

# MC-21 HEALTHCARE, LLC PHARMACY PROVIDER MANUAL

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Pharmacy agrees to not copy, distribute, or share information included in this Manual, except as required for business or contract purposes only

Revision Date 05/27/2025

# **GENERAL INFORMATION:**

As a participating "Network Pharmacy", a pharmacy providing drug administration or consultation services to persons covered by a plan sponsor for prescription drug benefits pursuant to a direct agreement, a Pharmacy Services Administration Agreement ("PSAO"), a chain agreement, or a Group Purchasing Organization ("GPO") agreement with MC-21 Healthcare, LLC ("PBM"), you have agreed to provide pharmaceutical Services to persons covered by Plan Sponsors for whom PBM provides pharmacy benefit management or pharmacy benefit administration Services.

This Pharmacy Manual ("Manual") is intended to serve as a guide to assist with submitting claims to PBM, as well as providing general terms, conditions, procedures, and policies for adherence as a Participating Pharmacy ("Pharmacy"). This Manual is incorporated into your Participating Pharmacy Agreement, along with any applicable Amendments or Addenda (collectively the "Agreement"). Pharmacies are responsible for reviewing and complying with all changes to the Manual. Failure to comply with any terms of the Agreement, which include this Manual, as well as all other applicable documents, will be considered a breach of the Agreement. The information provided in this Manual is current as of the time of publication. This Manual will be updated as necessary and is subject to change without notice.

The current version of this Manual is posted at https://www.mc-rx.com. PBM, at its sole discretion, may modify this Manual at any time. Changes to the Manual will be communicated via, email and posted online via https://www.mc-rx.com. Please refer to the online claims adjudication system for the most current messaging and benefits information. For additional Network participation requirements, please refer to your most recent Agreement.

Any updates to your Pharmacy's mailing/remit or physical address, telephone number, fax number, license number(s), DEA number, or any other data must be submitted to the National Counsel for Prescription Drug Programs (NCPDP). PBM will not make manual updates to Pharmacy demographic or licensure information unless it can be verified via NCPDP. PBM is not responsible for lost/late payments or delayed notifications due to incorrect Pharmacy affiliation or mailing addresses.

Please visit PBM's Pharmacy Portal (https://mc-rx.com) to create an account to access important information, forms, and notifications.

PBM is committed to providing Drug Products and/or Services to Covered Persons and Pharmacies without regard for race, color, national origin, ethnic origin, religion, sex, age, disability, or physical/mental health status.

PBM appreciates your participation in our Pharmacy Networks and your role delivering quality Services to persons covered by our Plan Sponsors.

# **CONTACT INFORMATION:**

### **Pharmacy Help Desk Support**

٠	Help Desk Phone Number, 7/24/365	800-699-3542
٠	PA Help Desk Phone Number	866-965-3784
٠	Help Desk Fax Number	678-281-7586

#### Network Development Department

Network Development Hours of Operation: Monday – Friday 8:00 am to 5:00 pm EST.

•	Phone Number:	800-277-2480
٠	Fax Number:	678-207-5090
٠	Email Address:	network@procarerx.com
•	Credentialing Department Email Address:	credproject@procarerx.com

# **Mailing Address**

MC-21 Healthcare, LLC Attn: Network Development 1267 Professional Parkway Gainesville, GA 30507

#### **Other Important Contact Information**

•	Claims-related Issues or Questions:	800-699-3542
٠	Member Eligibility:	800-699-3542
٠	Report Fraud, Waste, & Abuse (FWA) Anonymous:	678-248-3180
٠	FWA Anonymous Email:	hotline@procarerx.com
٠	Pharmacy Dispute Resolution:	network@procarerx.com
٠	Generic Pricing Appeals (MAC) Inquiries:	reimbursement@procarerx.com
•	Payment, Remit (835 Files), and EFT Questions:	payremit@procarerx.com

# **PBM Pharmacy Websites**

•	PBM Website:	https://www.mc-rx.com

- PBM HospiceCare Website: https://phc.procarerx.com
- PBM Pharmacy Portal: https://mc-rx.com

# PHARMACY RESPONSIBILITIES:

The following terms are the Pharmacy's basic responsibilities as a Participating Pharmacy ("Pharmacy"). Please refer to the Participating Pharmacy Agreement ("Agreement") for additional information.

In accordance with the Agreement, Pharmacy has agreed:

- 1. To comply and adhere to all provisions set forth herein this Manual. Failure to abide by the provisions and/or terms set forth shall be considered a breach of the Agreement;
- 2. To provide professional Pharmacy Services to Covered Persons, according to applicable local, state, and federal laws and regulations, the Agreement, and the Manual;
- 3. To comply with all applicable state and federal privacy and security laws;
- 4. To verify, before dispensing Drug Products, whether an individual is a Covered Person by reviewing a valid Prescription Identification Card AND verifying the Covered Person's eligibility on the date of service via online processing system (the "System"), OR by verifying eligibility by telephone in situations where online eligibility verification is unavailable;
- 5. To collect the applicable copayment, coinsurance, and deductible on each prescription as specified by PBM's online processing System, unless approved otherwise by PBM;
- 6. Pharmacy shall not waive the copayment, coinsurance, or deductible on part of a Covered Person without the written consent of PBM, or as specified below, or as required by applicable state or federal law, and that the copayment, coinsurance, or deductible returned solely from the System is the maximum allowable amount to collect from the Covered Person, and no amount shall be collected above the amount sent back, unless approved by PBM. Pharmacy shall follow the applicable rules and regulations as specified on discount coupons where applicable (refer to reverse side of coupon or the System);
- 7. To submit <u>all</u> claims for Drug Products and Services online through the System for adjudication, in either the NCPDP Version D.0 variable format or a more current and approved format, unless Pharmacy has received prior approval from PBM. Usual and Customary ("U&C") price must be submitted on each claim. Manually submitted claims may require Prior Authorization;
- 8. To maintain either a manual or electronic signature log or another form of signature verification, as allowed by state or federal law, at each dispensing location that contains the signature of each Covered Person or Representing Agent, fill date, prescription number, and the date the Drug Product was delivered to Covered Person or Representing Agent so that pick up can be ascertained during any Pharmacy audit or review;
- 9. To complete annual Compliance and Fraud, Waste, and Abuse training in accordance with CMS laws, rules, and regulations pertaining to 42 CFR § 423.504(b)(4)(vi)(c), where and when applicable, and as required by the Network and/or Plan Sponsors, in addition to frequently checking the OIG listing of excluded individuals and entities and removing any such employee from direct administration from applicable federal benefit programs. In support of the above, audits may also be conducted by PBM, an applicable Payer, or other regulatory agency, as outlined in 42 CFR § 422.504(e) and 42 CFR § 422.503(d)(2);
- 10. To maintain valid Pharmacy and Pharmacist DEA license(s) in order to dispense a narcotic or controlled substance Drug Product;

- 11. To comply with all provisions of e.Prescribing standards as stated in the regulation 42 CFR § 423.160(b) when receiving or transmitting electronic prescriptions or prescription related information;
- 12. To only use e.Prescribing to prescribe and dispense Services if the Pharmacy is a designated dispensing Physician ("Physician Dispensary");
- 13. To validate the prescribing Physician's NPI prior to submitting a claim via the System;
- 14. To submit accurate Prescription Origin Codes, Patient Location Codes, and other Coverage Codes (where applicable);
- 15. To use the "Use as Directed" prescription instructions (SIG) only when an actual dispensing instruction is not available (please refer to the Audit section for further information);
- 16. To comply with grievance resolution for complaints filed by Covered Persons and/or Plan Sponsors against Pharmacy, in accordance with local, state, or federal laws or regulations;
- 17. To inform Covered Persons covered under a federal program or a federally backed program, where applicable, of any differential between the price of the lowest-priced, therapeutically equivalent and bio-equivalent generic drug at the point of sale, unless the lowest price drug is being purchased in accordance with 42 CFR § 423.132(a).
- 18. To provide Drug Products and/or Services to all Covered Persons without regard for race, color, national origin, ethnic origin, religion, sex, age, disability, or physical/mental health status.

# NETWORK PARTICIPATION REQUIREMENTS & CREDENTIALING PROCESS:

PBM has a formal Credentialing process that all Pharmacies must complete for Network participation. PBM's credentialing process is conducted in accordance with URAC and CMS standards. Pharmacies are required to comply with all Credentialing and attestation policies set forth by PBM and/or the Plan Sponsor. The Credentialing process may vary depending on Pharmacy type (i.e. independent, chain, PSAO) and service type (i.e. retail, mail service, compounding, LTC, Physician dispensaries, etc.).

PBM monitors the licensure of its Pharmacies in accordance with PBM policies and procedures, or as mandated by law. Failure to comply with licensure requirements and/or PBM's Credentialing process may result in Pharmacy's suspension or immediate termination. Any Pharmacy not eligible to participate in state or federal healthcare program(s) will not be allowed access into any of PBM's Networks.

Pharmacies must comply with and promptly respond to requests for documentation in order to secure and maintain Network participation status. Failure to respond may result in termination from the Network(s). PBM reserves the right to request Credentialing documentation at any time during Pharmacy's participation in PBM's Network(s).

PBM credentials Pharmacies prior to Network acceptance. PBM reserves the right, at its sole discretion, to determine eligibility of any Physician and Pharmacy of participation status within any of its Networks.

# LICENSURE:

Pharmacy must submit a copy of a valid, current state pharmacy license in good standing. Pharmacy must immediately notify PBM, in writing, if the Pharmacy's license has been cancelled, suspended, revoked, or has any other action taken against it. The same requirement applies to Pharmacist in Charge ("PIC") licensure. In the event the Pharmacy fails to notify PBM or maintain the required licensure, PBM may immediately terminate the Pharmacy from its Networks.

The Pharmacy and PIC must hold a valid, current Drug Enforcement Administration (DEA) registration certificate and submit copies upon Credentialing. Pharmacy must immediately notify PBM, in writing, if the Pharmacy and PIC DEA registration has been cancelled, suspended, revoked, or has any other action taken against it. In the event the Pharmacy fails to notify PBM or maintain the required registration, PBM may immediately terminate the Pharmacy from its Networks.

# **INSURANCE**:

Pharmacy must maintain professional liability insurance at all times in the amounts required by state or local guidelines. If there are no specified state or local guidelines, Pharmacy must maintain liability amounts of <u>no less</u> than \$1 Million (occurrence) and \$3 Million (aggregate) or in accordance with state law. If the Pharmacy's liability insurance coverage lapses, Pharmacy agrees to notify PBM immediately and take action to correct lapse in coverage. If Pharmacy loses liability insurance, Pharmacy shall be terminated from all PBM Networks until coverage is reinstated and proof of insurance is provided.

# MAIL ORDER:

In addition to completing the Pharmacy Credentialing Form and providing the requested documentation, Mail Order Pharmacies must be licensed and provide copies of such licensure in their respective state and all states in which Drug Products are dispensed, mailed, or shipped. Proof of licensure does not guarantee access in PBM's Mail Order Network. Access must be granted in writing by PBM.

# **COMPOUNDING PHARMACIES:**

Pharmacies providing Compounded Drug Products will be required to submit additional documentation to validate proof of accreditation from a nationally recognized compounding accreditation agency or provide a state certificate of inspection, or proof, as required by state or federal law, as applicable. Pharmacies providing sterile compounding must meet current USP standards and provide proof from a nationally recognized compounding accreditation agency or provide state inspection documentation before participation with the Compounding Network will be granted. Compounding is Plan Sponsor-specific and may or may not be a covered benefit. Refer to the System for coverage eligibility. Pharmacies may not circumvent the Plan Sponsor's PA process in order to submit Compounded Drug Claims. All Compounded Drug Claims are subject to review by the Plan Sponsor and/or PBM.

# PHARMACY CREDENTIALING PROCESS:

Pharmacy shall provide necessary documentation, licenses, and any other information as required by PBM, or as applicable law permits. PBM uses Primary and Secondary Source Verification during the Pharmacy Credentialing process.

The Credentialing process includes, but is not limited to, a review of the following for independent, non-affiliated Pharmacies:

A completed, signed, and dated Pharmacy Credentialing Form with a copy of the following documents:

- 1. State Pharmacy License
- 2. State Pharmacist in Charge ("PIC") License
- 3. DEA License
- 4. Certificate of Liability Insurance (must not expire within 30 days of receipt)
- 5. Proof of sterile compounding from a nationally accredited compounding entity, if applicable
- 6. Any history of disciplinary action, including loss, restriction, or limitation on license
- 7. Malpractice claims history within the past ten (10) years
- 8. Fraud or abuse convictions within the past ten (10) years
- 9. Additional documentation/information, as determined by PBM

PBM will verify all submitted documents and review the following:

- 1. Search of Office of Inspector General ("OIG") Exclusions Database
- 2. Search of State Department of Licensure for pending/prior Pharmacy and PIC sanctions
- 3. Search of the U.S. Department of Justice Drug Enforcement Administration (DEA) Diversion Control Division website for verification of licensure status

The Chain/PSAO Credentialing process includes, but is not limited to, a review of the following documents:

- 1. Credentialing Form, signed and dated (required every two years)
- 2. Attestation Form, signed and dated (required annually)
- 3. Chain Contact Form (required annually)
- 4. Chain Pharmacy roster including each Pharmacy's information
- 5. Pharmacy information must match NCPDP's records for each Pharmacy location

PBM will perform random quarterly Credentialing audits of chain-affiliated Pharmacies by requesting the following documentation of the selected stores:

- 1. Copy of State Pharmacy License
- 2. Copy of State Pharmacist In Charge ("PIC") License
- 3. Copy of Verification DEA License
- 4. Certificate of Liability Insurance (must not expire within 30 days of receipt)

- 5. Copy of Proof of sterile compounding from a nationally recognized compounding accreditation entity, if applicable
- 6. Any history of disciplinary action, including loss, restriction, or limitation on license
- 7. Malpractice claims history within the past ten (10) years
- 8. Fraud or abuse convictions within the past ten (10) years
- 9. Additional documentation/information, as determined by PBM

PBM will verify all documents submitted and review the following for each selected Pharmacy:

- 1. Search of Office of Inspector General ("OIG") Exclusions Database
- 2. Search of State Department of Licensure for pending/prior Pharmacy and PIC sanctions
- 3. Search of the U.S. Department of Justice Drug Enforcement Administration (DEA) Diversion Control Division website for verification of licensure status

# TELEPHARMACY:

The practice of Telepharmacy is governed by the respective state's definition of "practice of pharmacy," unless the governing state specifically provides an exception, and in which case the exception will govern. Pharmacies designated and acting as a Telepharmacy must be licensed in their respective state and each state where Services are performed. Each state's law will dictate recordkeeping requirements for any Pharmacy designated and acting as a Telepharmacy. Electronic transaction data in lieu of physical Pharmacy records may be accepted in accordance with state law.

#### PHYSICIANS:

Physicians are required to comply with all Credentialing and Attestation policies set by PBM and/or the Plan Sponsor. Physicians must provide necessary documentation, licenses, and any other information required by PBM, or as applicable law permits. Failure to comply may result in removal from PBM's Network(s). Physicians who are not eligible to participate in any state or federal healthcare program(s) shall not provide Services for any Covered Person. Any Physician with sanctions against their state license(s), dispensary license (if applicable), and/or DEA license will be reviewed by the Credentialing Committee to determine eligibility into PBM's Network(s). PBM reserves the right, at its sole discretion, to determine Physician eligibility to participate in PBM's Physician Network(s).

# OIG VALIDATION:

Pharmacy is required to have a process for checking and verifying the Office of Inspector General's ("OIG") List of Excluded Individuals/Entities ("LEIE"); System for Award Management ("SAM") - Excluded Parties Listing System ("EPLS") to confirm entity, employees, and/or contractors have not been excluded from participation in federal programs. Verifications must be completed on a monthly basis. Proof of such validation may be requested at PBM's and/or Plan Sponsor's discretion. Pharmacy agrees to report all employees/contractors found on the LEIE or EPLS exclusion list, along with any claims associated with the individual(s). In addition, Pharmacy agrees to notify PBM if Pharmacy is found to be listed on the exclusion list(s).

- OIG: https://exclusions.oig.hhs.gov/
- SAM: https://www.sam.gov/portal/SAM/#1

To report a Pharmacy or Pharmacist exclusion, please send an inquiry to the Network Development team via email: network@procarerx.com.

# TERMINATION:

Any Pharmacy terminated from the PBM Network(s) for reason(s) other than alleged FWA must wait a minimum of three (3) years from the termination date to apply for reconsideration for Network participation. Pharmacy will be required to meet PBM's Credentialing requirements before Network participation will be granted. Pharmacies terminated for FWA violations will not be allowed to reapply for Network participation at any time.

PBM reserves the right, at its own discretion, to deny or suspend a Pharmacy's Network participation, with or without a thirty (30) day notice, should Pharmacy be found in material breach of one or more sections of this Manual or any Agreement. PBM reserves the right, at its sole discretion, to determine eligibility of any Physician and Pharmacy of participation status within any PBM Network(s).

# **<u>RE-CREDENTIALING</u>**:

PBM mandates that all Pharmacies must re-credential every other year (i.e. 2-year cycles), to ensure the continuation of Network compliance. Re-Credentialing will be based on Pharmacy's enrollment date ("Effective Date") in PBM's Network(s). For independent, non-affiliated Pharmacies, PBM's Credentialing team will notify the Pharmacy in advance via the email address found in the Pharmacy's NCPDP record. For chains/PSAOs and their affiliated Pharmacies, PBM will notify the point of contact designated by the chain of all re-Credentialing requirements. No credentialing or re-credentialing fee will be charged.

# **PAYER INFORMATION:**

The listing below represents an example of the Plan Sponsors and their respective Bin Identification Numbers ("BIN"), all of which are subject to change. For a specific copy of applicable payer sheets, please email network@procarerx.com.

CASH DISCOUNT CARD BINS			
GENERAL PLAN NAME	BIN	PCN	
Agelity (AGL)	610198, 012965, 009265	BLANK FILL	
Allegiance Rx	020826	BLANK FILL	
AVIA Discount Card	018778	BLANK FILL	
Intelisys Health	022733	POMS	
Intelisys Health	022740	AERX	
Managed Care Pharmacy (MPC)	013832	BLANK FILL	
ProCare Discount Card	900014, 900020	SEE CARD	

ProCare Discount Card	017614, 017670, 018372	SEE CARD
RX123, LLC	021056	BLANK FILL
SlashRx	610711	SEE CARD

Note: As of the date of publication, the BIN list above is all-inclusive and is subject to change at any time.

