Basis of Cost NCPDP field (423-DN), unless prohibited by applicable law.

To view the specific claim processing requirements, please go to **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 (0) 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 mL 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. (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, 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 prior authorizations (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 Submission Clarification Code "08" to receive payment for all covered ingredients. Not all benefit plans support the use of Submission Clarification Code "08."
- Each benefit set-up 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 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 reference of 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 non-sterile products, to which only water, alcohol or sodium chloride solution are added to the active ingredient (e.g., children's antibiotic suspensions, antibiotic IVs with only one legend drug)
- Any prescription that is subdivided into unit dose(s)
- Injectable drugs that are drawn into syringes for administration
- 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 additional 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 pays (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 requiring 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 not literature that supports the 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 resulted 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 at **800.821.4795**.

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.
- 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.
- Diabetic supplies submitted to insurance are considered prescriptions and must follow all terms and conditions outlined in this Manual, as revised.

Long-Term Care (LTC) and Home Infusion (HI) Processing Requirements

Prime requires LTC and 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 (2) 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 (1) 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 (1) year. Pharmacies must not dispense more units per dose than what is necessary and must not dispense short-dated product.

Medicare Part D Program Coordination of Benefits (COB)

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. Prime's Supplemental to Medicare Part D Payer sheets are available on **Prime's website**.

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

Time Limits for Coordination of Benefits

There are time limits for coordinating benefits with State Pharmaceutical Assistance Programs, other entities providing Prescription Drug Service or other payers.

The time limits cannot exceed three (3) years from the date the prescription for the Medicare drug was filled. This does not affect time frames for Medicare secondary payer (MSP) prescription drug claims and the ability to recover amounts.

Medicare Parts A & B vs. D Claims Adjudication

Medicare Part D excludes any drugs covered under Medicare Part A or Part B, such as drugs that are administered in a pump, covered under hospice benefits, or End Stage Renal Disease (ESRD) 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. For example, insulin, when used in a pump, must be billed under Medicare Part B.

On applicable insulin products, a POS message will be returned on the claim that states, "If used in non-disposable pump, submit to Medicare Part B." The Pharmacy must verify insulin is not being used in a pump before submitting the claim to pay under Medicare Part D. In situations where the Covered Person is using an insulin pump, the claim is not eligible for Part D submission.

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.

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 circumstance. For example, Pharmacies may receive 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 have been identified with a retroactive ESRD date of service or claims where insulin is used in a 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 where coverage is available 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.

Many Benefit Plans no longer require Pharmacies to submit Part B covered products to separate BIN and PCN.

If a claim is submitted to the incorrect BIN/PCN, Prime will 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 **Prime's website**.

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

UTILIZATION MANAGEMENT PROGRAM

Drug Formularies

Prime manages many Drug Formularies for Benefit Sponsors and administers Formularies through the POS system. Drug Formularies can be accessed on **Prime's website**.

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. Medicare Part D Drug Formularies are updated monthly to reflect additions, deletions, tier changes and utilization management changes. Updated lists are posted monthly 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 lower cost-sharing tier and with the same or fewer restrictions (utilization management, for instance). The brand may remain on the Formulary but may be subject to a higher cost-sharing tier or additional restrictions. These changes may be made with notice to affected Covered Persons after the change.

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 becomes effective. 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 prior authorization (PA), quantity limits (QL) 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 (PA)

Here are several types of PAs Benefit Sponsors use:

- **One-time override** — Prime uses the one-time override for:
  - Processing dosage changes
  - Requesting a vacation supply
  - Replacing lost, stolen, damaged or spilled medications
  - Fixing an incorrect days' supply, or
  - Requesting to dispense through mail rather than retail

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 call Prime's Contact Center at **800.821.4795** to ask about the availability of an administrative PA override for one of these situations through a Covered Person's Benefit Plan.

- **Dynamic PA** — Some Benefit Sponsors use an automatic override process referred to as dynamic PA. The Pharmacy must enter a pre-determined PA number for certain conditions, such as a vacation request, adverse weather 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, 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, 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. In no event may the Pharmacy complete a PA for 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 (3) 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 Identification Card.
  - The Covered Person can call the toll-free number on the back of the Covered Person's Identification Card.
  - The Covered Person can visit their Benefit Sponsor's website.
- **Clinical PA** — This PA is used for 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. In no event may the Pharmacy complete a Clinical PA. The Pharmacy must follow POS messaging and notify the Covered Person and/or Prescribing Provider of the need for a PA. POS messaging may vary based on the drug or program and may include quantity limit, step therapy, or clinical necessity requirements in addition to the PA. Regardless, 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. Claims for these drugs will reject with the NCPDP reject codes of 75 "Prior Authorization Required" or 76 "Plan Limitations Exceeded." For the most current information on medications that require a PA, visit the Covered Person's Benefit Sponsor's website.
- **Medicare Part D Eligibility Verification** — This PA is used specifically for certain drugs (such as Cialis and fentanyl) 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 conduct outreach to the Pharmacy where the initial claim rejected and inform that 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 (nonnarcotic, opioid, and anti-inflammatory)

  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 a 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 at **800.821.4795** to request the fax number and initiate this process.

