

Medicaid Drug Rebate Dispute Resolution Program

I. Manufacturer Dispute Prevention

1. Be Familiar With Your Drugs

Dispute prevention saves staff time and money for all parties involved. A comprehensive understanding of your drugs is a key element of dispute prevention. Familiarize yourself with drug information including:

- Dosing for both labeled and off-label indications. This information may be helpful when identifying whether a pharmacy billing error has resulted in an overstatement of invoiced units.
- Formulation – Is your drug a liquid? Is it in a single or multi-use vial? Is it a gel capsule, a scored tablet, a patch or powder-filled vial? When unit-of-measure disputes arise, knowing your drug's formulation and packaging helps to identify and resolve disputes.
- Sales and Distribution – Know where your drugs are sold and how they are distributed. Mail-order pharmacies, nursing home dispensing, pharmacies or warehouses on state borders, and other arrangements should be known before you can dispute effectively.
- Product Package Size - Because a product's package size or packaging characteristics may affect the number of units dispensed per prescription, a good understanding of a product's packaging may help to identify potential billing errors.
- Other Considerations – Does your drug have seasonal utilization spikes (e.g., allergies, cold/flu drugs)? Does a particular state or county have a higher average senior population that could account for higher utilization? Know your drug's variables.

2. Ensure Accurate Data Reporting

By accurately and timely reporting required product and pricing data to CMS and independent data sources, you can help ensure that Unit Rebate Amounts (URAs) and ultimately, state invoices, are correct. In this way, timely and accurate reporting can prevent disputes. Some specific guidelines related to reporting follow:

- Ensure Accurate Listing of Unit Types/Units Per Package Size (UPPS) – Review information from CMS to ensure that Unit Types and UPPS are listed correctly. As some of the CMS reporting standards will differ from those established by NCPDP and other independent data sources (e.g., First Data Bank, Red Book), you should be aware of CMS reporting standards. Unit types and UPPS must be developed together.

- Make Pricing Corrections/Edits on a Timely Basis – Once you have received a CMS edit report, you should submit corrected data as soon as possible. If you need assistance, promptly contact CMS. After any changes have been made, inform independent data sources of those changes as appropriate.
- Promptly Report Contact Changes – To avoid potential lost invoices or edit reports as a result of incorrect/outdated contact information, immediately notify CMS when the contact person(s) or contact information has changed.
- Report Basic Information to Independent Data Sources – Although you are not required to report data to independent data sources, many states and pharmacy providers use drug data from these sources. Therefore, it is important that you provide basic product information for all NDCs (including product description, product indications, Average Wholesale Prices (AWPs), unit types, package sizes, etc...) to independent data sources.

3. Obtain an Understanding of State Reimbursement Prices

For dispute resolution purposes, state reimbursement may be used as a mechanism for validating questionable utilization. Therefore, it may be helpful to become familiar with the various reimbursement processes used by states in their Medicaid drug programs.

4. Be Familiar With Heavily Discounted Prices or Third Party Payments

When using state reimbursement analysis to validate questionable utilization, consider that some manufacturers enter into agreements with pharmacies whereby the dispensing pharmacy receives a purchasing discount from the manufacturer. In addition, a Medicaid claim can sometimes be paid in part by the state and in part by another third party insurance company. If the state has paid any portion of a Medicaid claim (including the dispensing fee only), rebates are due.

5. Learn From Previous Resolutions

Sometimes disputes can be proactively avoided by identifying recurring issues or problems. Once a recurring issue has been discovered, you should inform the state who can then work with providers to correct the billing for the NDC and/or implement edits that would resolve the problem before invoices are sent. After a state has researched and identified trends, manufacturers should not continue to repeatedly request the same data.

6. Work With States to Resolve Discrepancies Before Discrepancies Become Disputes

Every effort should be made to reconcile state utilization data discrepancies before rebate payments are due each quarter. Sometimes a simple call to the state prior to the payment of invoices can prevent disputes.

7. Educate New Staff/Resource Library Retention

Resource library retention and the education of new staff are essential to ensure a smooth transition when a rebate coordinator change occurs within your company.

8. Maintain Documentation

The lack of adequate and accurate documentation can prolong the rebate payment process and can affect the timely payment of disputes in the event of staff turnover. Therefore, record maintenance (e.g., resolution letters, invoices paid, state contacts, etc...) is helpful to the dispute resolution process.