# **ONLINE PROCESSING SYSTEM:**

A Claim Form is prepared in accordance with current National Council for Prescription Drug Programs (NCPDP) standards. The Claim Form, whether paper or electronic, must include all required fields necessary for adjudication ("Clean Claim"). If a claim is determined, at the sole discretion of PBM, to be discrepant, fraudulent, or not authorized under applicable law or federal regulation, the claim will not be considered a Clean Claim and will be subject to recoupment by PBM.

Pharmacy is required to submit all claims electronically to PBM (see individual Payer sheets) via the system ("System") within thirty (30) days of the date of fill. Pharmacies designated as Long-Term Care shall submit claims within ninety (90) days of the date of fill, or in accordance with state law. Claims from third-party billing entities submitted on behalf of the Pharmacy will not be accepted, and Pharmacy or its third-party billing entity is not entitled to any payment under this Agreement, unless prior written approval is given by PBM. Notwithstanding the above, any claim(s) granted such prior approval shall be reimbursed to the Pharmacy directly per the contractual obligations between Pharmacy and PBM. The System is available to accept electronic transactions 365 days per year.

A transaction is any request and response, such as paid, reversed, rejected, duplicate, or adjusted, transmitted through the System or manually keyed into the System. The claim response governs, unless an overpayment is made. The System, however, may be unavailable during off-peak hours, such as overnight, for short periods of time, or due to scheduled System/file maintenance. Pharmacy has thirty (30) days from the original fill date to submit a claim online (submission window may vary based on line of business and government regulations). Pharmacies designated as Long-Term Care shall submit claims within ninety (90) days of the date of fill, or in accordance with state law. If Pharmacy is not able to submit a claim due to System unavailability, Pharmacy should hold the claim for later online resubmission and/or contact PBM's Help Desk to verify eligibility and resubmit the claim when the System becomes available.

PBM may charge a Network transaction fee to Pharmacy of up to fifteen cents (\$0.15) per online transaction submitted via the System, unless prohibited by state law. Out-of-Network or non-preferred Pharmacies may incur a higher Network transaction fee of up to fifty cents (\$0.50), unless prohibited by state law. The transaction charge assists in the support of Pharmacy Help Desk operations and Pharmacy financial (payment and reconciliation) Services, in addition to Network compliance, communications, education, Geo-Access fees, directory management and notices, and is not Plan Sponsor-specific. In the event of disruptive, excessive, or non-compliant Pharmacy behavior, higher transaction charges or penalty fees may be incurred.

# MANUAL CLAIMS SUBMISSION:

Universal Claim Forms ("UCF") will only be accepted for processing if absolutely necessary, with prior approval given by PBM and at a service fee of \$1.00 per transaction, unless prohibited by state law, although some specific pre-authorized claims may have this fee waived by PBM in certain situations. Claims submitted with incomplete information will be rejected and may be charged an additional \$1.00

per transaction handling, unless prohibited by state law, to be deducted from a future Pharmacy remittance. Unauthorized manual claims submitted by Pharmacy may be subject to a \$3.00 handling fee, unless prohibited by state law. If approved, however, the following information will be required on all manual claims:

Manual Claim Required Information		
Covered Person Identification Number	Prior Authorization Number (if required)	
Patient Name	New or Refill Indicator	
Patient Date of Birth	Metric Quantity Dispensed	
Patient Sex	Days' Supply	
Patient Relationship to Cardholder	11-Digit NDC Number	
Pharmacy NPI Number	Requested Ingredient Cost	
Prescription Number	Requested Dispensing Fee	
Appropriate DAW Code (if necessary)	Copay Paid by Covered Person	
Date Prescription Was Filled	Requested Tax (if applicable)	
Prescriber NPI Number		

All approved UCFs should be submitted to:

ATTN: Claims Department MC-21 Healthcare, LLC 1267 Professional Parkway Gainesville, GA 30507

Claims must be received by PBM from Pharmacy within 365 days of the date of fill for manual claims to be entered into the System (this may vary for specific Plan Sponsor and Plan eligibility).

# SUBMITTING COMPOUNDED DRUG CLAIMS:

PBM, at its sole discretion, may require Pharmacy to complete additional Credentialing to process claims for Compounded Drug Claims. Pharmacy will be required to meet all Credentialing standards as established by PBM, to include, but not be limited to; Pharmacy Compounding Accreditation Board (PCAB) accreditation, proof of federal and/or state registration of sterile compounding, state/federal inspection reports, compliance with Stark and Anti-Kickback laws, and a compliance review, including business operations/practices and on-site review of stability and sterility. Failure to maintain compliance with the requirements may result in removal from applicable Networks or termination of the Agreement. Any evidence of unsafe compounding practices reported to the State Board of Pharmacy, Food and Drug Administration (FDA), or applicable regulatory agency will warrant removal from PBM's Compounding Network and/or termination of the Pharmacy Agreement, at PBM's sole discretion. Documented unsafe compounding practices could lead to claim recoupments or non-payment of Compounded Drug Claims.

Pharmacy acknowledges and agrees that the approval of Compounded Drug Claims is based on Plan Sponsor approval and may be subject to quantity limits, dollar thresholds, and/or Prior Authorization ("PA"). Pharmacy understands submitting the level of effort ("LOE") code may not result in a change in the reimbursement of the Compounded Drug Claim. When approved by Plan Sponsor, LOE code reimbursement may differ by Plan Sponsor. A Compounded Drug Claim contains a Drug Product that is weighed or measured by a licensed Pharmacist who combines, mixes, and/or alters ingredients to create a medication for a Covered Person for which a commercial Drug Product is not available. This <u>excludes</u> reconstitution and/or dilution of a Drug Product according to manufacturer guidelines. Sweeteners and flavorings are also excluded.

All Compounded Drug Claims must be submitted through the System using the compounding code indicator "2" in NCPDP field .0 406-D6 with each ingredient NDC, cost, and quantity used. If LOE code is approved for use, the appropriate LOE code must be submitted in field 474-8E of the NCPDP D.0 claim format.

#### PHARMACY OBLIGATIONS

Pharmacy <u>agrees</u> to the following:

- 1. To follow the PA process as required by Plan Sponsor and PBM for all Compounded Drug Claims.
- 2. Not to engage in acts of resubmitting a Compounded Drug Claim multiple times with the same quantity and different U&C until the claim is paid to circumvent the PA process, also known as price rolling.
- 3. Not to bill a different NDC or dosage than what was used.
- 4. Not attempt to obtain higher reimbursement by replacing ingredients (unless Prescriber authorizes or a new Prescription with different ingredients is received).
- 5. Not to increase dispensing fees, ingredient cost, quantities, and/or days' supply amounts.
- 6. Not to submit a Compounded Drug Claim for a drug that is equivalent to a commercially available drug (such claims are subject to full recovery in an audit).
- 7. Not to submit a Compounded Drug Claim for a single NDC pre-made compound or compound kit.
- 8. Not to submit reconstituted preparations as compound drugs (i.e. mixing water or saline with other Federal Legend Drugs prior to dispensing).
- 9. Not to submit prescriptions sub-divided into unit dose(s) as compound drugs.
- 10. Not to submit injectable drugs drawn into syringes for administration as compound drugs.
- 11. Not to charge for ancillary supplies, such as flavorings/sweeteners, equipment depreciation, and/or labor under the terms of the Agreement.
- 12. To submit all Compounded Drug Claims via the System using compounding code indicator "2" and use the appropriate level of effort (LOE) code.
- 13. The following acts may result in termination from PBM's Network(s): (1) waiving the Covered Person's copayment/coinsurance amount, (2) charging the Covered Person a higher copayment/coinsurance amount, (3) charging for non-covered ingredients, (4) refusing to fill due to reimbursement, unless otherwise specified under state law, (5) engaging in acts of questionable billing practices, (6) using inappropriate LOE code.

Pharmacy is expected to observe all applicable state and federal laws pertaining to U.S. Pharmacopoeia ("USP") Chapter Guidelines, Federal Drug Administration (FDA) communications, and professional standards when dispensing Compounded Drug Products. If, for any reason, evidence of unsafe/ unprofessional compounding is found, said evidence will be reported to the FDA and applicable State Board of Pharmacy, which may result in termination of the Agreement.

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# **GENERAL CLAIMS, PRICING, AND PAYMENT INFORMATION:**

Claims submitted by Pharmacy through the System will be reimbursed at the lesser of the Pharmacy's U&C charge or cash price; submitted ingredient cost; submitted total amount due; maximum allowable cost ("MAC"); or AWP minus the applicable Network rate, plus the applicable dispensing fee (including any applicable state or local tax); or as required by state or federal law. The reimbursement rates may vary by Plan Sponsor. Tax will be calculated based on available and approved state or local tax on prescription drugs when submitted by Pharmacy.

PBM utilizes Medi-Span, First Databank, or any other such nationally accepted database as its pricing source, including for MAC pricing. AWP pricing for Drug Products shall be calculated using the current AWP benchmark and methodology on aggregate, where applicable, at an individual Plan Sponsor level. Plan Sponsor participation may vary in the implementation, application, and utilization of the post AWP methodology at point-of-sale via the System. Should AWP become obsolete or market conditions warrant a change in pricing methods, other nationally recognized referenced based pricing sources, such as WAC based pricing or suggested wholesale price, may be implemented and utilized. Upon the return of a paid claim response to the Pharmacy via the System, Pharmacy has agreed to accept terms, rates, and participation. Pharmacy may not bill a Covered Person in excess of the applicable copayment amount returned on a paid claim via the System, unless allowed by state and/or federal law.

The Agreement does not exclude or guarantee access into all Networks, and Plan Sponsors may utilize alternative, limited, or restricted Networks. PBM's Pharmacy Network and reimbursement includes, but is not limited to, commercial, Medicare Part D, Medicaid, Long Term Care, home infusion, hospice, consumer operated and orientated plan programs, worker's compensation, discount cards, cash cards, coupon vouchers, reward and restricted programs, vaccinations (including professional allowance), specialty, mail order, healthcare cooperatives, or other custom Plan Sponsor Networks. Pharmacy acknowledges and agrees the acceptance of a successfully adjudicated claim means:

- 1. Pharmacy agrees to participation in applicable Network(s).
- 2. Pharmacy agrees to accept rates and reimbursement of claim for applicable Network(s).

In the event of a conflict between the Agreement, Addenda, Exhibits, Amendments, Manual, or the System adjudication response, the System response shall govern, unless an overpayment error occurs. PBM shall recoup overpayments on behalf of the Plan Sponsor, or in accordance with state law.

Pharmacy agrees and understands contacting a Plan Sponsor who utilizes PBM's Networks directly for any pricing disputes or claim processing issues, unless permitted by PBM in writing, is strictly prohibited. Furthermore, Pharmacy also agrees and understands PBM submits payments to the Pharmacy for approved claims and Pharmacy will not pursue a Plan Sponsor for any additional financial payments or incentives. Such violation is considered prohibited and may be subject to financial penalties of one thousand dollars (\$1,000) per incident/per day and Pharmacy's termination from the Network(s).

If Pharmacy is affiliated with a third-party contracting/purchasing group, Pharmacy is subject to all terms and conditions of this Manual and the third party's Agreement, Addenda, Amendments, and Exhibits. If affiliated Pharmacy is found to be in breach of any terms or conditions of said Agreement, Addenda, Amendments, Exhibits, and/or Manual, Pharmacy may be terminated from all PBM Networks at PBM's sole discretion.

PBM processes Pharmacy payments twice per month, or sooner, as required by state or federal law and/or requirements. Financial cycles may be changed or altered because of a contractual obligation to a Plan Sponsor, or in accordance with state Prompt Pay regulations or federal laws. In these situations, PBM will notify Pharmacy in the next subsequent check issuance of any future financial cycle modifications, if applicable.

PBM shall not reimburse a Pharmacy or Pharmacist in any state an amount less than the amount that PBM reimburses its affiliate pharmacy for providing the same Pharmacy or Pharmacist services.

# MAC LIST:

PBM's MAC list(s) are considered proprietary and confidential and are updated by PBM, at its sole discretion. PBM utilizes multiple sources to ensure the MAC list(s) reflect market pricing and Generic Drug Product availability. PBM updates its MAC list every seven (7) calendar days.

PBM's MAC list only includes prescription drugs that are:

- 1. Not obsolete;
- 2. Generally available for purchase by pharmacies from a national or regional wholesaler operating and licensed in the state where the Pharmacy is located;
- 3. Listed as "A" or "B" rated in the most recent version of the United States Food and Drug Administration's approved drug products with therapeutic equivalence evaluations, also known as the orange book, or has an "NR" or "NA" rating or similar rating by a nationally recognized reference;
- 4. Not temporarily unavailable;
- 5. Not listed on a drug shortage list; and
- 6. Eligible for lawful substitution.

Should a prescription drug on PBM's MAC list not meet the above requirements, PBM will remove the drug from its MAC list.

A digital copy of PBM's MAC list is readily available in searchable form to Pharmacies through PBM's pharmacy portal. PBM's MAC list includes:

- 1. The generic code number,
- 2. The national drug code, and
- 3. The effective date of the MAC reimbursement amount.

Historic lists of MAC pricing are available through PBM's pharmacy portal.

# **CLAIM ADJUSTMENTS AND REVERSALS:**

Pharmacy may adjust a claim when it has been submitted incorrectly, or if the Covered Person wishes a switch to Brand or Generic Drug dispensing. To request a paid claim be adjusted, Pharmacy should submit the claim online (reversal and re-submission), or, under limited circumstances, submit a Manual Claim Form indicating "REVERSAL" or "ADJUSTMENT".

For *online claims*, all requests for claim adjustments must be received and processed by PBM within thirty (30) days of the fill date, or as required by applicable federal or state law. Pharmacies designated as Long-Term Care shall submit claims within ninety (90) days of the date of fill, or in accordance with state law.

For *manual claims* (when allowed), all requests for claim adjustments must be received and processed by PBM within ninety (90) days of the date of fill to be eligible for an adjustment. However, PBM may, at its own discretion, approve submission outside of the ninety (90) day window.

Pharmacy agrees to reverse claims within fourteen (14) days of original submission for all medications not picked up by a Covered Person. Failure to reverse claims not picked up by a Covered Person are subject to claim reversal plus a five hundred dollar (\$500.00) penalty per claim, if found via Pharmacy audit.

# **GENERAL CLAIM DISPUTES:**

In the event a Pharmacy wishes to dispute a claim due to an alleged discrepancy, error, or noncompliance with regard to terms of the Pharmacy Agreement, Pharmacy must notify PBM in writing within sixty (60) days of the date of fill, or in accordance with the Agreement or state or federal laws, if applicable. The claim dispute notification must include Pharmacy's NCPDP or NPI number, Covered Person's ID number, prescription number, date of fill, claim reference number and detailed information stating the reason for the dispute. PBM shall have thirty (30) business days to respond to the notification, provided all documentation/information is obtained from the Pharmacy. In the event PBM requests additional documentation. Once the additional requested information is received from the Pharmacy, PBM has thirty (30) business days to respond to the Pharmacy, PBM has thirty (30) business days to respond to the Pharmacy. Claim dispute notifications should be emailed to network@procarerx.com.

PBM's appeals process provides three (3) levels of review:

- 1. First Level Appeal PBM's Clinical team
- 2. Second Level Appeal PBM's Clinical team [2]
- 3. Third (and final) Level Appeal a contracted external review organization ("ERO")

Expedited appeals are determined and verbal notification to the Member and Prescriber is provided within 72 hours from receipt of request and written notification within three (3) calendar days of request.

Non-expedited (standard) appeals are responded to within 30 calendar days of request.

This policy is available to Members and Prescribers upon request.

# CLAIM APPEALS PROCEDURE:

If the initial coverage decision is denied and First Level Appeals are not delegated to PBM, the notification will refer the Member to their respective health plan.

The First Level Appeals process shall be as follows:

- 1. When the appeal is received in writing or telephonically, the request shall be forwarded to PBM's Clinical team for review.
- 2. PBM's Clinical team may obtain additional information from the treating Prescriber and or claim information, and other such clinical materials, including FDA approved package inserts, industry clinical journals, and other information that may be relevant to making an impartial decision.
- 3. PBM's Clinical team shall review the appeal and document their decision in writing.
- 4. If the decision is to deny, the Member and Prescriber are notified of the denial in writing, along with the process to file a secondary appeal if the Member/Prescriber does not agree with the findings. If secondary appeals are not delegated by the Client to PBM, the appeal letter will refer the Member to their health plan.

If the appeal is overturned, the Member and Prescriber are notified in writing. PBM's Clinical team will add a rule into the System allowing the claim to pay.

The Second Level Appeals process shall be as follows:

- 1. The case, including all documentation in the previous steps, shall be submitted to PBM's Clinical Pharmacist.
- 2. PBM's Clinical team [2] may obtain additional information from the treating Prescriber and or claim information and other such clinical materials, including FDA approved package inserts, industry clinical journals, and other information that may be relevant to making an impartial decision.
- 3. A review shall be performed by PBM's Clinical Pharmacist, and their decision is documented in writing.
- 4. If the First Level Appeal is overturned, the Member and Prescriber are notified in writing.
- 5. If the decision is to uphold the original denial, the Member and Prescriber are notified of the denial in writing, along with the process to file a final appeal if the Member/Prescriber does not agree with the findings.

The Third (and final) Level Appeals process shall be as follows:

- 1. The case, including all documentation in the previous steps, will be submitted to a contracted external independent review company for review.
- 2. A review shall be performed by the contracted external independent review company, and their final decision is documented in writing.
- 3. Client shall be notified in a summary document of the final decision by the contracted external independent review company.
- 4. In accordance with the arrangement between PBM and the Client, the Member shall be notified of the final decision of the contracted external independent review company.

5. For health plan Clients and other approved entities that may accept PHI, the documentation provided by PBM may include Patient-specific information.

Appeal documentation is managed electronically. The documentation of appeals includes the following:

- Consumer demographics.
- Correspondence from the Consumer/Prescriber.
- Dates (open, reviewed, and closed).
- Name and credentials of clinical peer.
- Clinical review criteria if a non-certification is determined.