Electronic Submission of PA Requests Supported by CoverMyMeds

If the Pharmacy has received POS Clinical PA messaging, the Pharmacy may initiate an electronic PA request through **CoverMyMeds.com**. The Pharmacy must notify the Covered Person and/or Prescribing Provider indicating 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 **CoverMyMeds**. See **CoverMyMeds** for more information.

Step Therapy (ST)/Contingent Therapy Programs

Some Benefit Sponsors require the Covered Person to try one or more preferred medications before a non-preferred medication is considered for payment. This is referred to as step therapy. Refer to the Benefit Sponsor's Drug Formulary to determine if a drug is subject to step therapy. For the most current information on step therapy, visit the Covered Person's Benefit Sponsor's website. Claims for drugs subject to step therapy will reject with the NCPDP reject codes of 75 "Prior Authorization Required" or 608 "Step Therapy Alternate Drug Therapy Required Prior to Use of Submitted Product Service ID" and 76 "Plan Limitations Exceeded." POS messages will vary based on the drug or program and may include quantity limit, step therapy, or clinical necessity requirements in addition to PA.

Quantity Limit (QL)

Many Benefit Sponsors restrict the quantity that may be dispensed on certain drugs, such as proton pump inhibitors or tobacco cessation medications. These limits follow clinical dosing guidelines and restrict the dispensing of the drug to a maximum quantity. A claim that exceeds the quantity limit will result in a NCPDP reject code 76 "Plan Limits Exceeded." An additional message accompanies the rejection and indicates the maximum quantity that may be dispensed. The Pharmacy's software system must be able to capture the reject code and associated POS message. This section titled "Quantity Limit" 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 quantity limit 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 prior to dispensing on the electronic documentation to reflect the Covered Person's request. Electronic documentation must have a system-assigned user, date and time stamp in order to take the place of hard copy documentation.

Drug Utilization Review (DUR)

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

- Drug regimen compliance screening
- Drug — drug interaction screening
- Drug — inferred health state screening
- Dosing/duration screening
- Drug — age caution screening
- Drug — sex caution screening
- Duplicate prescription screening
- Duplicate therapy screening
- Additive toxicity screening
- Apparent drug misuse screening

The Pharmacy is responsible for reviewing any claim with a 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 provide professionally appropriate counseling regarding the DUR messages.

Prime requires Pharmacies in Prime's Medicare Programs Network to review, update and implement quality assurance systems and procedures at the POS as required by CMS regulations. Pharmacies are required to 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 (MAC)

Prime's Maximum Allowable Cost (MAC) program lists 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 (7) days or in accordance to 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 at Prime's sole discretion. The drug may be added back when Prime's market sources confirm adequate supply and distribution.

Pharmacies can appeal Prime's MAC pricing by submitting an appeal through **Prime's website** or sending a MAC appeal to Prime at **PharmacyOps@primetherapeutics.com** or by fax to **877.823.6373**.

Please refer to **Prime's website** for registration instructions to access 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.

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 fourteen (14) days of submission, unless a shorter time period is required by law. Claims not reversed within fourteen (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 thirty (30) days of the date of the remittance advice for each submitted claim. Failure to report alleged errors in payment constitutes a waiver for any claims for adjustment or correction.

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 any Pharmacy from any or all Benefit Plan(s) with respect to any or all Pharmacy Networks through which the Benefit Sponsor provides prescription drug benefits to members.

LONG-TERM CARE (LTC) 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 an LTC facility in order to be eligible for LTC reimbursement. At the time of dispensing, the level of care must be documented on the prescription hard copy or the electronically submitted prescription.

SERVICES PROVIDED TO FAMILY MEMBERS

In accordance with a Covered Person's Benefit Plan, Prescription Drug Services prescribed by or provided to a family member may not be covered and such Prescription Drug Services may be identified after claim adjudication.

PRODUCT SELECTION CODE (PSC)

For purposes of this Manual, as revised, Dispense as Written (DAW) and PSC are used interchangeably. The Pharmacy must submit an accurate PSC, in accordance with NCPDP specifications, when processing claims electronically. PSC submissions may change the calculation of the claims adjudication depending upon the Benefit Plan.

GENERIC SUBSTITUTION

PSC 1: The Pharmacy must dispense a generic drug whenever permitted and in accordance with applicable laws. However, there are instances where the Prescribing Provider may request that a brand-name product be dispensed instead of the generic equivalent drug. These claims must be submitted with a PSC of 1. If a PSC of 1 is used in processing a claim, 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.

