

Generic Drug Pricing Dispute Appeal Process

This document outlines the policies and procedures for appealing generic drug pricing disputes, intended for use by contracted pharmacies, Pharmacy Services Administration Organizations (PSAOs), and Group Purchasing Organizations (GPOs).

I. Introduction

Purpose:

To establish a fair, transparent, and efficient process for contracted pharmacies, PSAOs, and GPOs to appeal generic drug pricing reimbursements that are believed to be inaccurate or not in compliance with contractual agreements.

Scope:

This policy applies to disputes related to the pricing of generic drugs. Specifically, this includes, but is not limited to, disputes concerning:

- Maximum Allowable Cost (MAC) pricing Average
- Wholesale Price (AWP) calculations
- Usual and Customary (U&C) pricing, when applicable to generics Errors in
- National Drug Code (NDC) mapping
- Contractual interpretation related to generic drug pricing
- Reimbursement rate disputes for generic drugs Dispensing fees
- specifically related to generic drugs

This policy does *not* cover disputes related to:

- Formulary decisions (i.e., which drugs are covered) Prior
- authorization requirements
- Brand-name drug pricing
- Changes to plan design

Guiding Principles:

The appeals process will adhere to the following principles:

- **Timeliness:** Appeals will be processed promptly and efficiently.
- **Fairness:** All parties will be treated equitably, and appeals will be evaluated objectively.
- **Transparency:** The appeals process will be clearly defined, and all decisions will be communicated in writing with a clear explanation.
- **Contractual Compliance:** All decisions will be consistent with the terms and conditions of the relevant contracts.
- **Accuracy:** Pricing data and calculations will be verified for accuracy. **Documentation:** All steps in the appeals process will be thoroughly documented.

II. Appeals Policy

A. Eligibility for Appeal:

- The following entities are eligible to file an appeal:
 - Contracted pharmacies
 - PSAOs (on behalf of their member pharmacies)
 - GPOs (on behalf of their member pharmacies)
- Appeals must be initiated by an authorized representative of the pharmacy, PSAO, or GPO.
- Specific requirements:
 - The pharmacy, PSAO, or GPO must have made a good-faith effort to resolve the dispute through informal channels (e.g., contacting the payer's customer service) before filing a formal appeal.
 - Appeals must be filed within the timeframe specified in this policy.

B. Grounds for Appeal:

An appeal may be filed if one or more of the following conditions exist:

- **Incorrect MAC Pricing:** The payer's MAC price is lower than the prevailing acquisition cost for the generic drug. Prevailing acquisition cost will be determined by reference to recognized industry sources (e.g., major wholesalers).
- **AWP Discrepancy:** The AWP used in the reimbursement calculation does not match the AWP specified in the contract or the contracted percentage off of AWP.
- **NDC Mapping Error:** The payer has used an incorrect NDC for the dispensed product, resulting in incorrect reimbursement.
- **Dispensing Fee Error:** The payer has incorrectly calculated or applied the dispensing fee for a generic prescription, as defined in the contract.
- **U&C Pricing Issues:** The payer's reimbursement is lower than the pharmacy's U&C price, where U&C is a contractually allowed basis for pricing generic drugs.
- **Contractual Interpretation Dispute:** There is a disagreement between the pharmacy/PSAO/GPO and the payer regarding the interpretation of a pricing term or clause in the contract.
- **Pricing Update Lag:** The payer has not updated its pricing files in a timely manner to reflect a decrease in drug costs.
- **Other Pricing Errors:** Any other error in the calculation or application of the generic drug price that is inconsistent with the contract.

C. Timeframe for Appeals:

- Appeals must be submitted within 30 calendar days from the *later* of:
 - The date of service.
 - The date of the Remittance Advice (RA) or Explanation of Benefits (EOB) that reflects the disputed payment.
- Failure to submit an appeal within this timeframe will result in the denial of the appeal, unless there are extraordinary circumstances, which will be evaluated on a case-by-case basis.