Appeal reports are submitted to the Quality Committee on a quarterly basis.

**NOTE:** All appeals are reviewed by Pharmacists or Physicians as permitted by state appeal laws, who were not involved in the original denial decision. Neither the individual who made the original non-certification, nor the subordinate of such individual is involved in the appeal.

PBM is committed to using good clinical practice guidelines, and uses information derived from a review of currently available clinical information, including clinical outcome studies in the peer-reviewed published literature, regulatory status of the procedure, evidence-based guidelines of public health research agencies, views of practitioners practicing in relevant clinical areas, and other relevant factors. PBM makes no representation and accepts no liability with respect to the content of any external information cited or relied upon in establishing the clinical practice guidelines. The description, background, and positions reflected in the clinical practice guidelines, including any reference to a specific Provider, product, process, or Service by name, trademark, or manufacturer, constitutes PBM's opinion and are made without intent to defame. PBM further makes no representation that these opinions are endorsed by any healthcare Provider or healthcare Provider society, and reserves the right to revise the clinical practice guidelines as clinical information changes.

The conclusion that a particular drug or Service is acceptable does not constitute a representation or warranty that this Drug Service is covered for a Member's benefit plan. The Member's benefit plan determines coverage.

# **GENERIC DRUG (MAC) APPEALS:**

PBM is committed to reviewing fully completed and submitted MAC appeals in a timely manner, or in accordance with state guidelines. Requirements for MAC appeals may be found on the *Generic Pricing Appeal Form* located on the Pharmacy Portal.

Pharmacy agrees not to delay, withhold, or affect Covered Person access to Services in the event a MAC appeal is generated by Pharmacy. In addition, Pharmacy shall not involve the Covered Person or Covered Person's Plan Sponsor of such reimbursement disputes.

An independent Pharmacy holding a direct Agreement with PBM may submit a MAC appeal directly to PBM via reimbursement@procarerx.com.

An independent Pharmacy under a third-party affiliation ("PSAO") or chain agreement must direct all MAC inquiries to their affiliation for proper handling, unless otherwise indicated by PBM. A MAC appeal sent

to PBM by an affiliated independent Pharmacy will not be reviewed unless prior permission has been granted solely by PBM. It is the expectation of PBM that all MAC appeals sent by a chain affiliation are fully reviewed and screened prior to submitting to PBM for review.

Appeals will not be reviewed for claims reimbursed at U&C, submitted ingredient cost, claims reimbursed at AWP discounts, or Brand Drug Claims. Duplicate claims will not be reviewed and are limited to one (1) individual claim reference number per appeal. Appeals submitted without the required supporting documentation, such as Pharmacy name, Pharmacy NCPDP/NPI, BIN, prescription number, fill date, Drug Product NDC, and acquisition cost shall be considered incomplete and will not be reviewed until all information is received.

All completed appeals must be emailed to reimbursement@procarerx.com within sixty (60) days of the actual claim fill date, or per federal and state guidelines.

Reviews and final determination of accepted MAC appeals shall average five (5) to seven (7) business days, and appeals will not pend for more than fourteen (14) calendar days, unless a shorter timeframe is stipulated by state law.

If PBM denies a MAC appeal, PBM will provide the Pharmacy with the national drug code number (NDC) of a prescription drug that is available from a national or regional wholesaler operating and licensed in the state where the Pharmacy is located and the reason for PBM's determination.

If PBM finds in favor of a Pharmacy for a MAC appeal, PBM will:

- 1. Change the MAC price of the appealed drug as of the initial claim fill date;
- 2. Adjust the MAC price of the appealed drug for the appealing Pharmacy and other similarly situated Pharmacies;
- 3. Timely notify the appealing Pharmacy and similarly situated Pharmacies that they can reverse and resubmit claims for the appealed drug;
- 4. Make a retroactive price adjustment for the appealed drug in the next payment cycle; and
- 5. Adjust resubmitted claims based on the adjusted MAC price, when applicable.

# PRESCRIPTION IDENTIFICATION CARD:

The Covered Person's eligibility must be verified through the System or by contacting the specific telephone number listed on the back of the applicable Prescription Identification (ID) Card. Covered Persons are instructed to provide their ID Card(s) when obtaining a Drug Product and/or Service from a participating Pharmacy.

Covered Persons in nursing homes, Long Term Care (LTC) facilities, and hospices are not required to present ID Card(s). PBM's Help Desk phone number is found either by referencing the back of the ID Card or by referring to the online claims response, when applicable.

Please Note: For <u>same-sex twins</u>, enter in first names and date of birth.

# Sample ID Card



**Member:** Drugs that are covered by your plan may be filled by participating Pharmacies per your plan requirements. This card is for identification purposes only, and you may be required to provide additional ID at the time your prescription is filled. Presentation of this card does not guarantee eligibility. Unauthorized or fraudulent use of this card is punishable by law and ProCare reserves the right to revoke this ID card at any time for cause. **Pharmacy:** ProCare is not responsible for payment of Claims to a non-

participating pharmacy. For Prior Authorizations, please call: **1-800-211-8592.** 

> PROCARE 1267 Professional Parkway Gainesville, GA 30507 Pharmacy Help Desk 1-800-699-3542

# **COORDINATION OF BENEFITS ("COB")**:

Coordination of Benefits (COB) with a Covered Person's other coverage may vary between Plan Sponsors and may or may not be allowed. Please refer to System or applicable payer sheet for proper direction and facilitation of all COB claim submissions after validation of all other information is initially made with the Covered Person.

#### **REMITTANCE ADVICE:**

PBM will provide Pharmacy with remittances (either paper or electronic) for claims processed, where applicable, within their respective payment cycle. Additional fees may apply for remittance recreations or additional Services where original remittances have already been delivered to Pharmacy or its authorized agent, without error, as confirmed by PBM. The below outlines the applicable fees.

Туре	Fee*
Paper and electronic remittance recreation	\$25 (per Pharmacy, per cycle)
Stop payment on check	\$35 per check
Remittance research or documentation request	\$25 per half-hour (minimum 1 half-hour)

\*Fees shall be charged and withheld through future billing cycle withholds to Pharmacy or its authorized agent.

#### CLINICAL P&T COMMITTEE:

PBM's P&T Committee will review the use and therapeutic effects of several classes of Drug Products within the same therapeutic class to identify preferred agents based on safety, efficacy, effectiveness, and dramatic cost variances. However, cost will not be a primary consideration in determining the safety and/or efficacy of a drug.

In general, the procedure for therapeutic class review will be as shown below. PBM's P&T Committee will not be specifically bound by the procedure below in determining which therapeutic classes to review, or under what time schedule, if additional factors such as new drugs entering the market, loss of patent, or FDA warnings occur.

- 1. The P&T Committee will approve inclusion or exclusion of individual therapeutic classes in the printed formulary on an annual or as needed basis.
- 2. Each of the top twenty (20) therapeutic classes, which are determined by utilization and general medical practice by the acting P&T Committee chairman, will be reviewed annually at PBM's

annual onsite P&T Committee meeting. Annual reviews will always be performed on the following primary therapeutic classes periodically, regardless of utilization or general medical practice priority:

- Diabetes
- Hypertension (Cardiovascular)
- High Cholesterol
- Blood Modifiers
- Rheumatoid Arthritis
- Multiple Sclerosis
- Respiratory Agents
- Oncology
- 3. Based on the outcomes of the therapeutic class reviews, and given current good medical practice, the P&T Committee will recommend the development of new drug use criteria, new treatment guidelines, or changes to the formulary, including change in tier placement, implementation of any Prior Authorization requirements, and/or implementation of step edit protocols or prescription quantity limits.
- 4. Formulary therapeutic categories and classes may be changed based on the guidance of the P&T Committee, which will include the addition of new drug entities and new therapeutic uses, or the reclassification or further breakdown of a specific therapeutic category or class listed to provide better guidance to practitioners and Prescribers.

# DRUG FORMULARY:

PBM may manage Drug Formularies for payers of healthcare, such as, employer groups, universities, regional HMOs, and other plan types, through its online claims adjudication system (the "System"). PBM's Pharmacy and Therapeutics ("P&T") committee meets at regular intervals to review which Drug Products are appropriate for inclusion in the drug formulary, based primarily on clinical efficacy and secondarily on payer cost. If a submitted claim is non-compliant with the drug formulary and the Plan Sponsor has opted for a closed formulary benefit, the claim will reject and an online message will be returned to the Pharmacy indicating the preferred Drug Product. For selective Formularies, the Covered Person's copayment may be higher, again with an indication of the preferred Drug Product. Printed Pocket Drug Formularies are available upon request by contacting the phone number listed on the back of the Covered Person's ID Card.

# ANCILLARY CHARGES:

Ancillary Charges are charges incurred beyond the standard copayment/coinsurance charge (i.e. deductible(s) and/or DAW penalties) and may vary by Plan Sponsor. If any Ancillary Charges have been applied to the Covered Person, Plan Sponsor, or the Pharmacy, such charges will be noted via the System.

# 340B PROGRAM:

In the event the Pharmacy is contracted, owned, or operated by an eligible 340B participating entity, allowing the purchase of Drug Products at a reduced cost under the Public Health Service Act, Section 340B program, Pharmacy shall immediately inform PBM with written notice of eligibility. Failure to provide such documentation shall constitute a material breach of the Agreement.

PBM will not reimburse a 340B entity or a 340B contract pharmacy for a pharmacy-dispensed drug at a rate lower than that paid for the same drug to similarly situated pharmacies that are not 340B or 340B contract pharmacies, and PBM shall not assess any fee chargeback, or other adjustment upon the 340B entity or 340B contract pharmacy on the basis that the 340B entity or 340B contract pharmacy participates in the 340B program.

PBM will not discriminate against a 340B entity or 340B contract pharmacy in a manner that prevents or interferes with a patient's choice to receive such drug from the corresponding 340B entity or 340B contract pharmacy.

# **ORIGIN CODE REQUIREMENTS:**

Prescriptions, including refills, must contain an Origin Code value according to the chart below on all claims submitted. Claims without a value will be rejected/denied at the point-of-sale.

VALUE	VALUE TYPE		
00	Original dispensing — the first dispensing		
01-99	Refill number — number of the replenishment		
AL	ALL NEW PRESCRIPTIONS MUST CONTAIN ONE OF THE FOLLOWING NUMERIC VALUES:		
1	Written		
2	Telephone		
3	Electronic		
4	Fax		
5	Used when a new prescription number needs to be created from an existing valid prescription (i.e. traditional/intra-chain transfers, file buys, and system/software upgrades). Also appropriate to use for over-the-counter, Plan B, Pharmacist's authority to prescribe, etc.		

# DISPENSE AS WRITTEN (DAW):

PBM utilizes all DAW/Product Selection Codes as specified by NCPDP. The matrix below serves only as a guide and may be used when dispensing a multi-source Brand Drug Product where an Orange Book 'A' rated Generic Drug Product is available. Additionally, these values are Plan Sponsor benefit-specific and may vary by Plan Sponsor. Valid DAW values are as follows.

DAW	REASON	ACTION	WHO PAYS PENALTY*	CO-PAY BASIS
0	No Product Indicator	Рау	Pharmacy	Brand
1	Physician Requested Product	Рау	None	Brand

# **DISPENSE AS WRITTEN (DAW) PAYMENT MATRIX**

DAW	REASON	ACTION	WHO PAYS PENALTY*	CO-PAY BASIS
2	Covered Person Requested Product	Pay	Covered Person	Brand
3	Pharmacist Requested Product	Pay	Pharmacy	Brand
4	Generic Drug Not in Stock	Pay	Pharmacy	Brand
5	Brand Drug Used as Generic	Pay	Pharmacy	Brand
6	Override	Pay	Pharmacy	Brand
7	Brand Mandated by State Law	Pay	Pharmacy	Brand
8	Generic Not in Marketplace	Pay	Pharmacy	Brand
9	Other	Reject	Pharmacy	Brand

\*Offered as a general guideline. May vary between Plan Sponsors. Penalty values may also vary per Plan. Invalid or incorrect DAW submissions may result in inaccurate reimbursement.

# **DRUG PRODUCT QUANTITY LIMITS:**

Maximum Days' Supply Parameters \*

DISPENSORY	LIMITATIONS
RETAIL:	30-34 Days' Supply. Refills Limited by State Law.
MAIL SERVICE:	90 Days' Supply for Maintenance Drugs. Refills Limited by State Law.

#### **Refill Parameters \***

ISSUE	LIMITATIONS	
Prescription Utilization Required Before Refill Allowed	RETAIL:	80%
	MAIL SERVICE:	85%

\* The examples above are the most commonly utilized at PBM; however, both the maximum days' supply and refill parameters vary by Plan Sponsor and benefit.

# SIGNATURE LOGS:

Pharmacy shall maintain, at each dispensing location, either a manual or electronic signature log, or other electronic proof of pickup. The log <u>must</u> contain the Covered Person's name, date of fill, prescription number, and the date the Drug Product or Service is received by Covered Person or Representing Agent.

<u>Home Delivery Logs</u>: If Pharmacy delivers a Drug Product to a home or business address, the log must include: Covered Person's name, address of delivery, prescription number, date of fill, signature of Covered Person or Representing Agent, date of delivery, time of delivery, and delivery person's signature, or any other required information in accordance with state law.

<u>Mail Order Pharmacy Logs</u>: For Pharmacies licensed and authorized by PBM to act as a Mail Order Pharmacy, shipping logs must include Covered Person's full name, Covered Person's mailing address, prescription number, date prescription filled, date prescription mailed, and delivery confirmation of each prescription, or in accordance with state law.

Failure to comply with signature log requirements may result in full recoupment of Drug Product or Service reimbursement and/or penalty. Signature Logs must be maintained for all claims submitted through the System.

# PRIOR AUTHORIZATION AND PROCEDURES:

Prior Authorizations ("PAs") may be required for eligibility, age restriction overrides, fast refill, vacation supply, compounds, maximum days' supply, and several other drug categories, as well as certain prescriptions filled at retail with a drug cost greater than five hundred dollars (\$500.00) or any prescription filled at Mail Order, when allowed, with a drug cost greater than one thousand dollars (\$1,000.00). To obtain a PA number, the Pharmacy must contact the Pharmacy support number listed on the back of the Covered Person's ID card.

PA numbers are specific to the Covered Person's ID number, prescription number, 11-digit NDC, fill date, and Pharmacy NCPDP/NPI. PA numbers may only be used once and are <u>not</u> applicable to any impending refills of the same prescription.

Standard timeframe coverage determinations (including medical necessities, plan benefit reviews, appeals, and reconsiderations):

- 1. The maximum timeframe from initial fax to final determination will not exceed fourteen (14) calendar days for initial determinations, and thirty (30) calendar days for standard appeals.
- 2. Once an initial fax is sent out, the Provider will have at least seven (7) calendar days to respond with a completed Prior Authorization (PA) form. If the Provider fails to complete a PA form, the request may be denied due to insufficient information within fifteen (15) total calendar days from the initiation of the Prior Authorization.

Expedited timeframe coverage determinations (including medical necessities, plan benefit reviews, appeals, and reconsiderations):

 Expedited appeals are completed with verbal notification of determination within seventy-two (72) hours of the request, followed by a written confirmation of the notification within three (3) calendar days to both the Member and the Prescriber.

# **GENERAL COVERAGE FOR PLAN SPONSORS:**

**Inclusions** – Drug Product(s) and/or Service(s) must meet the following criteria:

- 1. Have been prescribed by a licensed Prescriber.
- 2. Be a Drug Product or device approved by the Food and Drug Administration (FDA).
- 3. Be a designated Federal Legend Drug Product.
- 4. Not be excluded from coverage under the Exclusions below.

**Exclusions** – The following products are *generally* not covered under a Covered Person's benefit plan, but may vary by Plan Sponsor:

1. Disposable and Durable Medical Supplies (DME), non-insulin products.

- 2. Applicators or devices.
- 3. Products used solely for cosmetic purposes (i.e. Rogaine and Propecia).
- 4. Anorexiants.
- 5. Drug Efficacy Study Implementation (DESI drugs).
- 6. Agents used for diagnostic purposes.
- 7. Experimental or investigational drugs (Drug Products & Services without FDA approved indication).
- 8. Over-the-counter (OTC) products other than insulin, syringes, and those deemed appropriate under a Prescription/Medical benefit plan.
- 9. Re-packagers outside of CMS accepted programs and procedures.
- 10. Serum/Allergens and Toxoids, where applicable.
- 11. Multi-Vitamins (other than prenatal or multi-vitamins with fluoride).
- 12. Replacement prescriptions resulting from loss, theft, or breakage.
- 13. Any compounded pharmaceutical Service that does not contain an ingredient that requires a prescription (Legend Drug Product).

# FRAUD, WASTE, AND ABUSE ("FWA") PROGRAM:

Healthcare fraud, waste, and abuse (FWA) is a very serious topic and potential offense. FWA is defined as the following and may not be interpreted by any other meaning other than the definitions below:

**Fraud**: A person who knowingly and willfully executes, or attempts to execute, a scheme or artifice to (i) defraud any healthcare benefit program to obtain, by false or fraudulent pretenses, representations, or promises, healthcare payments under which no entitlement exists; (ii) knowingly soliciting, receiving, offering, and/or paying remuneration to induce or reward referrals for Services reimbursed by any healthcare benefit program; (iii) making prohibited referrals for certain health Services to any healthcare benefit program; (iv) billing any healthcare benefit program for Services not rendered; (v) falsifying records to show delivery of Services not rendered; (vi) paying for referrals for monetary gain; (vii) billing a higher level of Service than what was provided (i.e. higher compound level of effort or delivery Services not provided); (viii) providing Services without proper licensure.

Some examples of fraud include, but are not limited to: altering a Physician's prescription, submitting bills/claims to multiple payers for the same prescription dispensing Generic Drug Products but billing for a Brand Drug Product, billing a different NDC than dispensed, submitting an invalid DEA or NPI to receive a paid Claim, splitting prescriptions to receive an additional dispensing fee, pill shorting a Covered Person, or filling prescriptions not medically necessary.

<u>Waste</u>: Is considered misuse or overutilization of any Service(s) rendered that may, directly or indirectly, result in unnecessary costs to any healthcare benefit program.