PSC 2: In addition, Covered Persons may request a brand-name product be dispensed instead of the generic equivalent. The Pharmacy must document or have a computer date and time stamp on the prescription that the Covered Person requested the brand-name product and submit the claim using a PSC of 2.

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.

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 habits of Prescribing Providers and 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.

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 specially prepared antigen which, upon administration to a person, will result in immunity 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 set up for the Vaccine administration program.

Medication Therapy Management (MTM)

Prime uses an internal team of MTM clinicians and external MTM vendors to provide annual Comprehensive Medication Review (CMR) services for MTM-enrolled Covered Persons. Prime also provides quarterly, criteria-based Targeted Medication Review (TMR) services to 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 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 by calling Prime's MTM department at **866.686.2223**.

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 limits (QL)

The transition process gives Covered Persons time to work with their Prescribing Provider to switch to a therapeutically equivalent medication or to get 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 ninety [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 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 the drug paid due to the standard transition benefit.

Supply Limits

If the claim is submitted for a days' supply 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 (1) month transitional supply of a non-formulary drug or a drug subject to certain limits. LTC Covered Persons are also allowed up to a one (1) month transitional 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 which is prepackaged in a 3-month supply).

Pharmacies, including Extended Supply Network (ESN) 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 for the drug to see if the Covered Person is still eligible for any remaining authorized supply during the remainder of the transition.

For instance, in the retail setting, a Covered Person may have received a 9-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 ninety (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 non-formulary 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 30DS DURING TRANSITION PERIOD. RESUBMIT W/LESSER DS. AUTH OR FORM ALT REQ. CALL 800.821.4795 IF NEW/RE-ENROLLEE."
- If the claim rejects because the Covered Person has already received a full or partial transition supply during their transition period:
  - "AUTH OR FORM ALT REQ/NONFORM/UM MEDS. MAX 30 DAY SUPPLY IN TRANSITION PERIOD. ‹##› DAY SUPPLY REMAINS 1.800.821.4795."
- When there is a paid claim the NCPDP approved message code "004" will be returned.

Reasons 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 800.821.4795 IF NEW/RE-ENROLLEE."
- If the claim rejects because the Covered Person has already received a full or partial transition supply during their transition period:
  - "AUTH OR FORM ALT REQ/NONFORM/UM MEDS. MAX 31 DAY SUPPLY IN TRANSITION PERIOD. ‹##› DAY SUPPLY REMAINS. 1.800.821.4795."
- 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 non-formulary 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 non-formulary 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 at **800.821.4795**.

Medicare Part D General Dispensing LTC 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 no more than once per month unless the claim meets the Short Cycle Dispensing requirements.
- Seven (7)-day unit packages must be logged and billed no more than once per month.
- The LTC facility (LTCF) must be documented on the prescription order for all dispensed controlled substances.
- OTC 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 [2] or seven [7] days) do not justify additional dispensing fees. One (1) 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 (SCC) combinations.

The following fields must be submitted on all LTC SCCs:

- 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.

MEDICARE PART B TRANSITION PROCESS

CMS requires that Medicare Part B Plans support an appropriate transition process to provide Covered Persons with a temporary supply of durable medical equipment (DME) when the Benefit Plan has a preferred brand of DME and the member attempts to fill a non-preferred diabetic product.

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 to get an exception to the preferred brand.

When a Covered Person in their transition period (e.g., within ninety [90] days of eligibility or within the first 90 days of the calendar year) presents a prescription for a diabetic supply that is not on the preferred list, 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 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.

Covered Persons are allowed at least a ninety (90) day transitional supply of a non-preferred product. 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 (ESN) 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.

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**. Covered Persons who continue enrollment in a Medicare Part B Benefit Plan are eligible for a transition benefit within the first ninety (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 non-preferred status of their product. 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 preferred product or request an exception for the non-preferred product. 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 800.821.4795 IF NEW/RE-ENROLLEE"
- If the claim rejects because the Covered Person has already received a full or partial transition supply during their transition period:
  - "AUTH OR PREF PROD REQ. MAX 90 DAY SUPPLY IN TRANSITION PERIOD. ‹##› DAY SUPPLY REMAINS 1.800.821.4795"

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 re-credentialing, claims submission or reporting, under any circumstances.

UPDATE INFORMATION WITH NCPDP

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, go to 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, fax number, phone number and Pharmacy Chain/Pharmacy Service Administration Organization (PSAO) affiliation. Prime's system supports only one (1) 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 EFT 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 (7) days, of any change.

OIG 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, etc.). 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 monthly thereafter. If a Pharmacy or a specific Pharmacy location is sanctioned by the 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:

- **Office of the Inspector General (OIG) website**
- **General Services Administration (GSA) website**
- **System for Awards Management (SAM) website**
- **CMS Prescription Drug Benefit Manual, Chapter 9**

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

PHARMACY'S AFFILIATION WITH PSAO

For a copy of Prime's Pharmacy Participation Agreement, a Pharmacy should contact their PSAO.