D. Information Required for Appeal:

The following information *must* be included in the written appeal:

1. Appellant Information:

- Pharmacy name, address, and National Provider Identifier (NPI)
- PSAO/GPO name and contact information (if applicable)
- Contact person name, title, phone number, and email address

2. Patient and Prescription Information:

- Patient name or unique identifier
- Prescription number
- Date of service
- NDC of the dispensed generic drug
- Quantity dispensed

3. Payment Information:

- Amount reimbursed by the payer
- Amount claimed by the pharmacy
- Date of the RA/EOB
- Claim number

4. Basis for Appeal:

- A clear and concise explanation of the reason for the appeal, referencing the specific ground(s) for appeal (from Section II.B).
- Identification of the specific contract clause(s) that support the appeal, if applicable.

5. Supporting Documentation:

- Copies of relevant RAs/EOBs
- Copies of wholesaler invoices or other documentation demonstrating the pharmacy's acquisition cost. The invoices must clearly show the drug name, NDC, quantity, and price.
- Screenshots from recognized drug pricing databases (e.g., First DataBank, Medi-Span), if applicable, to support MAC challenges.
- A copy of the relevant section(s) of the pharmacy contract.
- Any other documentation that supports the appeal.

6. Appeal Form: A completed appeal form, if required by the payer.

E. Limitations on Appeals:

- The payer reserves the right to limit the number of appeals a pharmacy may submit within a specified period (e.g., per month). This limit will be specified in the pharmacy contract.
- The payer may establish a minimum dollar amount for appeals to be considered. This amount will be communicated to contracted pharmacies.
- Appeals for clerical errors (e.g., typographical errors in claim submission) may be subject to a different process.

F. Confidentiality:

- All information submitted in connection with an appeal will be treated as confidential

and will be used only for the purpose of resolving the appeal.

- The payer will comply with all applicable federal and state privacy laws, including HIPAA.

III. Appeals Procedure

1. **Identification of Discrepancy:** The contracted pharmacy, PSAO, or GPO identifies a potential generic drug pricing discrepancy.
2. **Initial Inquiry (Optional):** The pharmacy, PSAO, or GPO may contact the payer's designated customer service or provider relations department to attempt to resolve the issue informally. This step is encouraged but not required. All communication should be documented.
3. **Formal Appeal Submission:**
 - The pharmacy, PSAO, or GPO must submit a formal written appeal to the payer within the timeframe specified in Section II.C.
 - The appeal must include all of the information and documentation listed in Section II.D.
 - The appeal must be submitted to the address or electronic portal designated by the payer. The payer will provide clear instructions on how to submit appeals.
 - Pharmacy may also call the EHO360 helpdesk to request an appeal at the time of occurrence. If agreed upon, EHO360 will update the MAC at the time of the call.
4. **Acknowledgement of Receipt:**
 - The payer will acknowledge receipt of the appeal within 10 business days of receiving it.
 - The acknowledgement will include a tracking number or other identifier for the appeal.
5. **Internal Review:**
 - The payer will conduct a thorough review of the appeal and all supporting documentation.
 - The review will be conducted by qualified personnel who are knowledgeable about pharmacy reimbursement, generic drug pricing, and the terms of the pharmacy contract.
 - The payer may consult with internal resources, such as pharmacy network management, claims processing, and legal counsel, as needed.
6. **Request for Additional Information:**
 - If the payer determines that additional information is needed to process the appeal, the payer will notify the appealing party within 10 business days of the initial receipt of the appeal.
 - The appealing party will have 10 calendar days to provide the requested information.
 - If the requested information is not received within the specified timeframe, the payer may deny the appeal.
7. **Determination:**

- The payer will make a determination on the appeal (i.e., approve, partially approve, or deny).
- The determination will be based on the terms of the contract, the submitted documentation, and the payer's internal policies and procedures.
- The payer may use external pricing data sources to validate pricing information.