<u>Abuse</u>: A practice that, either directly or indirectly, results in unnecessary costs to any healthcare benefit program, or any practice inconsistent of Services that are not medically necessary. Abuse includes: billing unnecessary or not medically necessary Services, charging or billing excessively for Services and/or

supplies, and misuse of NDCs on claims to obtain higher reimbursement from any healthcare benefit program.

Federal laws governing FWA include:

- False Claims Act (FCA)
- Anti-Kickback Statute (AKS)
- Physician Self-Referral Law (Stark Law)
- Social Security Act
- United States Criminal Code, specifically, 18 U.S. § Code 1347. Health Care Fraud

PBM monitors its Pharmacy Network regularly for compliance and risk (please refer to the Audits section for further detail). Network Pharmacies are required to report any potential or suspected FWA to PBM and as required by law. Pharmacies must cooperate with and assist in aiding state and/or federal agencies with investigation(s) by providing any documentation requested and access to premises and records upon request. PBM investigates all claims of FWA activity reported by any of its contracted Pharmacies, Physicians, vendors, associates, contractors, Covered Persons, and/or other business entities capable of potential FWA.

- To report an FWA-related incident anonymously, please call 1-678-248-3180 to leave a confidential voice mail; or
- Email our confidential Hotline anonymously at hotline@procarerx.com.

# PHARMACY AUDITS

All Claims submitted are subject to audit. Pharmacy agrees to permit either an authorized PBM representative or an independent third-party auditor designated and approved by PBM or Plan Sponsor, access to its books, records, logs, and facilities, as well as access to scans and photographs for the sole purpose of conducting an audit to ensure compliance of Pharmacy in dispensing Drug Products and/or Services to Covered Persons within the terms of the Agreement. Pharmacy agrees audits may be completed during normal business hours via phone call, desktop audit, or on-site visit, in accordance with federal, state, and/or local law.

Compounded claims are subject to audit review and may require full disclosure of compound recipe upon request. Pharmacy agrees to provide a copy of the compound recipe worksheet identifying ingredients used in the compounded drug, when requested.

Institutional packaging NDC numbers are not covered.

Pharmacy shall maintain proper prescription and financial records, including, but not limited to, books, records, signature logs, Patient information, hardcopies of prescriptions, Physician information, wholesaler or distributor purchasing invoices, policies and procedures, and any additional information as required by local, state, or federal law, for a minimum of seven (7) years, or as required by applicable law. PBM reserves the right to audit claims during the term of the Agreement and for two (2) years following termination of the Pharmacy or Agreement, or longer, only if part of a legal case, or in accordance with federal, state or local law.

PBM or its Pharmacy audit contractor will abide by the following rules when performing Pharmacy audits:

- 1. Neither PBM nor its contractor will use extrapolation when conducting an audit, including calculating recoupments or penalties for audits, unless otherwise required by federal law.
- 2. PBM will not compensate an employee or contractor participating in an audit in a manner that is based on the amount claimed or the actual amount recouped from the Pharmacy being audited.
- Neither PBM nor its contractor will include a dispensing fee in the calculation of an overpayment, unless a prescription was (1) not actually dispensed, (2) the prescriber denied authorization for the prescription, (3) the prescription dispensed was a medication error by the pharmacy, or (4) the identified overpayment is solely based on an extra dispensing fee.
- 4. Neither PBM nor its contractor will assess any recoupment in the case of an error that has no actual financial harm to the covered person or the health benefit plan, unless the error occurred due to the Pharmacy failing to comply with a formal corrective action plan.
- 5. Neither PBM nor its contractor will charge back or recoup an overpayment identified during an audit for an amount that exceeds the amount the Pharmacy was overpaid.
- 6. PBM or its contractor will consult with a licensed pharmacist for any part of an audit that involves clinical or professional judgment.
- 7. Neither PBM nor its contractor will consider a clerical or record-keeping error, such as a typographical error, scrivener's error, or computer error regarding a required document or record as fraud, unless PBM or its contractor identifies additional evidence to substantiate a fraud allegation.
- 8. PBM or its contractor will use a statistically reliable sample size, if claims for the audit are selected randomly.
- 9. PBM or its contractor will limit its audits to claims adjudicated in the prior twenty-four (24) months, unless audit of additional claims is required by state or federal law.
- 10. PBM and its contractor will determine the sample size of claims for an audit based on the total volume of claims adjudicated in the prior twenty-four (24) months and will not include less than 100 claims or more than 300 claims in the audit unless otherwise specified in the Pharmacy's contract with PBM or required by state or federal law.
- 11. PBM and its contractor will conduct audits for similarly situated pharmacies using the same standards and parameters.
- 12. PBM or its contractor will not conduct an audit more frequently than annually, unless fraud is alleged.

PBM may share audit findings with Plan Sponsors, governmental entities, and/or an audit agency acting on behalf of PBM, as required. If Pharmacy belongs to a third-party affiliation (PSAO), PBM, at its own discretion, may notify PSAO of audit findings. Pharmacy shall cooperate either with audits conducted by PBM, or contractor acting on behalf of PBM. Pharmacy's failure to cooperate during an audit will be considered a breach of the Agreement and Pharmacy shall be subject to immediate suspension and/or termination of Network participation.

PBM may offset audit recoupment amounts and/or penalties charged through future payment cycles or via invoicing, at PBM's sole discretion, unless otherwise specified by state law.

# **On-Site Audits**

PBM may conduct an audit, provided it is reasonable in scope, and provided that PBM has notified Pharmacy in writing at least fourteen (14) days prior to the audit, or in accordance with state or federal law. Neither PBM nor its contractor will conduct an audit within the first five (5) business days of the month or on a state or federal holiday, unless the Pharmacy consents to an audit during this timeframe, or more restrictive parameters are set forth by state or federal law.

Neither PBM nor its contractor will interfere with the delivery of Pharmacist services to a patient and will utilize every effort to minimize inconvenience and disruption to Pharmacy operations during the audit process, and neither PBM nor its contractor will enter a Pharmacy area where patient specific information is stored without an escort.

Pharmacy agrees not to refuse a prescheduled on-site audit at the time of auditor arrival. Pharmacy agrees to provide a work area for the auditor, to be adequately staffed to assist in, and to answer questions, and retrieve information during the audit. Auditors must be given full access to any records, files, logs, copies, invoices, and any documentation pertaining to claims transactions submitted to PBM. Auditor reserves the right to request copies or take digital images during audit. Failure to assist in audit will be determined a denial of access and a breach of the Agreement, and Network participation shall be terminated immediately.

The scope of an on-site audit will include claims review, interviews with staff, an assessment of the Pharmacy premises, review of the Pharmacy's policies and procedures, and review of the educational materials Pharmacy provides to its staff members.

PBM or its contractor will create an onsite visit report for each onsite audit performed.

Please see the Audit Guide posted to Pharmacy Portal for further information on PBM's audit process.

#### **Desktop Audits**

Pharmacy shall provide records or copies of records requested by PBM, or its designated auditor, within ten (10) days from the date of notification of the request for such records, or in accordance with state or federal law.

In instances where a quantity differs between the actual prescription written by the Physician and the actual amount given to the Covered Person, full detail of the reason for the action and variance must be documented. A hard copy prescription must be kept on file for every prescription and must be accessible upon request, as required by law. For prescriptions labeled "As Directed," only the prescription written by the actual Physician will be accepted as documentation for an appeal consideration.

Please see the Audit Guide posted to Pharmacy Portal for further information on PBM's audit process.

#### **Investigational Audits**

Investigational audits are audits performed by PBM and may include, but are not limited to: Credentialing documentation, prescription records, signature logs, electronic signature logs, and/or Claims. In the event PBM requests records pertaining to an investigational audit, Pharmacy must agree to comply with the request for documentation immediately. Investigational audits are small and considered an inspection of the Pharmacy's documentation requested. These audits are necessary when initiated by a Plan Sponsor and/or PBM.

# **Network Recovery Program**

Pharmacy agrees that PBM and/or Plan Sponsor shall have the right to reclaim any money, either full or partial, previously paid to Pharmacy for Drug Products and/or Services found incorrectly billed/paid, or not to be in compliance within the terms of the Agreement or Pharmacy practice in accordance with state or federal law. PBM shall provide reports in writing for any or all Services stating exact non-compliant details for each Drug Product or Service for which recovery has been determined.

Please see the Audit Guide posted to Pharmacy Portal for further information on PBM's audit process.

#### **Preliminary Audit Reports**

PBM or its contractor will send a preliminary audit report to the Pharmacy within ten (10) calendar days of completion of the audit. A preliminary audit report will include an audit discrepancy report, and instructions on how to submit a preliminary audit report appeal. The preliminary audit report will serve as the final audit report if the PBM or contractor does not make any adverse findings.

Pharmacies will have thirty (30) calendar days to appeal any deficiencies listed in the preliminary audit report, unless a longer timeframe is required by state or federal law.

#### **Final Audit Report**

PBM or its contractor will issue a final audit report within ten (10) days of the expiration of the preliminary audit appeal timeframe, or following the conclusion of its review of documentation provided by the Pharmacy in its preliminary audit appeal. The final audit letter will list claims details for claims that will be recouped or adjusted, and any other information required by state or federal law.

# **CONFIDENTIALITY**:

Pharmacy shall comply with all laws applicable pertaining to confidentiality, use, disclosure, and maintenance of Covered Person's protected health information (PHI). Except as required by law, Pharmacy, on behalf of itself and its employees, contractors, and other representatives, agrees to treat all PHI, Agreements, Addenda, Exhibits, and Manuals as confidential and proprietary, and to take reasonable precautions and care to prevent unauthorized use and/or disclosure of the terms of the agreement, as well as any other information relating to PBM's business operations/Services in which PBM considers proprietary information to include, but not be limited to: Pharmacy Agreements, MAC listings, reimbursement, pricing, programs, Services, business practices, software, processes, applications, Systems, technology, files, Exhibits, publications, protocols, information pertaining to Clients, benefit plans, and formularies. All proprietary information remains the exclusive property of PBM and Pharmacy agrees not to discuss or disclose any proprietary information.

In addition, Pharmacy agrees reimbursement terms are considered proprietary and are not to be discussed with any Client, Plan Sponsor, Covered Person, Covered Person's Representing Agent, or other Pharmacy (participating or non-participating), without prior written authorization from PBM. Pharmacy acknowledges and agrees any discussions pertaining to the reimbursement of Drug Products and Services with any Client, Plan Sponsor, Covered Person, Covered Person's Representing Agent, other Pharmacy (participating or non-participating) is considered a breach of the Agreement and could result in immediate termination from PBM's Network(s).

For affiliated Pharmacies (Pharmacies contracted with a chain, PSAO, or a third-party contracting entity), all reimbursement inquires and communications are required to be directed through the Pharmacy's affiliation, unless otherwise specified by PBM. Affiliated Pharmacies are not permitted to discuss reimbursement with any Client, Plan Sponsor, Plan Sponsor's staff, Covered Person, or Covered Person's Responsible Party. Any discussion pertaining to the Pharmacy's reimbursement with any party other than Pharmacy's chain affiliation, or in some cases, PBM directly, is considered a breach of the chain affiliation Agreement with PBM and could result in immediate termination from PBM's Networks. The chain affiliated Pharmacy is subject to all current terms and conditions of the Agreement between the respective

chain and PBM through the allowance of such sub-contracting during the time the Pharmacy is active with the respective chain affiliation, as reported by NCPDP.

# MISCELLANEOUS:

Additional information regarding PBM's Network, including forms, communications, notices, and updates, may be obtained by visiting https://www.mc-rx.com.

This Manual is updated periodically, at the sole discretion of PBM. PBM shall post the most current version of the Manual on the Pharmacy Portal. The Manual applies to all lines of business and is considered an extension on the Pharmacy's Agreement. It is the Pharmacy's responsibility to ensure they are using the most current version of the Manual when referencing.

Pharmacies who leave their affiliated chain entity will not be considered contracted/participating after the date of termination with the chain entity, as reported by NCPDP. The Pharmacy will need to request a direct contract via network@procarerx.com to obtain the applicable contracting documents to apply for participating status within PBM's Network(s). Agreement effective dates will not be retro-activated unless authorized in writing by Plan Sponsor and/or PBM.

PBM updates its files regularly through monthly data feeds from NCPDP, or other nationally recognized Provider data vendors, as determined by PBM. Such data includes, but is not limited to, Pharmacy NCPDP number, NPI number, Pharmacy chain affiliation, demographics, licenses, Pharmacy status, dispenser types, and chain termination dates, if applicable. It is the Pharmacy's responsibility to contact NCPDP and update any information and/or changes to ensure the integrity of PBM's files and database. PBM will not make changes to any Pharmacy record unless NCPDP reflects such change(s). If Pharmacy refuses to update NCPDP, Pharmacy will be responsible for any errors in data provided to Covered Persons, Pharmacy payments, and any reimbursement-related issues. PBM reserves the right to recoup any monies due on behalf of Plan Sponsors should Pharmacy fail to maintain NCPDP with the correct data.

PBM is committed to quality surrounding the Network and may at times engage the Pharmacy in Quality Improvement initiatives, activities, or surveys through communications via direct outreach or via the PBM Provider Portal. Pharmacy may submit suggestions directly to PBM via email, telephone, or fax.

Pharmacy understands participation in a Network does not grant access into all Networks. PBM and/or Plan Sponsor reserves the right to limit participation in a Network, at its sole discretion. Furthermore, Pharmacy agrees to participate all in applicable Networks and shall not be allowed to opt-out without written consent from PBM.

PBM may immediately terminate or suspend the Agreement or any applicable Amendment, Addendum, or Exhibit pursuant to business needs, Plan Sponsor request, or any of the following reasons, provided such termination is not prohibited by state law, including but not limited to:

- Failure to meet/maintain Credentialing standards, failure to retain liability insurance (i.e. lapse, cancellation, or suspension), loss of state licensure, excluded from federal programs (OIG).
- Fraudulent claim submission activity detected.
- PBM has reason to suspect Pharmacy is/has engaged in fraudulent practices of federal and state law.
- Covered Person(s) are refused Services for reasons for which refusal is prohibited by the
   Confidential & Proprietary

Agreement.

- Any automated reversal process(es).
- Rejecting Covered Persons at the point-of-sale for a non-clinical reason.
- Breach of any term set forth in the Agreement and/or Manual.
- Refusing to provide Services to a Covered Person based on reimbursement.
- Covered Person is charged more than the copayment.

Pharmacy agrees not to advise, counsel, or solicit Covered Persons with Plan Sponsors utilizing PBM for any reason, including, but not limited to, compensation. Pharmacy agrees not to advise, counsel, or solicit Plan Sponsor to terminate its relationship with PBM for any reason. Pharmacy agrees such behavior is strictly prohibited and shall be grounds for immediate termination under the Agreement.

PBM's Pharmacy Manual is considered confidential and proprietary. Pharmacy agrees not to copy, distribute, or share information included in this Manual, except as required for business or contract purposes only.

# **STATE STATUTES AND REGULATIONS**

#### ARKANSAS

The following provisions apply to Pharmacies located in the State of Arkansas:

1. Pursuant to ACA §23-92-507, PBM, through the Arkansas dispensing Pharmacy/Pharmacist, will inform Covered Persons, where applicable, of any differential between price of the lowest-priced, therapeutically equivalent and bio-equivalent generic drug at the point of sale, unless the lowest priced drug is being purchased. The Pharmacist contract shall not prohibit, restrict, or limit disclosure or information to the Insurance Commissioner, law enforcement, or state and federal governmental officials investigating or examining a complaint or conducting a review of a PBM's compliance with the requirements under Ark. Code § 23-92-507.

2. Pursuant to ACA §17-92-507, "Maximum Allowable Cost List" shall mean a listing of drugs or other methodology used by a pharmacy benefits manager, directly or indirectly, setting the maximum allowable payment to a Pharmacy or Pharmacist for a generic drug, brand-name drug, biologic product, or other prescription drug.

3. Pursuant to ACA §17-92-507, for every drug which PBM establishes a maximum allowable cost to determine the Drug Product reimbursement, PBM shall ensure that:

- Reimbursement for a drug subject to maximum allowable cost is based solely on that drug and drugs that are therapeutically equivalent if the therapeutically equivalent drugs are listed in the most recent version of the United States Food and Drug Administration Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the Orange Book.
- Reimbursement for a "B" rated drug subject to maximum allowable cost is based solely on that drug and drugs that are not therapeutically equivalent to a "B" rating in the most recent version of the United States Food and Drug Administration Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the Orange Book.
- Reimbursement for a "NR" or "NA" drug with a similar rating by a nationally recognized reference subject to maximum allowable cost is based solely on that drug and other drugs

with a "NR" or "NA" rating or similar rating by a nationally recognized reference that meets criteria for therapeutic equivalence used in the United States Food and Drug Administration Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the Orange Book.

- Reimbursement for a drug subject to maximum allowable cost is based solely on that drug if there is no other therapeutically equivalent drug.
- Reimbursement for a drug subject to maximum allowable cost is not based on a drug that is
  obsolete, temporarily unavailable, listed on a drug shortage list, or that cannot be lawfully
  substituted.

Pursuant to ACA § 17-92-507(c), PBM's administrative appeal procedure shall include the following:

- A dedicated telephone number, email address, and website for the purpose of submitting administrative appeals;
- The ability to submit an administrative appeal directly to PBM regarding the Pharmacy benefits plan or program or through a service administrative organization; and
- No less than thirty (30) business days to file an administrative appeal:
  - PBM shall respond to the challenge in accordance with Arkansas law within thirty
  - (30) business days after receipt of the challenge.
  - i. If the appeal is upheld:
    - i. Make the change in the MAC list reimbursement to at least Pharmacy acquisition cost;
    - ii. Permit the challenging Pharmacy to reverse and rebill the claim in question;
    - iii. Provide the NDC that the increase or change is based on to the Pharmacy; and
    - iv. Change the reimbursement for similarly situated Pharmacies to the reimbursement received by the appealing pharmacy.
  - ii. If the appeal is not upheld:
    - i. Provide the appealing Pharmacy with the NDC and the name of a national or regional pharmaceutical wholesalers operating in Arkansas that have the drug currently in stock at a price below the MAC.
    - ii. If the NDC is not available to the Pharmacy at a national or regional pharmaceutical wholesaler operating in Arkansas at or below the MAC price, reimburse the Pharmacy its acquisition cost and adjust the MAC reimbursement, and permit the Pharmacy to reverse and rebill each claim affected by the inability to procure the drug at a cost that is equal to or less than the Pharmacy's acquisition cost. below the pharmacy acquisition
- 4. Pursuant to ACA § 23-92-506(4), PBM shall not reimburse a Pharmacy or Pharmacist in the state an amount less than the amount that PBM reimburses its affiliate for providing the same Pharmacist services. The amount shall be calculated on a per unit basis based on the same generic product identifier or generic code number.
- 5. Pursuant to ACA § 17-92-507(c)(4), PBM shall not pay an Arkansas Pharmacy or Pharmacist less than the Pharmacy's acquisition cost of the Pharmacy providing Pharmacist services.
- 6. Pursuant to ACA § 17-92-507(c)(4)(B), PBM has thirty (30) days to investigate and respond to the completed MAC appeal form received.
- 7. Pursuant to ACA § 17-92-507(e), an Arkansas Pharmacy or Pharmacist has discretion to decline

providing Pharmacist services to a patient or PBM if, as a result of a Maximum Allowable Coast List, a Pharmacy or Pharmacist would be paid less than the Pharmacy's or Pharmacist's cost for the services.