Pharmacies must notify NCPDP immediately upon change of affiliations with a PSAO. Prime is not liable under any circumstances for any losses suffered by 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 (1) 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 or Networks. 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, etc.)
- The effective date of the PSAO and Pharmacy affiliation
- Confirmation that the PSAO has verified the following:
  - Pharmacy is licensed in all applicable states within which it provides Prescription Drug Services.
  - Pharmacy has a full and current DEA certificate for all scheduled controlled substances.
  - 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 in 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 (2) business days and promptly remove the Pharmacy from the affiliation. PSAOs must re-credential Pharmacies at least every three (3) years.

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

THIRD PARTY PAYMENT RECONCILIATION COMPANY

Pharmacies must update the EFT and 835 health care electronic remittance advice forms located on **Prime's website** upon using a Reconciliation Company for the first time or upon changing the Reconciliation Company.

RE-CREATION FEE

In the event the Pharmacy, or a Reconciliation Company, requests that Prime resubmit a properly submitted remittance advice, Prime may charge the Pharmacy a re-creation and resubmission fee ("Re-creation Fee") in the amount of fifty dollars ($50). Prime will separately invoice 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, effective Jan. 1, 2020, 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 after the initial fill. Covered Persons must opt in to an auto-ship program for 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 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 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 with CMS Medicare Marketing Guidelines, 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 and supply all supporting documentation requested during Credentialing, including, but not limited to, standard operating procedures, copies of licenses, and pharmacy statements. Prime re-credentials all Pharmacies at least once every three (3) years. Prime follows non-discriminatory practices in the credentialing process. Participation in Prime's Network(s) is not based on factors such as race, religion, gender/gender identity, color, national origin, age or sexual orientation.

Re-credentialing is a requirement for continued participation. Failure to complete the re-credentialing application or supply all documentation requested by Prime during re-credentialing 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:

- Pharmacy License in all states in which the Pharmacy provides Prescription Drug Services
- Pharmacist-in-Charge (PIC) License
- Full and current DEA Certificate
- Certificate of Insurance with proof of General and Professional Liability Insurance

Pharmacies must clearly write the Pharmacy name and NCPDP number on each of the required documents. The Pharmacy must label required documents as outlined in Prime's credentialing instructions.

Pharmacies must provide accurate information on their credentialing application and notify Prime in writing within seven (7) business days of any change to information submitted for credentialing or re-credentialing.

Pharmacies must meet Prime's credentialing criteria. Credentialing criteria are determined by Prime in its sole discretion. These criteria include, but are not limited to, dispensing criteria, billing thresholds for compound prescription drugs, non-FDA approved drugs, single ingredient drugs and products, and applicable clinical programming and reporting, as determined by Prime. Credentialing criteria may be amended by Prime 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. Additional documentation may be requested for review during credentialing to include, but not limited to: dispensing records and wholesaler reports. The pharmacy's location may impact the pharmacy's eligibility for network participation.

Prime reserves the right to request credentialing and re-credentialing 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.

Ownership or Control Changes

Pharmacies must immediately notify Prime and/or PSAO, if applicable, in the event of a change of ownership or control. Any successor owner or operator must be accepted to participate by Prime and meet all of Prime's credentialing and participation requirements. Each participating Pharmacy must be credentialed by Prime. Prime is not bound to any of its obligations under an Agreement where the Pharmacy has assigned or subcontracted the Agreement without Prime's consent, or where ownership or control of the Pharmacy or any of its locations has changed, without Prime's prior written consent. 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 Prime's non-specialty pharmacy credentialing criteria. Specialty terms and conditions include 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 not inconsistent with applicable law. Pharmacies must maintain compliance with credentialing criteria for continued participation, including through re-credentialing. Specialty terms and conditions are available to specialty Pharmacies by contacting Prime by email 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:

- 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 dispensing of medications based on standard industry practice.

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

- Consistent and adequate number of well-designed studies with sufficient numbers 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

Nothing in this Provider Manual or a Prime Pharmacy Participation Agreement prohibits a Pharmacy from informing a Covered Person about their cost share for a drug or about alternative drugs within the Covered Person's Benefit Plan that are more affordable or less costly.

Unacceptable Dispensing Practices

The following types of documentation do not meet the expectation of 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 from National Comprehensive Cancer Network (NCCN) category of evidence Class I or Class IIa
- Patient case reports

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.

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 or local laws, rules or 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.

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 non-preferred provider Network status.

SIGNATURE OR DELIVERY LOGS

The Pharmacy must maintain a paper or electronic signature log or delivery log that all Covered Persons (or his or her authorized agent) who receive a Prescription Drug Service signs, 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 name
- Prescription number
- Covered Person (or legal representative) signature
- Date and time of sale
- Date and time of receipt by the Covered Person
- Covered Person cost share receipt, evidencing the cost share was collected, when applicable
  - When cost share was not collected due to a copay assistance program, 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 confirmation 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.