II. Dispute Resolution Steps for Manufacturers

1. Schedule, Prioritize, and Understand Available Resources

Begin by working with states to identify common priorities related to dispute resolution. Older disputes and those involving large dollar amounts should receive priority. In addition, both you and the states must understand each other's schedules, resource capabilities, and limitations when beginning the dispute resolution process. In instances where resources, including staff, time, and technology are an issue, both parties can agree to begin the dispute resolution process at a later time. However, that time should be specified and documented.

2. Dispute Using ROSI/PQAS

Once you decide to dispute, you must do so officially using the appropriate OMB-approved form. The Reconciliation of State Invoice (ROSI) form is used for the current invoice and the Prior Quarter Adjustment Statement (PQAS) is used for all other quarters. The completed ROSI or PQAS must be submitted, along with the appropriate dispute code and any other required information, at the time of the dispute.

3. Work With the State to Agree on a Resolution Process and Keep the Lines of Communication Open

Throughout the dispute resolution process, communication between you and the state is a key element to successful resolution. This communication may include the exchange of NDC-specific information, informal negotiations, and an assignment of duties and timeframes between both parties. As you proceed, you may need to request additional documentation in support of invoiced data; however, you should only ask for the minimum data needed to resolve the dispute. Some examples of the additional documentation you may need include the following:

- Drug utilization data
- Zip-code level utilization data
- Pharmacy level utilization data
- A sampling of pharmacy claims
- Historical claims data
- Third party data

4. Reconcile Utilization Data Disputes

Disputes can occur when manufacturers suspect the number of units invoiced is incorrect. Some of the most common reasons for utilization disputes include:

- Unit Type Discrepancies - The unit type reported on the invoice doesn't match the CMS unit type.
- Units Dispensed Discrepancies – The units dispensed do not correlate with other reported utilization information.
- Keying Errors
- Processing Problems (e.g., field justification problems, inappropriate conversions, etc...)
- Rounding Problems or Incorrect Decimal Positions
- PHS Units Not Extracted From the Invoice
- Units Billed under the Wrong NDC

5. Agree to Necessary Unit Adjustments and Document Appropriately

Dispute resolution can occur when both parties agree that invoiced units are correct, or when both parties agree to adjust units. Fully document the steps taken by each party, results of all research, unit changes, and any follow-up. A copy of the documentation should be kept in your files.

6. Obtain a Resolution Statement from the State

After you and the state have come to resolution with respect to the corrections and the final dollar amount due, you may obtain a reconciliation statement/letter from the state. This document should reiterate that both parties agree to the number of units paid and/or

dismissed. The appropriate state representative should sign the letter and a copy should be placed in the manufacturer's files.

III. Steps to Take if the Process is Unsuccessful

1. Encourage the State to Attend a National Dispute Resolution Meeting

If repeated attempts to resolve disputes fail, you should encourage the state(s) in question to attend a national dispute resolution meeting. These meetings, usually held twice a year, enable labelers to meet with several states during the course of one week and provide a venue for resolving multiple disputes in a short period of time. CMS staff is present at these meetings and can serve as facilitators in the event that difficult issues arise. For more information and for a schedule of the national dispute resolution meetings, go to the CMS dispute resolution web page at www.cms.hhs.gov/medicaid/drugs/drp/default.asp.

Outside of the national meetings, you have several other options when difficulties arise during the dispute resolution process:

- State Hearings
- Mediation Review
- Non-Binding Arbitration
- Binding Arbitration
- Administrative Hearings
- Other Remedies as Allowed by State Law

2. Contact One of the CMS Regional Offices

If a state is unwilling to enter into dispute resolution discussions, you should consider contacting one of the CMS Regional Office Dispute Resolution Coordinators for assistance in getting the state involved. A list of CMS Regional Office Dispute Resolution Coordinators can be found on the CMS dispute resolution web page at www.cms.hhs.gov/medicaid/drugs/drp/drpcoor.pdf.

3. Contact CMS Central Office

If you have exhausted the abovementioned options and have not been able to engage the state in dispute resolution discussions, you may seek the intervention of the CMS Central Office Dispute Resolution team. A list of CMS Central Office dispute resolution staff can be found on the CMS dispute resolution web page at www.cms.hhs.gov/medicaid/drugs/drp/default.asp.