8. Notification of Determination:

- The payer will notify the appealing party of its determination in writing within 7 calendar days of receiving the *complete* appeal (i.e., including any requested additional information).
- The notification will include:
 - The outcome of the appeal (approved, partially approved, or denied). Additionally, dates will also be maintained in the system.
 - A clear and concise explanation of the rationale for the decision, including specific references to the relevant contract clauses, pricing data, or policies.
 - Instructions on how to proceed if the appeal is denied or partially approved (i.e., information about the second level appeal, if available). EHO360 contact information will also be included with the appeal results.

9. Payment Adjustment (If Approved):

- If the appeal is approved or partially approved, the payer will make the necessary payment adjustments to the pharmacy's reimbursement.
- Submitting pharmacy must reverse and resubmit the claim for proper payment of adjusted claim.
- Other pharmacies that have processed a claim with the same NDC on or after the successful appeal will be notified of the MAC update. They can then reverse and resubmit the affected claims.

10. Second-Level Appeal (Optional):

- If the appealing party disagrees with the initial determination, they may have the option to file a second-level appeal.
- A request for a second-level appeal must be submitted in writing within 7 calendar days of the date of the initial determination.
- The second-level appeal will be reviewed by a different reviewer or a higher-level authority within the payer organization.
- The second-level appeal process will have its own set of timelines and requirements, which will be provided to the appealing party.

11. External Review (If Required by Law or Contract):

- In some cases, an external review by an independent third party may be available if all internal appeal levels have been exhausted, and if such a review is required by applicable law or the pharmacy contract.
- The payer will provide information about the process for requesting an external review, if applicable.

12. Record Keeping:

* The payer will maintain records of all appeals, supporting documentation, communications, and determinations for a period of [Number] years, or as required by law or contract.

* The pharmacy, PSAO, or GPO should also maintain copies of all documents related to the appeal.

IV. Roles and Responsibilities

A. Contracted Pharmacy/PSAO/GPO:

- Identify potential generic drug pricing discrepancies.
- Gather and organize all required documentation.
- Submit timely and complete appeals.
- Respond to requests for additional information from the payer.
- Monitor the status of appeals.
- Ensure compliance with the terms of the pharmacy contract and this appeals policy.

B. Payer:

- Establish and maintain a clear and accessible appeals process.
- Acknowledge receipt of appeals in a timely manner.
- Conduct thorough and objective reviews of appeals.
- Request additional information from the appealing party when necessary.
- Make timely determinations on appeals.
- Communicate appeal decisions clearly and in writing, with detailed explanations.
- Process approved payment adjustments accurately and promptly.
- Maintain accurate records of all appeals.
- Ensure that staff is trained on the appeals process.
- Comply with all applicable laws and regulations.

V. Performance Monitoring and Review

- The payer will track and monitor the following metrics related to generic drug pricing appeals:
 - Number of appeals received
 - Types of pricing disputes
 - Appeal processing times
 - Appeal outcomes (approved, partially approved, denied)
 - Reasons for denials
 - Number of second-level appeals
- The payer will periodically review the appeals process and this policy to:
 - Identify areas for improvement.
 - Ensure fairness and efficiency.
 - Address recurring issues.
 - Ensure compliance with contractual and regulatory requirements.
- The payer may establish a joint committee with pharmacy representatives to discuss and resolve systemic pricing issues and improve the appeals process.

VI. Legal and Regulatory Considerations

- This appeals process is subject to all applicable federal and state laws and regulations, including those related to:
 - Pharmacy reimbursement
 - Contract law
 - Administrative procedures
 - HIPAA and other privacy laws
- This policy will be reviewed and updated as necessary to ensure compliance with changes in laws and regulations.
- The terms of the pharmacy contract will take precedence over this policy in the event of any conflict, unless such terms violate applicable law.