LONG-TERM CARE (LTC) AND HOME INFUSION (HI) ANNUAL VALIDATION PROCESS

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

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

TERMINATION APPEALS

For terminations based on 90-days written notice to Pharmacy, Pharmacies have thirty (30) days from the date of notification of termination or an extended time as required by law to submit a termination appeal. Appeals must be submitted in writing and include the Pharmacy's name and an explanation of the appeal. Prime accepts appeals of 10-day breach terminations within the noticed 10-day appeal period and appeals of 5-day participation terminations within the noticed 5-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 Pharmacy Network Contracting 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 (5) years.

CONFIDENTIALITY AND PROPRIETARY RIGHTS

Confidentiality

Any information or data obtained from, or provided by, Prime to the Pharmacy is confidential. Confidential Information means any non-public, confidential or proprietary information disclosed or made available, either directly or indirectly, during an audit or the course of the Agreement and includes all technical and business information relating to the parties, whether in written, oral, graphic, electronic or other format. Confidential Information includes, but is not limited to, audit findings and audit results, notes, Pharmacy's records, including, but not limited to, original prescriptions, signature logs, daily prescription logs, purchasing invoices, refill information, Prescribing Provider information, patient profiles, compound logs, medication administration records, receipts and other documentation showing the copayment paid by the Covered Person or third party, and prescription inventory, relationships with third parties, credit card information, personally identifiable information, and information relating to suppliers, pharmaceutical drug manufacturers, trade secrets, computer software programs and descriptions of functions and features of software, products, programs, services, business practices, procedures, MAC lists or other information acquired from the contacts of the Agreement, this Manual and related Exhibits or other documents provided by Prime or Benefit Sponsor.

- 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 and records including Protected Health Information (PHI) as required by applicable law, including 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.

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, including those through RelayHealth or other switch operators and manufacturer sponsored copay assistance programs. To view the specific manufacturer assistance reporting requirements, please go to **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 claim audits, onsite audits and investigations ("oversight activities") to monitor compliance with state and federal regulations, Prime's Pharmacy Participation Agreements and this Manual. These activities verify the integrity of claims submitted to Prime and payments made to Pharmacies. Through the oversight activities, Prime reviews the accuracy of the claim information submitted to Prime to identify potential FWA or otherwise improper Prescription Drug Service or claims activity.

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

EDUCATION

Prime provides information to Pharmacies through Prime Audit Advisors and *Prime Perspective* newsletter, in addition to direct correspondence, updates to this Manual, as revised, and resources provided on **Prime's website**. These documents provide information and tools to Pharmacies to use 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 provide Prime with adequate access to records related to Prescription Drug Services provided under the Agreement. This includes, but is not limited to:

- Wholesaler invoices and pedigrees
- 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, onsite audits, security camera footage or other interactions without Prime's prior written consent. Such activity may result in termination of the Pharmacy Participation 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" means written prescriptions, refill authorizations, institutional orders, verbal or telephoned orders, facsimile (fax) orders, prescription transfers, and electronic prescriptions relied on by the Pharmacy 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 and 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 Pharmacy Participation 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 dispensing:

- Full name, address and date of birth of the Covered Person
- Date of Issuance
- Full name, NPI, and telephone number of the Prescribing Provider and, if the prescription is for a controlled substance, the Prescribing Provider's 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 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 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. Specific directions for "Use as Directed" are required. The direction "As Directed" is not allowed. Directions may be obtained through direct communication with the Prescribing Provider. Directions 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 at the time of dispensing. For drugs that are administrated 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 there are no refills indicated by the Prescribing Provider, the Pharmacy should assume 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 (e.g., 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. The ordering of these products and supplies 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 accepted 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 Identification Card number.
- **Date of issuance** — The date of issuance must be on the prescription.
- **Drug name and strength** — The 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 in order 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.

Insulin Vials Billing Guide

Prescribed Units Per Day								
Qty	40	60	80	100	120	140	160	200
10 mL	25	N/A	N/A	N/A	N/A	N/A	N/A	N/A
20 mL	50	33 30/ 31*	N/A	N/A	N/A	N/A	N/A	N/A
30 mL	75	50	37 30/ 31/ 34*	30	N/A	N/A	N/A	N/A
40 mL	100 90*	66	50	40	33 30/ 31*	28	25	N/A
50 mL	N/A	83	62	50	41	35 30/ 31/ 34*	31 30*	25
60 mL	N/A	100 90*	75	60	50	42	37 30/ 31/ 34*	30
90 mL	N/A	N/A	112	90	75	64	56	45

*Insulin vial products must be dispensed in a manner that most closely aligns with the prescribed dose and maximum benefit to minimize waste. The Pharmacy must bill a slightly lower days' supply of 30, 31, 34, or 90 days depending on the Covered Person's Benefit Plan and the actual days the medication will last.