- 8. Pursuant to ACA§23-92-505(b)(2)(c), spread pricing is illegal in the State of Arkansas.
- 9. Pursuant to ACA §23-92-506, PBM shall not pay or reimburse a Pharmacy or Pharmacist for the ingredient Drug Product component of Pharmacist services less than the national average drug acquisition cost or, if the national average drug acquisition cost is unavailable, the wholesale acquisition cost.
- 10. Pursuant to ACA 23-92-512, PBM will issue, mail, or otherwise transmit payment with respect to a clean claim submitted by a Participating Pharmacy within seven (7) to fourteen (14) days after receipt of an electronic claim or thirty (30) days from the date of receipt of a claim for any other paper or manually submitted claim.

# CALIFORNIA

The following provisions apply to Pharmacies located in the State of California:

1. PBM or Plan Sponsor, as may be necessary from time to time for compliance by PBM, must agree to any applicable provisions of the Knox-Keene Act. Pharmacy acknowledges that it shall maintain such records for at least six (6) years from the date of last Service, or six (6) years from the date that a minor Eligible Member has achieved the age of majority. All records will be provided by Pharmacy to PBM in a manner consistent with data privacy statutes and other applicable laws or regulations. PBM will have access at reasonable times, upon request, to all books, records, and papers relating to the Pharmacy that have been provided to Eligible Member(s), in addition to those relating to Services provided by Pharmacy to Eligible Member(s). The obligations set forth will survive any Participating Pharmacy ("Pharmacy") agreeing to comply with all applicable laws and regulations, directly or indirectly, including the requirements of the Knox-Keene Health Care Services Plan Act ("Knox-Keene Act") and the Medi-Cal program, as they relate to the Agreement and applicable Plan Sponsors.

2. Pharmacy agrees to adhere to regulations as directed by the California Department of Managed Health Care to assure Eligible Persons have access to Services in a timely manner. Pharmacy also agrees to provide any applicable reporting in a timely fashion, upon request of PBM, to ensure compliance with such access standards. CA. H&S §1371.2.

3. Pharmacy shall not collect or charge copayment amounts greater than those calculated and returned to the Pharmacy via the System, unless otherwise directly instructed by PBM, and Pharmacy acknowledges that an Eligible Member's copayment, when calculated based on a percentage for the Services rendered to the Eligible Member, are calculated from the applicable Pharmacy reimbursement schedule set forth in the Agreement and in accordance with this provision. CA. H&S § 1373.18; CA. Ins. Code § 10133.2, 10133.3.

4. Pharmacy acknowledges it shall only collect copayments, deductibles, or other charges or payments permitted to be collected or billed for Services covered by the Agreement or Plan Sponsor, as communicated via the System or PBM directly, as imposed by Section 1379 of the Knox-Keene Act. Pharmacy shall report to PBM, upon request, or on a monthly or other agreed upon periodic basis, all such other charges collected by Pharmacy.

5. Pharmacy acknowledges that it is prohibited from balance billing or invoicing an Eligible Member

for the difference between the Pharmacy's U&C or billed Services and the reimbursement paid by PBM or Plan Sponsor. Pharmacy will accept payment from PBM or Plan Sponsor as provided herein as payment in full for all Services rendered to Eligible Members pursuant to the Agreement. In the event PBM or Plan Sponsor fails to pay for Services, Pharmacy shall not hold any Eligible Member financially responsible for any amount owed to Pharmacy by PBM or Plan Sponsor, even if PBM or Plan Sponsor becomes insolvent. Neither Pharmacy nor its agents, trustees, nor assignees may take any legal action against an Eligible Member in an attempt to collect amounts owed by PBM or Plan Sponsor. CA H&S §1358.10(e)(1)(E); 1379; 28 CCR § 1300.67.8(e), 1300.71(g)(4).

6. Pharmacy acknowledges that it is prohibited from imposing any surcharges or additional fees against Eligible Members for Services administered that are not provided by or under the Plan Sponsor. Any notification of such action received by PBM will result in appropriate actions taken, and Pharmacy will cooperate with such actions, including, but not limited to, prompt reporting by Pharmacy, in writing to PBM, that outlines all surcharges or monies paid by Eligible Member directly to Pharmacy. CA. H&S §1379, 1385, 28 CCR § 1300.67.8.

7. Pharmacy agrees to maintain reasonable hours of operation during regular business hours to ensure Eligible Members have access to Services.

8. Pharmacy will maintain records for each Eligible Member under industry standard and accepted practices, and as may be necessary for compliance with provisions and regulations of the Knox-Keene Act. Pharmacy will release, upon appropriate request and consent, such information to termination of the Agreement with PBM.

9. In the event of termination of the Agreement, or while in the process of termination, Pharmacy agrees that it shall assure continuity of care to Eligible Members, at the request of the Eligible Member or Plan Sponsor, in acute care with a serious chronic condition, or who is pregnant, and can obtain continuation of care from the terminated Pharmacy for a reasonable transition period of at least ninety (90) days after termination. CA H&S § 1373.96 (e).

10. Pharmacy shall comply with any applicable Quality Improvement or Drug Utilization Management Programs or procedures of PBM or Plan Sponsor, provided that advance notice is given to Pharmacy. However, PBM or Plan Sponsor may make changes to Quality Improvement or Utilization Management Programs or procedures at any time, with or without notice, to comply with state and/or federal laws and regulations that may be required.

11. Pharmacy acknowledges and shall comply with PBM's grievance processes and procedures. PBM shall be promptly notified of any unresolved dispute with an Eligible Member. Pharmacy also agrees to comply with any final decision made by the applicable grievance committee for any reported grievance by Eligible Member or Pharmacy. 28 CCR 1300.51 (k).

12. Any provisions required to be in the Agreement, by or under Chapter 2.2 of Division 2 of the California Health and Safety Code or Subchapter 5.5 of Chapter 3 of Title of the California Code of Regulations, will be binding upon Pharmacy and PBM, even if not specifically provided for herein.

13. Pharmacy Provider has fourteen (14) business days following the submission of a claim to submit a Generic Pricing Appeal Form (MAC appeal). PBM will investigate and resolve the MAC appeal within seven (7) business days after the completed request is received. If the MAC appeal is denied, PBM will provide Pharmacy Provider an NDC of a Drug Product that can be purchased at or below the MAC price **Confidential & Proprietary**  determined by PBM. If the MAC appeal results in favor of the Pharmacy Provider, PBM will update the MAC pricing accordingly and advise the Pharmacy Provider to resubmit the claim.

# CONNECTICUT

The following provisions apply to Pharmacies located in the State of Connecticut.

Pursuant to CGS §38-a-477dd, PBM's Pharmacy Provider Agreement shall not contain any provision prohibiting or penalizing through increased utilization review, reduced payments or other financial disincentives, disclosure of any information to a Covered Person, as defined in Section 38a-591a, concerning: (1) the cost of a covered benefit, including, but not limited to, the cash price of a covered benefit; or (2) the availability and cost of any healthcare Service or product that is therapeutically equivalent to a covered benefit, including, but not limited to, the cash price of any such healthcare Service or product.

Pursuant to CGS § 38a-477f, all PBM Agreements concerning data or analytical Services to evaluate and manage healthcare Services shall provide for the disclosure of (1) billed or allowed amounts, reimbursement rates, or out-of-pocket costs, or (2) any data to the all-payer claims database program established under section 19a-755a.

# DELAWARE

The following provisions apply to Pharmacies located in the State of Delaware.

The purpose of this policy is to establish standards regarding Maximum Allowable Pricing for Prescription Drugs.

**1 (a)** Pursuant to *18 Del. C. § 3323A*, To place a drug on a maximum allowable list, PBM must ensure that the drug meets all of the following requirements:

- (1) If it is manufactured by more than 1 manufacturer, the drug is available for purchase by a contracted pharmacy, including a contracted retail pharmacy, in Delaware from a wholesale distributor with a permit in Delaware, with whom the pharmacy has an existing relationship.
- (2) If it is manufactured by only 1 manufacturer, the drug is generally available for purchase by a contracted pharmacy, including a contracted retail pharmacy, in Delaware from at least 2 wholesale distributors with a permit in Delaware.

(b) At the beginning of the term of a network Provider's contract, and upon renewal, PBM shall provide to network Providers a telephone number and email address at which a network Provider can contact PBM to process an appeal under this section.

(c) If the appeal is granted, PBM shall do the following:

- (1) For an appealing Pharmacy, do all of the following:
  - **a.** Adjust the maximum allowable cost for the drug as of the date of the original claim for payment.
  - **b.** Without requiring the appealing Pharmacy to reverse and rebill the claims, provide reimbursement for the claim and any subsequent and similar claims under similarly applicable contracts with PBM as follows:
    - **1.** For the original claim, in the first remittance to the Pharmacy after the date the appeal was granted.
    - **2.** For subsequent and similar claims under similarly applicable contracts, in the second remittance to the Pharmacy after the date the appeal was granted.

- (2) For a similarly situated contracted Pharmacy in Delaware, do all of the following:
  - **a.** Provide notice to the Pharmacy or the Pharmacy's contracted agent of all of the following:
    - **1.** That an appeal was granted.
    - 2. That without filing a separate appeal, the Pharmacy or the Pharmacy's contracted agent may reverse and rebill a similar claim.

(d) PBM shall make available on its website information about the appeal process, including all of the following:

- 1. A telephone number at which the contracted Pharmacy may contact the department or office responsible for processing appeals for PBM to speak to an individual specifically or leave a message for an individual or office who is responsible for processing appeals.
- 2. An email address of the department or office responsible for processing appeals to which an individual who responsible for processing appeals has access.

(e) PBM may not charge a contracted Pharmacy a fee related to the re-adjudication of a claim resulting from a granted appeal under subsection 2(d) of this section or the granting of an appeal under subsection (h) of this section.

(f) PBM may not retaliate against a contracted Pharmacy for exercising its right to appeal to the pharmacy benefits manager under subsection2 (a) of this section or to the Commissioner under subsection 2(h) of this section.

(g) 1. PBM denies an appeal and a contracted Pharmacy files an appeal with the Commissioner, the Commissioner shall do all of the following:

- a. Review PBM's compensation program to ensure that the reimbursement for Pharmacy benefits management services paid to the Pharmacist or a Pharmacy complies with this subchapter and the terms of the contract.
- b. Based on a determination made by the Commissioner under paragraph 2(h)(1)a of this section, do 1 (one) of the following:
  - i. Deny the appeal.
  - ii. Grant the appeal and order PBM to pay the claim in accordance with the Commissioner's findings.
- 2. All pricing information and data collected by the Commissioner during a review required by paragraph 2(h)(1) of this section is confidential and not subject to subpoena or the Freedom of Information Act, Chapter 100 of Title 29.

# FLORIDA

The following provisions apply to Pharmacies located in the State of Florida.

Pursuant to FL. Stat. §626.8825(2)(f), PBM will not condition Pharmacy participation in one pharmacy network on participation in any other pharmacy network or penalize a Pharmacy for exercising its prerogative not to participate in a specific pharmacy network.

Pursuant to FL. Stat. §626.8825(2)(h), PBM will provide a covered person with a 60-day continuity-of-care supply of a covered prescription at the previously set price, after revising its formulary to remove or change the tiering of a prescription drug if such change increases the cost of the drug to the covered person.

Pursuant to FL. Stat. §626.8825(2)(h)(2), PBM shall, on an annual basis, submit to the Florida Office of Insurance Regulation, under the penalty of perjury, a statement attesting to its compliance with the requirements of this subsection.

Pursuant to FL. Stat. §626.8825(3)(a), at the time of adjudication for electronic claims or the time of reimbursement for nonelectronic claims, PBM shall provide the pharmacy with a remittance, including such detailed information as is necessary for the pharmacy or pharmacist to identify the reimbursement schedule for the specific network applicable to the claim and which is the basis used by PBM to calculate the amount of reimbursement paid. This information must include, but is not limited to, the applicable network reimbursement ID or plan ID as defined in the most current version of the National Council for Prescription Drug Programs (NCPDP) Telecommunication Standard Implementation Guide, or its nationally recognized successor industry guide.

Pursuant to FL. Stat. §626.8825(3)(b), PBM shall ensure that any basis of reimbursement information is communicated to a pharmacy in accordance with the NCPDP Telecommunication Standard Implementation Guide, or its nationally recognized successor industry guide, when performing reconciliation for any effective rate guarantee, and that such basis of reimbursement information communicated is accurate, corresponds with the applicable network rate, and may be relied upon by the pharmacy.

Pursuant to FL. Stat. §626.8825(3)(c), PBM will neither perform financial clawbacks, reconciliation offsets, or offsets to adjudicated claims, nor charge, withhold, or recoup direct or indirect remuneration fees, dispensing fees, brand name or generic effective rate adjustments through reconciliation, or any other monetary charge, withholding, or recoupments as related to discounts, multiple network reconciliation offsets, adjudication transaction fees, and any other instance when a fee may be recouped from a pharmacy with the following exceptions:

- 1. Any incentive payments provided by PBM to a network pharmacy for meeting or exceeding predefined quality measures, such as Healthcare Effectiveness Data and Information Set measures; recoupment due to an erroneous claim, fraud, waste, or abuse; a claim adjudicated in error; a maximum allowable cost appeal pricing adjustment; or an adjustment made as part of a pharmacy audit pursuant to s. 624.491.
- 2. Any recoupment that is returned to the state for programs in chapter 409 or the state group insurance program in s. 110.123

Pursuant to FL. Stat. §626.8825(3)(d), PBM may not unilaterally change the terms of any participation contract.

Pursuant to FL. Stat. §626.8825(3)(e), unless prohibited by law, PBM will not prohibit a pharmacist from:

- 1. Offering mail or delivery services on an opt-in basis at the sole discretion of the covered person.
- 2. Mailing or delivering a prescription drug to a covered person upon his or her request.
- 3. Charging a shipping or handling fee to a covered person requesting a prescription drug be mailed or delivered if the pharmacy or pharmacist discloses to the covered person before the mailing or delivery the amount of the fee that will be charged and that the fee may not be reimbursable by the covered person's pharmacy benefit plan or program.

Pursuant to FL. Stat. §626.8825(3)(f), PBM will provide a Pharmacy with a list of pharmacy benefit plans or programs that include the Pharmacy in their network, upon request by the Pharmacy. PBM will provide this list no more frequently than every seven (7) business days.

Pursuant to FL. Stat. §626.8825(3)(g), PBM will ensure that the Electronic Remittance Advice contains claims level payment adjustments in accordance with the American National Standards Institute Accredited Standards Committee, X12 format, and includes or is accompanied by the appropriate level of detail for the Pharmacy to reconcile any debits or credits, including, but not limited to Pharmacy NCPDP or NPI

identifier, date of service, prescription number, refill number, adjustment code, if applicable, and transaction amount.

Pursuant to FL. Stat. §626.8825(3)(h), PBM shall provide a reasonable administrative appeal procedure to allow a pharmacy or pharmacist to challenge the maximum allowable cost pricing information and the reimbursement made under the maximum allowable cost as defined in §627.64741 for a specific drug as being below the acquisition cost available to the challenging pharmacy or pharmacist.

- 1. The administrative appeal procedure must include a telephone number and e-mail address, or a website, for the purpose of submitting the administrative appeal. The appeal may be submitted by the pharmacy or an agent of the pharmacy directly to PBM or through a pharmacy service administration organization. The pharmacy or pharmacist must be given at least 30 business days after a maximum allowable cost update or after an adjudication for an electronic claim or reimbursement for a nonelectronic claim to file the administrative appeal.
- 2. PBM must respond to the administrative appeal within 30 business days after receipt of the appeal.
- 3. If the appeal is upheld, PBM must:
  - a. Update the maximum allowable cost pricing information to at least the acquisition cost available to the pharmacy;
  - b. Permit the pharmacy or pharmacist to reverse and rebill the claim in question;
  - c. Provide to the pharmacy or pharmacist the national drug code on which the increase or change is based; and
  - d. Make the increase or change effective for each similarly situated pharmacy or pharmacist who is subject to the applicable maximum allowable cost pricing information.
- 4. If the appeal is denied, PBM must provide to the pharmacy or pharmacist the national drug code and the name of the national or regional pharmaceutical wholesalers operating in this state which have the drug currently in stock at a price below the maximum allowable cost pricing information.

Every 90 days, PBM shall report to the Florida Office of Insurance Regulation the total number of MAC appeals received and denied in the preceding 90-day period, with an explanation or reason for each denial, for each specific drug for which an appeal was submitted pursuant to this paragraph.

## INDIANA

The following provisions apply to Pharmacies located in the State of Indiana.

## MAC List and Appeals

Pursuant to IC 27-1-24.5-23, 760 IAC 5-4-1(a), Pharmacies can promptly access PBM's MAC costs and updates in a format that is readily available and accessible through PBM's Pharmacy portal. The MAC pricing information is available by:

- 1. Logging into PBM's pharmacy portal
- 2. Scroll down to MAC List for Pharmacies
- 3. Select link for date of MAC list pricing

Pursuant to IC 27-1-24.5-23, 760 IAC 5-4-1(a), PBM will provide Pharmacies a current list of the sources used to determine MAC pricing within ten (10) calendar days of the request, in a format that is readily available and accessible.

