

MEDICAID DRUG REBATE DISPUTE RESOLUTION PROGRAM

I. STATE DISPUTE PREVENTION

1. Educate Pharmacy Providers on Proper Billing Procedures

Errors made during the pharmacy billing process can subsequently lead to errors in your utilization data. You can help prevent billing errors by sending out periodic provider bulletins or other notifications that educate pharmacies on correct Medicaid billing procedures. Provider notifications should specifically address the following:

- Unit of Measure Errors – Provider claims often list incorrect units of measure (i.e., a product’s Unit Type and/or Units Per Package Size). To prevent these errors, you should identify products that are consistently billed with incorrect units and provide notice to pharmacy providers, through phone contact or site visits, about such products. In addition, you should remind pharmacies that information obtained from independent data sources should be verified to ensure consistency with Medicaid units of measure for each NDC.
- Proper Use of the NDC – Proper submission of the NDC for the drug dispensed is essential to the integrity of your state’s utilization. As a result, pharmacy providers should be aware of: NDCs covered under Medicaid, NDCs that are excluded or restricted from coverage and the limitations or conditions of that coverage, NDCs that are subject to prior authorization, and NDCs that are subject to reimbursement policies such as Federal Upper Limit (FUL) or State Maximum Allowable Cost (MAC) pricing. If pharmacies better understand the importance of the correct NDC on a claim, then disputes regarding whether or not a manufacturer’s product was actually dispensed can be avoided.
- Recurring Provider Problems – Recurring billing errors should first be addressed by calling the pharmacist or billing clerk to provide detailed instructions on proper billing procedures. If the problem continues, consider a site visit to reiterate billing procedures. If several pharmacies are making the same error, you should provide billing procedure guidance via a provider newsletter, bulletin or web posting.

2. Ensure the Accuracy of the State Medicaid Drug File

To avoid potential errors when invoicing manufacturers, you should ensure that your drug reference or pricing file is accurate. Two particularly problematic areas are unit of measure and expired and/or discontinued NDCs. To avoid unit of measure issues, always verify that the unit of measure being used on the invoice conforms to that which is included on the CMS tape and make any necessary conversions prior to rebate billing. In addition, you should ensure that expired and/or discontinued NDCs do not appear in the drug file. One way to accomplish this is by adding an edit to deny claims after a drug has been discontinued.

3. Perform Upfront Edits and Audits to Avoid Invoice Errors

Performing edits and audits upfront can often eliminate the need to correct mistakes after an invoice has been generated. Some examples of errors that can be prevented through the use of upfront edits or review follow:

- Keying Errors – A keying error in the unit field will result in the invoicing of an incorrect rebate amount. You should consider an initial manual review of the invoices for these types of errors or, if your system allows it, implement edits that check minimum and maximum quantities or that check for large variances between billed amounts and Medicaid calculated amounts.
- Pricing – If the rebate requested exceeds the Medicaid reimbursement amount, a billing error may have occurred. Comparing rebate amounts to reimbursement amounts can help to identify such errors. In addition, third party payments and unit of measure/conversion issues should also be considered when comparing rebate and reimbursement amounts.
- Unbreakable Packages – Special packaging of certain drug products can sometimes result in billing errors. Therefore, consider adding an edit to detect claims that are being billed with the incorrect package size as reported by the manufacturer.

4. Configure Claims Processing Systems to Accept Decimal Quantities

Most state systems can now accept metric decimal billing. However, for those states that cannot bill metric decimal units, CMS has issued billing guidelines in Medicaid State Release #18 and in the Operational Training Guide. Please see these resources for additional information.

5. Review Invoices/CMS Utilization Reporting for Errors

Invoice errors are commonly made in the following areas:

- Rebate-Excluded NDCs – Verify that non-rebate units, such as those from PHS providers, are excluded from the invoice.
- Adjustments to Original Claims – Adjustment transactions occur when a pharmacy provider or Medicaid staff makes a change to a claim that was previously paid by Medicaid. This process involves voiding the original claim, followed by “rebilling” a new claim with corrected information. These adjustments should appear in the quarter the original claim was invoiced, thereby reducing or increasing that quarter’s utilization, and should be reported to the manufacturer in a separate section following the current quarter’s invoice information or on a separate adjustment invoice.