- **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 timeframe needed based on use instructions (e.g., writing for twenty [20] doses per month when directions are to infuse three [3] times weekly) or unless 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 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 upon 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, while 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 medications commonly billed erroneously, visit **Prime's website**.
- **Refill instructions** — Refill history will 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, DUR overrides, and the use of Submission Clarification Codes.
- **Prescribing Provider ID number** — The Pharmacy must enter the correct and valid Prescribing Provider's ID number on the claim submission.
- **Usual and Customary (U&C)** — 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 U&C and must not underreport or conceal U&C or other pricing for Prescription Drug Services.

Prime relies on the original documentation provided in the audit or an 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. Understating the days' supply may exceed the Covered Person's Benefit Plan, 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. Calculate eye drops days' supply using 15 drops per mL for solutions and 12 drops per mL for suspensions).
- **Reversal of claims** — All prescriptions not received by the Covered Person within fourteen (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.

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 OTC 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
- Dispensing a generic drug but billing for the brand drug
- Submitting claims with an NDC other than the NDC from the package from which the product was dispensed
- For general 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 drugs in greater than 14-day increments for short cycle dispensing

- Overriding DUR rejects without properly resolving and documenting the resolution
- 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 U&C
- Billing the Covered Person for any associated audit and/or investigation recovery
- Misrepresenting the origin code
- Billing for drugs that were never purchased by the Pharmacy
- 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 supporting the legitimate purchase record of the drug
- Submitting a claim for a non-FDA approved drug (such as compound kits and patches)
- Billing greater vial size than what is necessary to supply the ordered dose
- Billing for drugs that are cyclic as continuous days' supply (e.g., 21-day cycle billed as 28 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 alternative products are available
- Billing for drugs that the Covered Person did not authorize to dispense
- Billing for drugs that the Prescribing Provider did not order
- 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 interchange 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 to be an immediate unacceptable billing practice, but may be reviewed for potential audit
- Billing for prescriptions in order to bypass POS edits or messaging

RECOVERY OF PHARMACY PAYMENTS

Prime will collect improper payments paid to Pharmacies in a manner determined by Prime in its sole discretion. Pharmacies will be informed of payment off-sets through remittance advice. Pharmacies will receive a report of claim adjustments performed directly by Prime.

REASONS FOR AUDITS

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 non-exclusive 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 the claim audits
- Referral from Prime's Fraud Tip Hotline or other sources that indicate potential FWA
- Routine audit of pharmacies selected on a random basis

AUDIT TIME FRAME

Claims selected for audit through the daily claim audit process generally include prescriptions billed to Prime within the previous fourteen (14) days. Historical claim audits generally include prescriptions billed to Prime within the previous twelve (12) months. Standard onsite audits generally include prescriptions billed to Prime within the previous twenty-four (24) months, or other time periods provided by applicable law. However, Prime has the right to audit or investigate claims for up to seven (7) years from the date of the Prescription Drug Service for commercial claims, and up to ten (10) years from the date of Prescription Drug Service for government program claims, or as otherwise permitted by law.

TYPES OF AUDIT ACTIVITIES

Daily and Historical Claim Audits

Prime monitors claims data to identify potential billing and compliance errors. When Prime identifies potential Pharmacy errors shortly after adjudication, 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, impacted claims may be resubmitted or reversed by Prime, in its sole discretion.

If a claim is identified for audit, 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 correlate to the prescription number and date of service
- 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 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, regulation and CMS guidance

If a Pharmacy processes Long Term Care (LTC) Facility claims, the following additional information may also be requested:

- Demographic information of any LTC facility serviced by the Pharmacy 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 documentation. The Pharmacy may fax, mail or email requested documentation.

Prime communicates with Pharmacies throughout the claim audit process and before claim adjustments are made. Despite these efforts, there may be instances where the Pharmacy identifies additional supporting documentation after the claim has been adjusted.

The additional information is reviewed through the claim audit grievance process within fourteen (14) calendar days, or as otherwise provided by law. Pharmacies may submit in writing any additional supporting documentation for claims where the Pharmacy does not agree with the claim audit outcome based on the original documentation provided. Pharmacies should provide the additional documentation to the auditor via fax or email.

Medicare/Medicaid Fax:

- 877.290.1516
- 866.466.7686

Commercial Fax:

- 877.825.7404
- 877.263.5543

Email: **pharmacyaudit@PrimeTherapeutics.com**

Mailing Address:

Prime Therapeutics LLC
ATTN: Pharmacy Audit
P.O. Box 64812, St. Paul, MN 55164-0812

A Prime auditor will review the requested claims to verify that the claims have been submitted in compliance with the Pharmacy Participation Agreement and this Manual. Pharmacies will receive a claim adjustment report for those claims adjusted directly by Prime.