Pursuant to IC 27-1-24.5-22(a)(3)(A) and (B), PBM will update and make available to Pharmacies the PBM's MAC list at least every seven (7) days or in a timeframe agreed upon by PBM and the Pharmacy.

Pursuant to IC 27-1-24.5-22(a)(4)(B), PBM will not place a drug on its MAC list unless it is generally available for purchase by Pharmacies in Indiana from a national or regional wholesaler licensed in Indiana.

Pursuant to IC 27-1-24.5-22(b)(1) and 760 IAC 5-4-2(2), PBM will allow Pharmacies to file a MAC appeal within sixty (60) days of the Pharmacy's initial filing of a claim.

Pursuant to IC 27-1-24.5-22(b)(2), 760 IAC 5-4-2(2), PBM's MAC appeal procedure allows it to receive, process, investigate, and resolve MAC appeals within fourteen (14) calendar days.

Pursuant to IC 27-1-24.5-22(b)(3), in response to a MAC appeal that is unfavorable to a Pharmacy, PBM will provide the appealing Pharmacy with the reason for the denial and the national drug number of the prescription that is available from a national or regional wholesaler operating in Indiana.

Pursuant to IC 27-1-24.5-22(b)(4)(B),(C), and(E), if a MAC appeal is favorable to the Pharmacy, PBM will:

- 1. adjust the MAC of the drug for the appealing Pharmacy and for all other contracted Pharmacies in the same network that filled a prescription for patients covered under the same health plan benefit beginning on the initial date of services the appealed drug was dispensed;
- 2. notify each Pharmacy in its network that the MAC for the drug has been adjusted as a result of an appeal favorable to a Pharmacy;
- 3. allow the appealing Pharmacy and all other contracted Pharmacies in the network that filled prescriptions for patients covered under the same health plan to reverse and resubmit claims and receive payment based on the adjusted MAC from the initial date of services the appealed drug was dispensed.

## <u>Audits</u>

Pursuant to 760 IAC 5-3-2(a), neither PBM nor its contractor will audit a Pharmacy more than once per calendar year, unless an audit results in a finding of material noncompliance and the Pharmacy, in which case PBM may audit the Pharmacy within the same calendar year to assess ongoing compliance.

Pursuant to IC 27-1-24.5-22(b)(5); 760 IAC 5-3-3(2), (3), (4), (7), (8), and (9); 760 IAC 5-3-5; 760 IAC 5-3-6 PBM or its contractor will comply with the following procedures when conducting an audit:

- 1. Not use extrapolation or any similar methodology;
- 2. For clerical or record keeping errors, such as typographical error, scrivener's error, or computer error related to or contained in a document, PBM or its contractor will
  - a. Not consider such errors to constitute fraud without proof of intent to commit fraud;
  - b. Allow the Pharmacy to obtain a prescription that corrects a clerical error from a prescriber; and
  - c. Not recoup payment of the claim if the patient received the drug for which the claim was submitted.
- 3. Not pay the auditor based on a percentage of the amount recovered from the audit.
- 4. Allow a Pharmacy to recover underpayments;
- 5. Not recover overpayments on claims that are not actually audited and discovered to include a recoverable error;
- 6. Not base a finding of an overpayment or underpayment on a projection.
- 7. For claims requiring clinical or professional judgment, conduct the audit using or in consultation with an individual licensed in as a pharmacist in Indiana;
- 8. Limit the scope of the audit to clams that were submitted or adjudicated by the PBM within the prior twenty-four (24) months prior to the audit date, unless a broader scope is required by

federal or state law;

- 9. Permit a Pharmacy thirty (30) days to resubmit any claims disputed by the audit electronically.
- 10. For an on-site audit:
  - a. not schedule the audit during the first seven (7) calendar days of a month without prior voluntary consent of the Pharmacy;
  - b. provide written notice to the Pharmacy at least fourteen (14) calendar days before conducing the initial audit for each audit cycle;
  - c. instruct the auditor not to interfere with the delivery of Pharmacy services to a patient, use every effort to minimize inconvenience and disruption to Pharmacy operations during the audit;

Pursuant to 760 IAC 5-3-3(5), (6), (10) and (11), an auditor conducting a claims audit of Pharmacies for PBM will:

- 1. allow the use of written or otherwise transmitted hospital, physician, or other health practitioner records to validate a Pharmacy record;
- 2. perform the audit according to the same standards and parameters that the auditor uses to audit all other similarly situated pharmacies; and allow Pharmacies or Pharmacists to produce documentation to address a discrepancy found during the audit;
- allow a Pharmacy to, within twenty-four (24) hours of receiving notice of the audit, reschedule the audit for a date not more than fourteen (14) calendar days after the date proposed by the auditor. If the PBM or its contractor is unable to reschedule the audit within the fourteen (14) calendar day period, the auditor must select and reschedule the audit for a day after the fourteen (14) day period;
- 4. allow the Pharmacy to produce documentation to address a discrepancy found during the audit.

Pursuant to 760 IAC 5-3-4 and 5-3-9, PBM or its contracted auditor will provide an audited Pharmacy with the following written reports and appeals process:

- 1. Preliminary Audit Report
  - a. A preliminary audit report will be delivered to a Pharmacy within ninety (90) calendar days of completion of the audit.
    - i. The Pharmacy will permit PBM or its contractor a reasonable extension of this timeframe.
  - b. A preliminary audit report will include a written appeal procedure for the Pharmacy to follow to appeal adverse findings.
    - i. The appeal procedure will permit a Pharmacy at least thirty (30) calendar days after the pharmacy receives the preliminary audit report, during which the pharmacy may file an appeal of the findings in the preliminary audit report.
  - c. PBM or its contractor will allow Pharmacy an appeal of a preliminary audit report that satisfies the following requirements:
    - i. Pharmacy may submit an appeal request within thirty (30) calendar days after receipt of a preliminary audit report, with reasonable extensions permitted;
    - ii. The appeal process set forth in the preliminary audit report will include
      - 1. A written explanation of the PBM or its contractor's internal appeals process, including the name, address, and telephone number of the person or entity to whom an internal appeal should be addressed.
- 2. Final Audit Report
  - a. A final audit report will be delivered to the Pharmacy not later than one hundred twenty (120) calendar days after:

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- i. The preliminary audit report is received by the Pharmacy; or
- ii. The date a final appeal determination is made;
- iii. Whichever comes first.
- b. The final audit report delivered to the Pharmacy will reflect the outcome of claims from the preliminary report that were appealed by the Pharmacy.

Pursuant to 760 IAC 5-3-7, PBM or its contractor will comply with the following regarding recoupment of overpayments, payment of underpayments, and interest:

- 1. PBM or its contractor will not recoup funds until at least thirty (30) calendar days after a final audit report is provided to an audited Pharmacy, unless the audit findings are indicative of fraud, willful misrepresentation, or alleged serious abuse, in which case recoupment may occur sooner.
- 2. PBM or its contractor will remit all monies due to a Pharmacy as a result of an underpayment of a claim sooner than thirty (30) calendar days after the final audit report is delivered to the Pharmacy
- 3. PBM or its contractor will not calculate interest on underpayments and overpayments during the audit and appeal process.

## KENTUCKY

The following provisions apply to Pharmacies located in the State of Kentucky.

PBM shall Identify to Kentucky contracted Pharmacies the sources used to calculate the drug reimbursement paid for covered drugs available under the pharmacy health benefit plan administered by PBM pursuant to KRS 304.17A-162(1)(a). In the event that the commissioner receives a written complaint about PBM's MAC policies and procedures, the commissioner shall send a copy of the complaint to PBM and PBM must respond to the commissioner within fifteen (15) calendar days from the date of the commissioner's letter. At such time, the commissioner shall make a finding to PBM and the complainant as set forth in KRS 304.2-165.

PBM follows the process to appeal MAC pricing pursuant to KRS 304.17A-162(1)(a & b) and that an appeal grants result in pricing updates pursuant to KRS 304.17A-162(2).

PBM shall make available to all contracted Pharmacies information identifying the national drug pricing compendia or sources used to obtain the drug price data in a manner established by the Kentucky Department of Insurance.

PBM shall review and make necessary adjustments to the maximum allowable cost for every drug at least every seven (7) calendar days and shall immediately utilize the updated maximum allowable cost in calculating the payments made to all Kentucky contracted Pharmacies pursuant to KRS 304.17A-162(6). PBM shall make available the list of maximum allowable cost for every drug on PBM's Kentucky Pharmacy Provider Page which can be accessed through the PBM Pharmacy Provider Portal.

PBM provides a process for electronically requesting and transmitting Prior Authorizations for a drug by Providers that meet the requirement of the most recent NCPDP SCRIPT standards adopted by HHS.

## MISSISSIPPI

The following provisions apply to Pharmacies located in the State of Mississippi.

Pursuant to the Mississippi Pharmacy Practice Act:

 Prescription drugs shall be dispensed only pursuant to a valid prescription or a valid order. A pharmacist shall not dispense a prescription which the pharmacist knows or should know is not a valid prescription. A Prescription Drug Order, to be effective, must be issued for a legitimate medical purpose by a Practitioner acting within the course of legitimate professional practice.

A Prescription Drug Order shall contain the following information at a minimum:

- (1) full name and street address (if required by law) of the patient;
- (2) name, address, and, if required by law or rules of the Board, DEA registration number of the prescribing Practitioner;
- (3) date of issuance;
- (4) name, strength, dosage form, and quantity of Drug prescribed;
- (5) directions for use;
- (6) refills authorized, if any;
- (7) if a written Prescription Drug Order, prescribing Practitioner's signature;
- (8) if an electronically transmitted Prescription Drug Order, prescribing Practitioner's electronic or digital signature;
- 2. A Prescription Drug Order must be communicated directly to a Pharmacist, or when recorded, in such a way that the Pharmacist may review the Prescription Drug Order as transmitted. A prescription/order may be accepted by a pharmacist in written form, orally, or electronically unless the order is for a Schedule II controlled substance (refer to ARTICLE XIX) of these regulations. Electronically transmitted prescription drug orders shall meet the following requirements:
  - A. Electronically transmitted prescription drug order shall meet the following criteria:
    - (1) be transmitted only to the pharmacy of the patient's choice; and
    - (2) be transmitted by an authorized Practitioner or his or her designated agent provided that the identity of the transmitting agent is included in the order; and
  - B. Prescription drug orders transmitted by facsimile or computer shall include:
    - (1) The complete name, address, and DEA Registration Number of the practitioner if required;
    - (2) The transmitters telephone number or any other suitable means to contact the transmitter for verbal and/or written confirmation;
    - (3) The name, address, and age of the patient;
    - (4) The time and date of the transmission; and,
    - (5) The full name of the person transmitting the order; and
    - (6) The identity of the Pharmacy intended to receive the transmission, as well as any other information required by federal or state law.
  - C. An electronically transmitted drug order which meets the requirements of this ARTICLE shall be deemed the original order.
  - D. The pharmacist shall exercise professional judgment regarding the accuracy, validity, and authenticity of the transmitted prescription drug order consistent with federal or state laws and rules and regulations adopted pursuant to the same.
  - E. An electronically transmitted prescription/order from a prescriber to a pharmacist shall be considered a highly confidential transaction and the said transmission shall not be compromised by interventions, control, change, altering or manipulation by any other

person or parties in any manner whatsoever.

- F. Any pharmacist that transmits, receives or maintains any prescription or prescription refill either orally, in writing or electronically shall ensure the security, integrity and confidentiality of the prescription and any information contained therein.
- G. To maintain the confidentiality of patient and prescriber records, a computer system shall have security and system safeguards designed to prevent and detect unauthorized access, modification or manipulation of patient records. Once the drug has been dispensed, any alterations in prescription drug order data shall be documented to include the identification of the individual responsible for the alteration.
- H. Electronic transmission of prescription orders for controlled substances must comply with DEA Regulations.
- 3. Pharmacists must maintain complete and accurate records of all prescription drugs received, disposed of, or dispensed at a permitted facility.
- 4. A prescription may not be refilled without authorization. When refills are dispensed pursuant to authorization contained on the original prescription or when no refills are authorized on the original prescription but refills are subsequently authorized by the prescriber, the refill authorization shall be recorded on the original prescription document and the record of any refill made shall be maintained on the back of the original prescription document or on some other uniformly maintained record and the dispensing pharmacist shall record the date of the refill, the quantity of the drug dispensed and his/her initials; however, an original prescription for a controlled substance which contains no refill information may not be authorized to be refilled more than five (5) times or after six (6) months from the date of issuance. Authorization for any additional refill of a controlled substance prescription in excess of those refills originally authorized or after six (6) months from the date of issuance of the prescription shall be treated as a new prescription.
- 5. When filling a prescription or refilling a prescription which may be refilled, the pharmacist shall exercise professional judgment in the matter. Except as provided below, no prescription shall be filled or refilled with greater frequency than the approximate interval of time that the dosage regimen ordered by the prescriber would indicate, unless extenuating circumstances are documented which would justify a shorter interval of time before the filling or refilling of the prescription. For non-controlled maintenance medications only, a pharmacist, exercising his/her professional judgment, may dispense additional dosage units authorized by the prescriber on the original prescription including refills.
- 6. The pharmacist who fills or refills a prescription shall record the date of the dispensing and indicate his/her identity as the dispensing pharmacist on the prescription document or some other appropriate and uniformly maintained record. If this record is maintained on the original prescription document, the original dispensing and any refills must be recorded on the back of the prescription.
- 7. A prescription shall not be refilled after twelve (12) months from the date of issuance.
- 8. A prescription becomes invalid thirty (30) days after the prescriber/patient relationship is terminated. When the patient is no longer able to seek personal consultation or treatment from the prescriber the prescriber/patient relationship is terminated.

- 9. A written prescription document prepared by the prescriber or his agent must bear an original signature of the prescriber, facsimile stamps are not acceptable. When an oral prescription or the oral authorization for the refilling of a prescription is received which is transmitted by someone other than the prescriber, the name of the transmitter and the date of the transmission must be recorded on the original prescription document by the pharmacist receiving the transmission.
- 10. A pharmacist licensed by the Mississippi Board of Pharmacy may dispense a one-time emergency dispensing of a prescription of up to a seventy-two (72) hour supply of a prescribed medication in the event the pharmacist is unable to contact the prescriber to obtain refill authorization, provided that;
  - A. The prescription is not for a controlled substance;
  - B. In the pharmacist's professional judgment, the interruption of therapy might reasonably produce undesirable health consequences or may cause physical or mental discomfort;
  - C. The dispensing pharmacist notifies the prescriber or his agent of the emergency dispensing within seven (7) working days after the one-time emergency dispensing;
  - D. The pharmacist properly records the dispensing as a separate non-refillable prescription. Said document shall be filed as is required of all other prescription records. This document shall be serially numbered and contain all information required of other prescriptions. In addition, it shall contain the number of the prescription from which it was refilled; and
  - E. The pharmacist shall record on the new document the circumstances which warrant this emergency dispensing.

This emergency dispensing shall be done only in the permitted facility which contains the non-refillable prescription.

Pursuant to MS Code Ann. 73-21-155(3)(a), PBM will pay clean electronic claims within seven (7) days and clean paper claims within thirty-five (35) days.

# MONTANA

The following provisions apply to Pharmacies located in the State of Montana:

Pursuant to 33-22-173, MCA, PBM will respond to a Pharmacy's MAC appeal within ten (10) calendar days. A Montana Pharmacy may call PBM at 678-248-4740 to discuss the status of a MAC appeal.

After resolving a MAC appeal in favor of an appealing Pharmacy, PBM will make price adjustments to payments made to similarly situated pharmacies within three (3) days.

Pursuant to 33-22-174, MCA, PBM acknowledges that Pharmacies and pharmacists have discretion to decline to provide a brand-name drug, multisource generic drug, supply, or service if the reference pricing amount for the drug is less than the acquisition cost paid by the pharmacy or pharmacist. However, should a Pharmacy or its pharmacist decline to provide such a drug, the Pharmacy must to the best of its ability provide the customer seeking the drug with adequate information as to where the prescription for the drug, supply, or service may be filled.

Pursuant to 33-22-175, MCA, PBM will not charge or hold a Pharmacy responsible for a fee related to a claim under any of the following circumstances:

- 1. If the fee is not apparent at the time the claim is processed;
- 2. If the fee is not reported on the remittance advice of an adjudicated claim;
- 3. After the initial claim is adjudicated; or
- 4. If the Pharmacy and PBM did not clearly agree to the fee in an executed document.

Pursuant to 33-22-175, MCA, if PBM collects a performance-based fee from a Pharmacy, it will only do so if the Pharmacy fails to meet the criteria established by a pharmacy performance measurement entity and the fee will only be applied to the professional dispensing fee outlined in PBM's contract with the Pharmacy and will not be imposed on the cost of goods sold by the Pharmacy.

Pursuant to 33-22-176, MCA, if a patient pays a copayment, PBM will permit the dispensing Pharmacy to retain the adjudicated reimbursement, and PBM will not alter the adjudicated reimbursement.

Pursuant to 33-22-177(1), MCA, PBM will not prohibit a Pharmacy or its pharmacists from:

- 1. Participating in a class-action lawsuit;
- 2. Disclosing to the plan sponsor or the patient information regarding the adjudicated reimbursement paid to the Pharmacy made in accordance with HIPAA;
- Providing relevant information to a patient about the patient's prescription drug order, including, but not limited to the cost and clinical efficacy of a more affordable alternative drug if one is available;
- 4. Mailing or delivering a prescription drug to a patient as an ancillary service of a Pharmacy, if such practice is not prohibited by state or federal law;
- 5. Charging a shipping and handling fee to a patient who has asked that a prescription be mailed or delivered, if such practice is not prohibited by state or federal law.

Pursuant to 33-22-177(2), MCA, PBM will not require pharmacy accreditation standards or recertification requirements inconsistent with, more stringent than, or in addition to federal and state requirements of licensure as a Pharmacy in Montana.

Pursuant to 33-22-177(3), MCA, PBM will not prohibit a Pharmacy that belongs to a PSAO from receiving a copy of a pharmacy services contract between the PBM and the Pharmacy's PSAO.

Pursuant to 33-22-177(5), MCA, PBM will do the following:

- 1. Offer a Pharmacy or a PSAO an opportunity to renew an existing contract minimally once every three (3) years;
- Allow a Pharmacy or a PSAO to terminate a pharmacy services contract upon a ninety (90) days' notice to PBM;
- 3. Not amend its pharmacy services agreement without an amendment signed by both PBM and the Pharmacy or PSAO.