ONSITE AUDITS

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

Onsite 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 with 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 onsite, the auditor will observe Pharmacy practices and review all related documentation. The auditor may request 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 Pharmacist-in-Charge (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 and date of service that was delivered
- Bleed and Dispensing Logs for Hemophilia products
- Documentation to include patient 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 Pharmacist-in-Charge (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 Long Term Care (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

Onsite audits will involve the disclosure of Covered Persons' Protected Health Information (PHI) for the purpose of disclosure of treatment, payment or health care operations. For Prime and the Pharmacy to remain HIPAA compliant, a Pharmacy staff person is required to retrieve documentation; however, the auditor must be present to observe the documentation retrieval.

Pharmacies may not refuse to comply with an onsite 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 Pharmacy Participation 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 onsite at the Pharmacy.

Pharmacies must cooperate with an onsite audit or investigation.

REPORTING ONSITE AUDIT RESULTS

Following the onsite 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 details of any issues of non-compliance 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 thirty (30) days from the date the final audit report is issued by Prime to submit an appeal or an extended timeframe 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 the thirty (30) days from the date of notification of the audit findings or an extended timeframe 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 Appeal form and Prime's Audit Guidelines, 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.

CORRECTIVE ACTION PLAN (CAP)

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 the satisfaction of Prime, additional remedial action may be taken by Prime, as permitted by the Agreement. Failure to comply with the terms of the corrective action plan may result in termination of the Pharmacy Participation 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 any supporting documentation to support claims submitted to Prime during the period under investigation. Pharmacies may not receive notification in advance of an onsite investigation. Timing of communications and reports to the Pharmacy may vary. Prime may record or video interviews conducted 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 investigations that 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 to Prime Therapeutics, 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, 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 activities that may result in FWA.

MEDICAID PHARMACY PROGRAM INQUIRIES

For general inquiries related to the Medicaid Program, please call:

- BCBSMN Blue Plus: **844.765.5940**
- BCBSIL Family Health Plan: **855.457.0173**
- BCBSIL Community ICP: **888.274.5218**
- BCBSNM Community Centennial: **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**

GENERAL MEDICAID REQUIREMENTS

Pharmacy Disclosure Statement

Pharmacies that participate in the Medicaid Program must complete the Pharmacy Disclosure Statement to comply with federal or 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 considered to be the payer of last resort. That is, Medicaid is properly responsible for payment of enrollees' costs, including prescription drug costs, only after other third-party sources have met their legal obligations.

ILLINOIS MEDICAID REQUIREMENTS

Automatic Refills

The use of automatic refills by Pharmacies in Prime's Illinois Medicaid Network is not allowed. All Prescription Drug Services refills must be initiated by a request from the physician, Covered Person, or other person acting as an agent of the Covered Person, e.g., a family member. Any Prescription Drug Services with remaining authorized refills does 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 auto refill process. Any claim for a Prescription Drug Service filled without a request from the Prescribing Provider, Covered Person, or agent of the Covered Person will be subject to recovery. Claims for Prescription Drug Services that have been filled using auto refill and inadvertently billed to HFS must be reversed by the Pharmacy.

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.

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 non-covered prescription drug provided that:

- The Covered Person is not enrolled in the restricted Covered Person program.
- All available covered alternatives have been reviewed with the Covered Person.
- The Pharmacy obtains a Covered Person signature on the MHCP Acknowledgment form.
- The prescription is not a controlled substance (except phentermine in certain circumstances, tramadol or gabapentin).

The Pharmacy may only accept a cash payment for a controlled substance, tramadol or gabapentin if the Pharmacy has received authorization from MHCP to do so on the date of service. To be considered for a cash payment authorization, the Prescribing Provider must contact the MHCP help desk at **800.366.5411** and explain why the covered alternatives are not viable options for the Covered Person.

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.

Cash for Phentermine

Pharmacies may accept cash for phentermine prescription drug claims as advised by the MHCP. Phentermine is not covered by Medical Assistance because weight loss drugs are excluded from coverage pursuant to Minnesota state law.

The Pharmacy may accept cash payment for a phentermine prescription drug provided that:

- The phentermine prescription drug is being used as part of a comprehensive weight loss program and is prescribed at the FDA-approved dosage.
- The Prescription Drug Monitoring Program has been reviewed and determined that the phentermine prescription drug is not being abused or overused.
- The Covered Person has been informed about the responsibility for payment before the phentermine prescription drug was dispensed.
- The Pharmacy or an authorized health care representative completes the **Advance Member Notice of Noncovered Prescription (DHS-3641) (PDF)** and the Covered Person signed the form.

For further information on Minnesota's Medicaid regulations, refer to:

- **Recipient Payment for Noncovered Prescriptions**
- **Pharmacy Services**

If you have questions regarding claims processing, please call Prime's Contact Center at **844.765.5940**.