In accordance with 33-22-173, MCA, PBM will allow Pharmacies and PSAOs to submit appeals in groups or batches.

#### NEBRASKA

The following provisions apply to Pharmacies located in the State of Nebraska:

MAC Price List, pursuant to R.R.S. Neb. §§ 44-4608(1)-(3)

1. PBM shall:

- A. Maintain its MAC list and a historical record of its MAC pricing list changes on its pharmacy portal in a readily accessible format (R.R.S. Neb. § 44-4608(1)(c));
- B. Investigate and resolve MAC price appeals within 7 business days following receipt (R.R.S. Neb. § 44-4608(3)(b))
- C. Maintain a procedure to eliminate a product from the maximum allowable cost price listed in a timely manner to remain consistent with any change in the market place. (R.R.S. Neb. § 44-4608(1)(b)
  - PBM's MAC tables are updated through the execution of a MAC manager program. The program is run weekly. Once the updated MAC table is created it is sent to PBM's information technology department and uploaded onto the Pharmacy portal.
- 2. PBM's MAC manager program includes all substitutable generic National Drug Codes ("NDC").

MAC Appeals pursuant to R.R.S. Neb. § 44-4608(3) and (4)

- 1. Process
- 2. Pharmacy has fifteen (15) business days to appeal an initial claim submission. R.R.S. Neb. § 44-4608(3)(a)
- 3. PBM will investigate and resolve a MAC appeal within seven (7) business days after the appeal is resolved. R.R.S. Neb. § 44-4608(3)(b)
- 4. Denial of Appeal: PBM will provide a reason for any denial of an appeal and identify the national drug code for the drug that may be purchased by the pharmacy at a price at or below the price on PBM's MAC list. R.R.S. Neb. § 44-4608(3)(c)
- 5. Valid Determination, pursuant to R.R.S. Neb. § 44-4608(4): If PBM determines that a MAC appeal is valid it shall:
  - a. Make an adjustment to the drug price no later than one day after the appeal is resolved;
  - b. Permit the appealing pharmacy to reverse and rebill the claim in question, using the date of the original claim.

Gag Clause Prohibitions, pursuant to R.R.S. Neb. §§ 44-4606 and 4606

- 1. PBM will not restrict or penalize Pharmacies and pharmacists from disclosing to any Covered Person any health information that the Pharmacy Provider deems appropriate regarding:
  - A. The nature of treatment, risks, or an alternative to such treatment; R.R.S. Neb. §§ 44-4606(1)(a)
  - B. The availability of an alternate therapy, consultation, or test; R.R.S. Neb. §§ 44-4606(1)(b)
  - C. The decision of a utilization reviewer or similar person to authorize or deny a service; R.R.S. Neb. § 44-4606(1)(c)
  - D. The process that is used to authorize or deny a healthcare service or benefit; R.R.S. Neb. § 44-4606(1)(d) or
  - E. Information on any financial incentive or structure used by the health carrier R.R.S. Neb. § 44-4606(1)(e).
- PBM will not prohibit Pharmacies and pharmacists from discussing information regarding the total cost for a pharmacist's services for a prescription drug or from selling a more affordable alternative to the Covered Person if a more affordable alternative is available (R.R.S. Neb. § 44-4608(2));
  - A. Pursuant to R.R.S. Neb. § 44-4606(5)(a), PBM will permit Covered Persons to purchase a covered prescription drug at an amount greater than the lesser of the Covered Person's cost-sharing amount under the terms of their health benefit plan or the amount the Covered Person would pay for the drug if the Covered Person were paying the cash price,

unless the pharmacist discloses trade secret information;

- 3. Pursuant to R.R.S. Neb. § 44-4606(5)(b), PBM will permit any amount paid by a Covered Person to be attributable toward any deductible, or other out-of-pocket maximum under the Covered Person's health benefit plan.
- 4. Pursuant to R.R.S. Neb. §§ 44-4606(3), PBM will permit pharmacists and Pharmacies to disclose information to the Nebraska Director of the Department of Insurance, law enforcement, or a state or federal government official, provided that:
  - A. The recipient of the information represents that such recipient has the authority, to the extent provided by state or federal law, to maintain proprietary information as confidential; R.R.S. Neb. § 44-4606(3)(a) and
  - B. Prior to the disclosure of information designated as confidential, the Pharmacy or pharmacist:
    - (1) Marks as confidential any document in which the information appears; or
    - (2) Requests confidential treatment for any oral communication of the information (R.R.S. Neb. § 44-4606(3));
- 5. Pursuant to R.R.S. Neb. § 44-4606(4), PBM will not terminate a Pharmacy's Participating Pharmacy Agreement or penalize a pharmacist or Pharmacy due to the pharmacist or Pharmacy:
  - A. Disclosing information about PBM, except information determined to be a trade secret, as determined by state law or the Nebraska Director of the Department of Insurance; or
  - B. Sharing any portion of PBM's contract with the Nebraska Director of the Department of Insurance pursuant to a complaint or query regarding whether the contract is in compliance with the Pharmacy Benefit Manager Licensure and Regulation Act.

## 340B-R.R.S. Neb. § 44-4609

- PBM shall not reimburse a 340B entity or the 340B contract pharmacy for the pharmacydispensed drug at a rate lower than that paid for the same drug to similarly situated pharmacies that are not 340B entities or 340B contract pharmacies, and shall not assess any fee, chargeback, or other adjustment upon the 340B entity or 340B contract pharmacy on the basis that the 340B entity or 340B contract pharmacy participates in the 340B program. R.R.S. Neb. § 44-4609(1)
- 2. PBM will not discriminate against a 340B entity or 340B contract pharmacy in a manner that prevents or interferes with a covered individual's choice to receive such drug from the corresponding 340B entity or 340B contract pharmacy. R.R.S. Neb. § 44-4609(2)

Claim Audits, pursuant to R.R.S. Neb. § 44-4607

- 1. PBM has the right to audit claims in accordance with the audit parameters set forth in R.R.S. Neb. §44-4607.
- 2. With regard to audits performed by PBM or its designated auditor, PBM or its designated auditor will:
  - A. Provide the Pharmacy advanced notice of fifteen (15) business days before conducting an initial on-site audit (R.R.S. Neb. § 44-4607(1)(a));
  - B. Ensure that audits involving clinical or professional judgment are conducted by or in consultation with a pharmacist (R.R.S. Neb. § 44-4607(1)(b));
  - C. Ensure that audits for similarly situated Pharmacies are conducted under the same standards and parameters (R.R.S. Neb. § 44-4607(1)(c));
  - D. Refrain from conducting audits on claims that were submitted more than twenty-four (24) months from the date the claims were submitted, unless a longer period is required by state or federal law (R.R.S. Neb. § 44-4607(2)(a));

- E. Use a statistically reliable sample size if the audit includes a random sampling of claims (R.R.S. Neb. § 44-4607(2)(b));
- F. Provide the Pharmacy with a masked list containing the prescription numbers or date range of claims being used for an audit (R.R.S. Neb. § 44-4607(2)(c));
- G. Instruct auditors not to enter any area of the Pharmacy where patient-specific information is available without being escorted by an employee of the Pharmacy and, to the extent possible, each auditor shall remain out of the sight and hearing range of any Pharmacy customer (R.R.S. Neb. § 44-4607(2)(e)); and
- H. Refrain from performing on-site audits during the first five (5) business days of the month without consent from the Pharmacy (R.R. S Neb. § 44-4607(2)(d)).
- 3. Where contractually required, PBM will provide a copy of the audit, including a list of the plan sponsor's claims that were included in the audit, and any recouped money shall be returned to the health benefit plan or plan sponsor. R.R.S. Neb. § 44-4607(7)

Interest, recoupment, remits related to audits, pursuant to R.R.S. Neb. § 44-4607

- PBM will not allow interest on claims to accrue during the audit period for either party, beginning with the notice of the audit and ending with the final audit report. R.R.S. Neb. § 44-4607
- 2. Pursuant to R.R.S. Neb. § 44-4607(2)(h), PBM may assess a recoupment of a claim when the information is not written on a prescription if:
  - A. Such information is required in the provider manual; or
  - B. The information is required by the federal Food and Drug Administration or the drug manufacturer's product safety program.
- 3. Neither PBM nor its designated auditor will receive payment or pay any person involved in an audit based on a percentage of any recoupment from the audit. R.R.S. Neb. § 44-4607(2)(i)
- 4. PBM will not deduct from or apply a recoupment against future remittance for the Pharmacy until after the appeal process and both the Pharmacy and PBM receive the results of the final audit. R.R.S. Neb. § 44-4607(2)(f)
- 5. Pursuant to R.R.S. Neb. § 44-4607(3), before effectuating a recoupment, PBM will:
  - A. Include consumer-oriented parameters based on manufacturer listings in the audit parameters; R.R.S. Neb. § 44-4607(3)(a)
  - B. Consider the Pharmacy's usual and customary price for a compounded medication as the reimbursable cost, unless the pricing method is outlined in the Participating Provider Agreement; R.R.S. Neb. § 44-4607(3)(b)
  - C. Base a finding of overpayment or underpayment on the actual overpayment or underpayment and not a projection that relies on the number of patients served who have a similar diagnosis, the number of similar orders, or the number of refills for similar drugs; R.R.S. Neb. § 44-4607(3)(c)
  - D. Not use extrapolation to calculate the recoupment or penalties, unless required by state or federal law; and R.R.S. Neb. § 44-4607(3)(d)
  - E. Not include a dispensing fee in the calculation of an overpayment, unless a prescription was not actually dispensed, the prescriber denied authorization, the prescription dispensed was a medication error by the Pharmacy, or the identified overpayment is solely based on an extra dispensing fee. R.R.S. Neb. § 44-4607(3)(e)
- PBM will not consider any clerical or record-keeping error, such as a typographical error, scrivener's error, or computer error, regarding a required document as fraud without further substantiation. PBM has discretion to recoup payment for any such error. R.R.S. Neb. § 44-4607(3)(f)
- 7. PBM will not assess any recoupment in the case of an error that has no actual financial harm

to the Covered Person or health benefit plan. An error that is the result of the Pharmacy's failure to comply with a formal corrective action plan may be subject to recoupment. R.R.S. Neb. § 44-4607(3)(g)

8. PBM will not allow interest to accrue during the audit period for either party, beginning with the notice of the audit and ending with the final audit report. R.R.S. Neb. § 44-4607(3)(h) PBM will remit any money due to a Pharmacy or pharmacist as a result of an underpayment of a claim within forty-five (45) days after the appeal process has been exhausted and the final audit report has been issued.

Documentation reviewed for audits, pursuant to R.R.S. Neb. § 44-4607(2) and (4)

- PBM will accept an authentic and verifiable statement or record, including a medication administration record of a nursing home, assisted-living facility, hospital, physician, or other authorized practitioner or an additional audit documentation parameter located in the Pharmacy's manual to validate the pharmacy and the delivery of a pharmacy service (R.R.S. Neb. § 44-4607(4)(a)).
- 2. PBM will permit any legal prescription that meets the requirements in R.R.S. Neb. § 44-4607 in connection with a prescription, refill, or change in prescription, including a medication administration record, fax, e-prescription, or documented telephone call from the prescriber to the prescriber's agent to validate a claim. R.R.S. Neb. § 44-4607(4)(b)
- 3. PBM will refrain from requiring information be written on a prescription, unless such information is required to be written on the prescription by state or federal law (R.R.S. Neb. § 44-4607(2)(g).

Audit Reports—R.R.S. Neb. § 44-4607(6)

- 1. A preliminary audit report shall be delivered to the pharmacy within one hundred twenty (120) days after the conclusion of an audit. R.R.S. Neb. § 44-4607(6)(a)
- A pharmacy shall be allowed at least thirty (30) days following receipt of a preliminary audit report to provide documentation to address any discrepancy found in the audit. R.R.S. Neb. § 44-4607(6)(b)
- 3. A final audit report shall be delivered to the pharmacy within one hundred twenty (120) days after receipt of the preliminary audit report or the appeal process has been exhausted, whichever is later. R.R.S. Neb. § 44-4607(6)(c)
- 4. An auditing entity shall remit any money due to a pharmacy or pharmacist as the result of an underpayment of a claim within forty-five (45) days after the appeal process has been exhausted and the final audit report has been issued. R.R.S. Neb. § 44-4607(6)(d)

## **NEW JERSEY**

The following provisions apply to Pharmacies located in the State of New Jersey:

Pursuant to NJRS 17B:27F-4, Pharmacy appeals of brand and multiple source generic drug pricing will be handled by PBM as follows:

- 1. Pharmacy has fourteen (14) calendar days to submit an appeal following submission of the initial claim.
- 2. PBM has fourteen (14) calendar days from the date it receives the appeal from the Pharmacy to investigate and resolve the appeal through its internal processes.
- 3. Pharmacy may contact PBM and speak with an individual involved in the appeal by calling 678-248-4740.

- 4. If PBM denies the appeal, PBM will:
  - a. Provide the reason for the denial to the PSAO and its contracted Pharmacies;
  - b. Provide the reason for the denial directly to the appealing Pharmacy;
  - c. Identify the national drug code of a drug product that is available for purchase by the specific Pharmacy that submitted the appeal from a wholesaler registered in New Jersey at a price which is equal to or less than the maximum allowable cost or the brand effective rate, generic effective rate or other pricing for the appealed claim;
  - d. Provide the name of wholesalers registered in New Jersey from which the appealing Pharmacy can obtain the brand or multiple source generic drug at or below the brand effective rate, generic effective rate, dispensing fee effective rate, maximum allowable cost or any other pricing formula used by PBM for Pharmacy reimbursement.

5. If PBM approves the appeal, PBM will make the price correction, permit the reporting pharmacy to reverse and rebill the appealed claim, and make the price correction effective for all similarly situated Pharmacies from the date the appeal is approved.

6. PBM will not terminate a Pharmacy licensed in the State of New Jersey solely on the basis that the Pharmacy offers and provides store direct delivery and mail prescriptions to an insured as an ancillary service.

## TENNESSEE

The following provisions shall apply to Pharmacies in the State of Tennessee:

Pursuant to TCA § 56-7-3206 and Tenn. Comp. R. & Regs. Ch. 0780-01-95:

Definitions:

- 1. "Actual Cost" means the amount a Pharmacy paid as evidenced by documentation that includes, but is not limited to, the invoice price minus discounts, price concessions, rebates or other reductions, but not including a Cash Discount.
- 2. "Allowed Amount" means the cost of a prescription drug or device after applying PBM's or the Covered Entity's pricing discounts available at the time of the prescription claim translation.
- 3. "Cash Discount" means a deduction from the invoice paid by a Pharmacy for a prescription drug or device if the invoice is paid on or before a specified date or in cash.
- 4. "Commissioner" means the commissioner of the Department or the commissioner's designee.
- 5. "Department" means the Tennessee Department of Commerce and Insurance.
- 6. "Initial Appeal" means the process required under T.C.A. § 56-7-3206(c)(2) and administered by PBM by which a Pharmacy, or a pharmacy services administrative organization acting on behalf of a Pharmacy, may appeal a reimbursement received from PBM that is not at least the Actual Cost to the Pharmacy for a prescription drug or device.
- 7. "Majority Wholesaler" means the wholesaler from whom a Pharmacy purchased the majority of its prescription pharmaceutical products for resale in the calendar year preceding the calendar year during which the claim that is the subject of an Initial Appeal is processed.
- 8. "Pharmacy" means pharmacy as defined in T.C.A. § 56-7-3102 and includes an agent acting on behalf of a pharmacy, including but not limited, to a pharmacy services administrative organization that is also a Network Pharmacy as defined above.
- 9. "Similarly Situated Pharmacy" means a Pharmacy in PBM's pharmacy network that purchases a particular drug or medical product or device to which the finding applies from the same pharmaceutical wholesaler as the Pharmacy that prevailed in an Initial Appeal; and to which PBM

applies the challenged rate of reimbursement or Actual Cost.

This section applies when a Pharmacy files an Initial Appeal asserting that PBM did not reimburse the Pharmacy for a prescription drug or device at an amount that is equal to or greater than the Pharmacy's Actual Cost.

- 1. The Pharmacy will include with its appeal a copy of invoice(s) demonstrating the Pharmacy's Actual Cost as of the date of filing the Initial Appeal.
- 2. Consideration of discounts, price concessions, rebates or other reductions in drug or device price reductions, excluding Cash Discounts, received by the Pharmacy:
  - A. **At the time of the appeal.** The Pharmacy will provide PBM with information regarding any discounts, price concessions, rebates, or other reductions, excluding Cash Discounts, during the pendency of an Initial Appeal, the Pharmacy received for the drug or device.
  - B. **During the pendency of the appeal**. The Pharmacy will notify PBM during the pendency of the Initial Appeal of any additional discounts, price concessions, rebates, or other reductions, excluding Cash Discounts that it receives for the drug or device.
  - C. After conclusion of the appeal. Additional discounts, price concessions, rebates, or other reductions received after the resolution of an Initial Appeal will not be grounds for reconsideration of any Initial Appeal previously considered and resolved.
- 3. When submitting an Initial Appeal, the Pharmacy will provide PBM with:
  - A. The name and contact information of the wholesaler or manufacturer from which it purchased the prescription drug or device at issue.

(1) If PBM denies an Initial Appeal as otherwise permitted by law or Tennessee regulation and the Pharmacy fails to provide this information, PBM may presume the prescription drug or device at issue is available at a lower cost from the wholesaler or manufacturer from which the Pharmacy purchased the prescription drug or device at issue.

(2) Failure of the Pharmacy to provide this information will not constitute grounds for PBM to deny an Initial Appeal.

- 4. PBM may consider additional discounts, price concessions, rebates or other reductions in the price paid by the Pharmacy, when calculating the Pharmacy's Actual Cost.
- 5. If the Pharmacy prevails in its appeal:
  - A. PBM will:

(1) Provide the Pharmacy with a written statement granting the appeal with a summary outlining the basis for its decision;

(2) Notify the Pharmacy in writing that it has adjusted the challenged rate of reimbursement;

(3) Provide detailed written instructions for how to reverse and rebill the claim upon which the Initial Appeal was based;

(4) Reimburse the Pharmacy for at least Actual Cost;

(5) Make the necessary change to the challenged rate or reimbursement or Actual Cost;

(6) Permit the appealing pharmacy to reverse and rebill the claim;

(7) Pay or waive the cost of any transaction fee required to reverse and rebill the claim: and

(8) Provide the Pharmacy or its agent with the national drug code number for the drug on which the change is based.

B. PBM will apply the findings from the Initial Appeal to Similarly Situated Pharmacies as the rate of reimbursement and actual price for the drug, medical produce, or device.

(1) Within seven (7) business days of resolution of an Initial Appeal, PBM will apply the findings of an Initial Appeal retroactively to all Similarly Situated Pharmacies that received the challenged rate of reimbursement for the drug or medical product, or device was at issue in the Initial Appeal, including any appeals pending where the challenged rate of reimbursement is the subject of the Initial Appeal by:

(i) Notifying all Similarly Situated Pharmacies of the adjusted rate of reimbursement in writing. The written notice will contain the applicable national drug code number or the unique device identifier at issue, as appropriate, and the rate of reimbursement to which the Similarly Situated Pharmacy is now entitled for the drug or medical product or device; and

(ii) Paying all Similarly Situated Pharmacies the difference in the original rate of reimbursement the Similarly Situated Pharmacy received and the adjusted rate of reimbursement that resulted from the Initial Appeal resolved in favor of a pharmacy. PBM will not charge any fees or require any additional documentation from Similarly Situated Pharmacies for reimbursement at the price determined during the Initial Appeal.

(2) The findings from an Initial Appeal resolved in favor of a Pharmacy shall be applied retroactively by applying the adjusted rate to all Similarly Situated Pharmacies beginning on the date of services of the claim that was the subject of the Initial Appeal and continuing to apply that rate going forward until the appealing pharmacy and the Similarly Situated Pharmacy or Pharmacies were no longer entitled to the same rate of reimbursement for the drug or medical product or device at issue.

(3) PBM will track Initial Appeals such that it can reasonably determine if an adjusted rate of reimbursement applies.

6. If the Initial Appeal is resolved against the Pharmacy:

A. PBM will provide:

(1) A written statement that the Initial Appeal is denied, along with a summary outlining the basis for its decision;

(2) If applicable, evidence PBM has adjusted the challenged rate of reimbursement;

(3) If applicable, detailed instructions for how to reverse and rebill the claim upon which the Initial Appeal is based; and

(4) Instructions on how to make an external appeal of PBM's decision to the Commissioner by:

(i) Explaining how to submit an appeal, including the appropriate phone number or website address for the Department where appeals are accepted.

(a) PBM is responsible for ensuring that the information provided to Pharmacies regarding appeals with the Department are accurate; and

(b) PBM will include the following statement with instructions on how to make and external appeal: "Pursuant to T.C.A. § 56-7-3206(g)(2), you have the right to appeal this decision to the Commissioner of the Tennessee Department of Commerce and Insurance."

B. PBM will determine whether the product associated with a national drug code number or the unique device identifier is available at a cost that is less than the challenged rate of reimbursement from a pharmaceutical wholesaler in Tennessee, within seven (7) business days after receiving notice of the appeal, PBM will provide the Pharmacy or its agent with:

(1) The name of the national or regional pharmaceutical wholesalers operating in this state that have the particular drug or medical product or device currently in stock at a price that is less than the amount of the challenged reimbursement; and

(i) A drug, medical product, or device shall be deemed available if, at the

time the Initial Appeal was received by PBM, the product was in stock with a wholesaler operating in Tennessee.

(ii) If after reasonable effort PBM is unable to make a determination of whether the drug, medical product, or device was reimbursed at or above the Pharmacy's Actual Cost because the wholesalers contacted by PBM failed to provide the information needed by PBM within the timeframe within which PBM must resolve Initial Appeals, PBM shall presume that the product associated with the national drug code number or unique device identifier at issue was not available at a cost that is less than the challenged rate of reimbursement from a pharmaceutical wholesaler in Tennessee as of the date the Initial Appeal was received from the appealing Pharmacy.

(iii) If PBM does not provide the Pharmacy with a determination that the drug, medical product, or device is available from a pharmaceutical wholesaler in Tennessee within seven (7) business days after receiving the appeal, it shall be deemed to have determined there is no pharmaceutical wholesaler operating in this state that offered the product associated with the national drug code number or unique device identifier at issue at a coat that is less than the challenged rate of reimbursement as of the date the Initial Appeal was received from the appealing Pharmacy.

(2) The national drug code number for a drug or the unique device identifier for a device.

C. The Pharmacy will provide PBM with the name of its Majority Wholesaler.

(1) PBM will then determine whether the prescription drug or device at issue is available from the pharmaceutical wholesaler at a cost that is less than the challenged rate of reimbursement as of the date the Initial Appeal was received from the appealing Pharmacy.

(i) If, after contacting the Pharmacy's Majority Wholesaler, PBM is unable to make the determination because the wholesaler failed to provide the information needed by PBM within the timeframe within which PBM must resolve Initial Appeals, PBM will presume that the product associated with the national drug code number of unique device identifier at issue was not available at a cost that is less than the challenged rate of reimbursement from the wholesaler as of the date the Initial Appeal was received from the appealing Pharmacy.

(2) If the Pharmacy fails to provide the name of its Majority Wholesaler within two (2) business days of a request by PBM to provide that name, PBM may presume the prescription drug or device at issue is available at a cost that is less than the challenged rate of reimbursement from the Pharmacy's Majority Wholesaler and take no further action.

(3) If the product associated with the national drug code number or unique device identifier at issue shall be deemed available if, at the time the Initial Appeal was received by PBM, the product was in stock from the Pharmacy's wholesaler.

(4) PBM will not deny an Initial Appeal because the Pharmacy or its Majority Wholesaler did not provide PBM with the name of its Majority Wholesaler, or the Pharmacy's Majority Wholesaler did not provide PBM with the information requested.

D. If the product associated with the national drug code number or unique device identifier is not available at a cost that is less than the challenged rate of reimbursement from the pharmaceutical wholesaler from whom the Pharmacy purchases the majority of prescription pharmaceutical products for resale, then PBM will adjust the challenged rate of reimbursement to an amount equal to or greater than the appealing pharmacy's Actual Cost and permit the Pharmacy to reverse and rebill each claim affected by the inability to procure the pharmaceutical product at a cost a cost that is equal to or less than the previously challenged rate of reimbursement. PBM will pay or waive the cost of any transaction fee required to reverse and rebill the claim.

- E. PBM will not include within the amount calculated to reimburse a Pharmacy for Actual Cost the amount of any professional dispensing fee that is payable to the Pharmacy.
- F. PBM will follow this appeals process for drugs, medical products, or devices for which a Pharmacy asserts it did not receive reimbursement from PBM sufficient to cover its Actual Cost, even if PBM has another basis for denying the appeal.
- G. If the Pharmacy's Initial Appeal is resolved against the appealing pharmacy, and PBM determines that the Pharmacy was entitled to reimbursement at Actual Cost for a drug, medical product, or device, PBM will apply its determination to Similar Situated Pharmacies as though the Pharmacy prevailed in its Initial Appeal.

a. PBM will notify Similarly Situated Pharmacies within seven (7) business days after it receives a Pharmacy's Initial Appeal regarding reimbursement for Actual Cost of a drug, medical product, or device.

- 7. Records retention for Initial Appeals.
  - A. PBM will retain all records related to an Initial Appeal for the greater of five (5) years or until PBM is audited by the Department.
- 8. PBM will not assess any costs to a Pharmacy for any services provided by PBM in connection with an Initial Appeal.
- 9. An Initial Appeal will not result in a Pharmacy, whether the appealing Pharmacy or a Similarly Situated Pharmacy, being required to reimburse or refund PBM any portion of a payment previously received by the Pharmacy.
- 10. Timing and notice requirements of Initial Appeal processes. PBM's Initial Appeal process, or a Pharmacy's participation in an Initial Appeal must meet the following requirements:
  - A. The Pharmacy must file its Initial Appeal within seven (7) business days of its submission of the initial claim for reimbursement for the drug or medical product or device.
  - B. PBM must make a final determination resolving the Pharmacy's Initial Appeal within seven (7) business days of PBM's receipt of an initial appeal that includes the following timeline:

(1) The timeline begins after PBM has received all required information sufficient to allow PBM to conduct a complete analysis of the Initial Appeal.

(2) PBM will be deemed to have all required information sufficient to allow PBM to conduct a complete analysis of the Initial Appeal upon receipt of:

(a) A complete version of either an Initial Appeal form provided by the Commissioner to be used by a Pharmacy to file an Initial Appeal or PBM's appeal form submitted and approved by the Department; and

(b) Certification from the Pharmacy that it has provided PBM with all invoices or other records demonstrating the Pharmacy's Actual Cost for the drug or medical product or device at issue, which shall take into account all discounts, price concessions, rebates or other reductions received as of the date the Pharmacy filed its Initial Appeal.

- C. If PBM receives an initial appeal from a Pharmacy that does not contain all information required in Section B above, PBM will accept the incomplete Initial Appeal and hold it open pending receipt of additional information from the Pharmacy.
- D. PBM may not delay the start of its review of an Initial Appeal by:

(1) Requiring additional or different information from a Pharmacy beyond what is required to be submitted to PBM under its Initial Appeal process approved by the commissioner; or

(2) Basing the delay on administrative or non-substantive errors or omissions in any of the filings that does not affect the overall validity of the Initial Appeal.

E. If PBM does not comply with the timing and notice requirements set forth above, the Pharmacy's Initial Appeal will be resolved by PBM in favor of the Pharmacy.

- F. If the Pharmacy does not comply with the timing requirements set forth above, PBM may deny the Initial Appeal.
- G. PBM's Initial Appeal process is available on its secure website, which includes all deadlines applicable to its Initial Appeal process, a description of the steps contained within its initial appeal process, and clearly state that its Initial Appeal process is available for all prescription drugs or devices in Tennessee for which a Pharmacy alleges it did not receive its Actual Cost.

## UTAH

The following provisions shall apply to Pharmacies located in the State of Utah:

Pursuant to UCA §31A-46-303(5), MAC appeals to PBMs must comply with the following provisions:

- 1. A Pharmacy may submit a MAC appeal for up to twenty-one (21) days following the initial claim adjudication;
- 2. PBM will investigate and resolve Pharmacy MAC appeals within fourteen (14) business days;
- If PBM denies a MAC appeal, PBM will provide Pharmacy with (1) the reason for the denial and
   (2) the national drug code of the drug that may be purchased by Pharmacy at a price at or below the price determined by PBM.

## **Pharmacy Audits and Audit Appeals**

## Audit Process

Pursuant to UCA §31A-46-303(1) and UCA 58-17b-622(2), (3) and (6), PBM or its contractor will perform audits of Pharmacies located in Utah consistent with this Pharmacy Manual and in accordance with the following requirements.

- 1. PBM or its contractor will require Pharmacies to submit records and other documents requested as part of an audit within thirty (30) calendar days of the date the Pharmacy received the audit request.
- 2. A pharmacist who is consulted for an audit involving clinical or professional judgment will be licensed by a state in the United States.
- For onsite audits, Pharmacy will receive written notice of the audit ten (10) days in advance of the audit that contains a range of the prescription numbers or date ranges included in the audit. Onsite audits will not be performed during the first five (5) business days of the month, unless Pharmacy agrees.
- 4. The audit will only include claims submitted by Pharmacy within the eighteen (18) months prior to the date of the audit, unless (1) federal law requires the audit include older claims, or (2) the originating prescription is dated in the preceding six (6) months.
- 5. Audits will not be conducted more frequently than annually and will be limited to two hundred (200) prescription claims.
- 6. PBM or its contracting entity will not, after the audit completion date, request additional records or other documents from the pharmacy before issuing a preliminary audit report.

These requirements do not apply to an audit of pharmacy records for a federally funded prescription drug program, or when PBM alleges fraud or other intentional and willful misrepresentation and PBM has evidence that the Pharmacy's actions reasonably indicate fraud or intentional and willful misrepresentation.

Pursuant to UCA §58-17b-622(4), (5) and (10), PBM or its contractor will assess potential overpayments and recoupments subject to the following limitations:

- 1. Dispensing fees will not be included in the calculations of overpayments unless the prescription is considered a misfill;
- Recoupment amounts will not include prescription clerical or recordkeeping errors, including typographical errors, scrivener's errors, and computer errors on a required document or record, unless PBM or its contractor alleges fraud or other intentional or willful misrepresentations and there is evidence that the Pharmacy's actions reasonably indicate fraud or intentional and willful misrepresentation.
- 3. Recoupment amounts will not include emergency refills unless the prescription dispensed by Pharmacy is not covered by the patient's health benefit plan.
- 4. Funds, charge-backs, or penalties will not be collected until the audit and all appeals are final, unless there is evidence that is reasonably indicative of fraud or intentional and willful misrepresentation, and the PBM or its contractor alleges fraud or other intentional or willful conduct.
- 5. Neither PBM nor its contractor will recoup or collect any funds, charge-backs, or penalties in response to an audit request until the Pharmacy confirms the date it received the audit request.
- 6. Unless required by state or federal law, PBM will only supply a copy of a previous audit of a Pharmacy to an auditor, if the auditor conducting the audit performed the previous audit.
- 7. PBM and its contractor will permit a Pharmacy to validate a claim for a prescription, refill, or change in a prescription with:
  - a. Electronic or physical copies of records of a health care facility, or a health care provider with prescribing authority;
  - b. Any prescription that complies with state law; and
  - c. The Pharmacy's own physical records, or valid copies of the physical or electronic records of a practitioner or healthcare facility.
- 8. Neither PBM nor its contractor will require Pharmacy to provide the following records to validate a claim for a prescription, refill, or change in a prescription:
  - a. If the prescription was handwritten, the physical handwritten version of the prescription; or
  - b. A note from the practitioner regarding the patient for a prescription that is not otherwise required for a prescription under state or federal law.

# Preliminary Audit Report

Pursuant to UCA §58-17b-622(6), PBM or its contractor will issue a preliminary audit report to Pharmacy within thirty (30) calendar days of receiving all records and documents requested from the Pharmacy as part of an audit. PBM or its contractor will:

- 1. Deliver the preliminary audit to the Pharmacy or its corporate office of record.
- 2. Include in the preliminary audit letter notation and a detailed explanation for each suspected error.
- 3. Allow the Pharmacy thirty (30) calendar days following receipt of the preliminary audit letter to respond to questions in the report, provide additional documentation, and comment on and clarify findings of the audit. The date of a Pharmacy's receipt of a preliminary audit report will be determined by the postmark or other evidence of mailing or the date the preliminary audit was electronically transmitted to the Pharmacy, whichever occurs first.
  - a. PBM or its contractor may grant a reasonable extension of this deadline upon request by the Pharmacy.

## **Confidential & Proprietary**

4. For the purpose of an audit, presume records maintained by the Pharmacy are valid.

Pursuant to UCA §58-17b-622(7), if an audit results in the dispute or denial of a claim, PBM or its contractor will allow Pharmacy to resubmit a claim using any commercially reasonable method, including, fax, mail, or electronic claims submission within thirty (30) days from the day on which the preliminary audit report is received by the Pharmacy.

#### Final Audit Report

Pursuant to UCA §58-17b-622(8), within sixty (60) days of completion of a preliminary audit appeal process, PBM or its contractor will deliver the final audit report to the Pharmacy or its corporate office of record. The final report will include:

- 1. A disclosure of any money recovered by the entity that conducted the audit; and
- 2. Legal or contractual information supporting any money recovered, recoupments, or penalties included in the report.

#### Final Audit Report Appeals

PBM or its contractor will permit Pharmacies to appeal the final audit report by submitting a written request for an appeal and supporting documentation. The Pharmacy's appeal of the final audit report must be submitted within thirty (30) days of receipt. PBM or its contractor will review the Pharmacy's appeal and any supporting documentation before issuing a final audit appeal determination letter.

#### VERMONT

The following provisions shall apply to Participating Pharmacies in the State of Vermont:

1. Pursuant to 18 V.S.A. § 3631, PBM will pay or reimburse a claim or notify Participating Pharmacy of a claim denial within fourteen (14) calendar days.

#### WEST VIRGINIA

The following provisions shall apply to Pharmacies in the State of West Virginia:

Pursuant to WVC §33-51-9(e), PBM will reimburse Pharmacies for a prescription drug or pharmacy service at least NADAC for the prescription drug or pharmacy services at the time the drug is administered or dispensed, plus a professional dispensing fee of \$10.49, unless the NADAC is not available. If NADAC is not available, PBM will reimburse Pharmacy at least WAC plus a professional dispensing fee of \$10.49.

#### WYOMING

The following provisions shall apply to Pharmacy Providers in the State of Wyoming:

- 1. Pursuant to Wyo. Stat. §26-52-104, In formulating the maximum allowable cost price for a drug, PBM will only consider the price of that drug and any drug listed as therapeutically equivalent to that drug in the most recent version of the United States Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book)
- 2. If a therapeutically equivalent generic drug is unavailable or had limited market presence, PBM will place on a maximum allowable cost list a drug that has:
  - A. A "B" rating in the most recent version of the United States Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book) or an "NR or "NA" rating or similar rating by a nationally recognized reference,

- 3. PBM shall provide each Pharmacy at the beginning of the term of the contract and upon renewal of the contract, the sources utilized to determine the maximum allowable cost pricing. PBM will provide a telephone number at which the pharmacies may contact an employee to discuss pharmacy appeals. PBM will review and update applicable maximum allowable cost price information at least once every seven (7) business days to reflect any modifications of cost pricing and ensure dispensing fees are not included in the calculation of maximum allowable cost.
- 4. Pursuant to Wyo. Stat. §26-52-104, PBM shall provide a reasonable appeal process to allow Pharmacies to challenge maximum allowable cost list and reimbursements for a drug subject to maximum allowable cost pricing. PBM shall respond to the appeal within ten (10) business days after the pharmacy makes the appeal.
- 5. If the appeal is upheld, PBM shall adjust the applicable maximum allowable cost no later than one (1) day after the date of the determination and make the adjustment applicable to all similarly situated network pharmacy providers, as determined by the insurer. PBM shall allow the appealing pharmacy to reverse and rebill the claim, which was the subject of the appeal.
- 6. PBM may not prohibit or penalize a pharmacy for disclosing information to a covered individual or offering a more affordable alternative if one is available.

End.