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

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" shall apply to Pharmacies that provide Prescription Drug Services to Covered Persons in the Texas Medicaid Network.

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 fifteen (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 a disciplinary action is found, 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, 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 will request the Prescribing Provider obtain a PA. 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.

Compound Drugs Billing Guidelines

Pharmacies must submit compound drugs through the Prime POS system using the following directions:

- Flag the compound as a compound drug in the Pharmacy's system prior to adjudication.
- Submit a zero (0) 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.
- Submit the final product quantity (the quantity of the finished compound product).
  - For a liquid, submit the number of mL 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 of the 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 multiple ingredient compound submission using NCPDP's compound segment for up to twenty-five (25) ingredients.
- The Pharmacy must submit the submission clarification code of "08" 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 requires a PA prior to submitting the "08" clarification code.

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 and/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 reference of an USP-approved reference material
- 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 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 (This exception may vary by state.)

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 form than what was used in the compound
- Billing for a quantity other than what was actually 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 United States Food and Drug Administration'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's MAC pricing is reviewed a minimum of once every seven (7) days or in accordance to applicable law. This ensures that 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 no later than the 15th day 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 Preferred Drug List.

How to Use the Drug Formulary

The Drug Formulary lists the brand name and generic name of a given drug. If a medication does not appear on this Drug Formulary, the medication is not covered under the pharmacy benefit. In some instances, a medication may require a PA. A PA form should 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 Formulary at the **Texas Vendor Drug Program** or through **Epocrates**.

Prior Authorization (PA)

PA is designed to encourage appropriate use of medications. Select medications may require a PA. Medication utilization must meet FDA-approved indications, as well as 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: A PA form should be completed by the Prescribing Provider for submission 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/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**
- **CoverMyMeds**

All PA fax forms may be submitted 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, 7 days a week—for assistance:

- STAR Pharmacy Contact Center at **855.457.0405**
- CHIP Pharmacy Contact Center at **855.457.0403**
- STAR Kids (in the Travis service area) Pharmacy Contact Center at **855.457.0757**
- STAR Kids (in the MRSA Central service area) Pharmacy Contact Center 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 of 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 3-day supply according to the directions for administration given by the Prescribing Provider

A 72-hour emergency supply of a prescribed drug must be provided 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 Hepatitis C drugs or any drug not considered to be an emergency in the judgment of the dispensing pharmacist.

The 72-hour emergency supply should be dispensed 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

BCBSTX allows up to a 34-day supply of medication. This program defines a standard 34-day supply of medication for a select list of medications. If a medical condition warrants a greater quantity supply than the defined 34-day supply of medication, a PA will ensure access to the prescribed quantity. Prior to dispensing, the Prescribing Provider must submit a PA form to Prime to determine medical necessity.

Dose Optimization

The Dose Optimization Program, or dose consolidation, is an extension to 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 written PA form for an internal review by Prime to determine medical necessity.

Benefit Exclusions

Benefit exclusions are services that are not covered under the Covered Person's Benefit Plan. These include:

- Infertility medications
- Erectile dysfunction medications
- Cosmetic and hair growth medications
- Dietary supplements
- Drugs not approved by the FDA
- OTC drugs for CHIP/CHIP Perinate Covered Persons
- 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 listing of these 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 **855.457.0758**

Retail pharmacies can dispense no more than a 34-day supply, but most prescriptions can be written with refills.

Prime's Information for Claims Processing

BIN 011552

PCN TXCAID

The Group# 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 go 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 he/she is 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.

Cost to Member

Member Type	Copay for up to 34-day supply
STAR	No copay
CHIP < 100% FPL	$0 for generic/$5 for brand
CHIP 101 – 150% FPL	$0 for generic/$5 for brand
CHIP 151 – 185% FPL	$10 for generic/$35 for brand
CHIP 186 – 200% FPL	$10 for generic/$35 for brand
CHIP Perinate	No copay
CHIP AIAN	No copay
CHIP No Cost Share	No copay

Advance Directives

The Pharmacy must comply with the requirements of state and federal laws, rules and regulations relating to advance directives and in accordance with 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, or 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)

Covered Person(s) who may be or are at risk for exposure to TB must be screened for TB. An at-risk Covered Person(s) 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 are in compliance with the guidelines recommended by the American Thoracic Society (ATS), the Centers for Disease Control and Prevention (CDC), and Texas Department of State Health Services' (DSHS) policies and standards.

Non-covered Services

If a Pharmacy receives non-covered Prescription Drug Services 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.

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 for 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, a Pharmacy must be a VDP pharmacy and attested with Texas Medicaid and Healthcare Partnership ("TMHP").

Important Toll-free Contact Numbers

Prime's Contact Center is available 24 hours, 7 days a week:

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

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

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

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