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

Every effort should be made to reconcile state utilization data discrepancies before a manufacturer’s rebate payments are due each quarter. If you know that you will not be able to conduct the necessary research and respond to a manufacturer’s request for information before rebate payments are due, work with the manufacturer to establish a specific time line by which the research can be completed and submitted.

7. 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 manufacturer and work with providers to correct the billing for the NDC and/or implement edits that would resolve the problem before invoices are sent.

8. Educate New Staff/Resource Library Retention

Resource library retention and the education of new staff are essential to ensure a smooth transition when drug rebate staff changes occur within your state. At a minimum, your resource library should include the following: the Operational Training Guide, State Medicaid Releases, the State Medicaid Manual, and any relevant websites.

9. Maintain Documentation

The lack of adequate and accurate documentation can prolong the rebate process and can affect the timely payment of disputes in the event of staff

turn-over. Therefore, record maintenance (e.g., resolution letters, invoices paid, manufacturer contacts, etc...) is helpful to the dispute resolution process.

II. DISPUTE RESOLUTION STEPS FOR STATES

1. Review Receivables to Identify Outstanding Balances

To help expedite the dispute resolution process, you should review a manufacturer's accounts prior to beginning work on resolving disputes. Such a review can be done at the time you prepare your quarterly utilization data submission for CMS. As part of this review, it may be helpful to separate your outstanding balances into the following categories to more easily identify those disputes with the highest priority:

- Disputes – Properly Documented
- Disputes – Not Properly Documented
- Late Payments
- Non-Payments
- URA Discrepancies

2. Schedule, Prioritize, and Understand Available Resources

Begin by working with manufacturers 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 manufacturer must understand each other's schedules, resource capabilities and limitations. In instances where resources (i.e., 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.

In addition, consider the cost-effectiveness of pursuing invoice collection. CMS has established a tolerance level threshold of \$50 per manufacturer per quarter should you choose not to pursue invoice collection; however, this tolerance level is optional and you may invoice manufacturers for amounts below the tolerance level if you wish. Please note that you will not risk loss of federal financial participation (FFP) if you choose to apply this threshold, but you should maintain appropriate documentation to identify the quarter, the manufacturer, the NDC(s) and the amount to which the tolerance was applied.

3. Work With the Manufacturer to Agree on a Resolution Process and Acquire Managerial Support

Once you have identified which disputes to pursue, you and the manufacturer should develop a strategy or “Plan of Action” that will ensure the resolution of those disputes in a timely manner. This plan should include the distribution of tasks, the exchange of information and an assignment of timeframes for both parties. In addition, the dispute resolution process can often be expedited by managerial involvement.

4. Reconcile Balances Due to Accounting/Bookkeeping Differences

The following accounting and bookkeeping issues can lead to balance discrepancies:

- Invoice Receipt and Payment Recording Issues – Sometimes a manufacturer’s payment is delinquent because the invoice was never received. You should follow up with the manufacturer from whom you have not received payment to verify invoice receipt. If the manufacturer claims that the invoice was received and paid, you should review your records to determine whether the payment was improperly recorded or was never recorded at all. To avoid payment recording errors, you should maintain documentation related to payment, including copies of received checks and any notes related to the check and settlement.
- Rate Issues – These issues occur when the unit rebate amount (URA) used to generate the invoice (i.e., the rate listed on the CMS tape) differs from the manufacturer’s ROSI or PQAS URA. When a zero URA appears on the CMS tape, the manufacturer is responsible for calculating the URA and including the URA on the ROSI along with the payment for all billed units. Similarly, if the URA provided on the CMS tape differs from what the manufacturer uses for payment, the manufacturer must use a ROSI to note the adjustment. If the manufacturer changes any URA, you should see the change in the next CMS tape. If two quarters pass with no corrections to the CMS tape, you should call the manufacturer and, if necessary, call CMS.

5. Reconcile Data Disputes

Disputes can occur when manufacturers question the accuracy of invoiced units. Some of the most common reasons for utilization disputes include:

- Units Billed Under the Wrong NDC – Manufacturers dispute on the basis that the NDC listed on the invoice is incorrect and that their product was not actually dispensed. This very often occurs when there has been generic substitution.

- Unit of Measure Discrepancies – The unit type and/or units per package size reported on the invoice don't match the CMS unit type/units per package size.
- Processing Problems (e.g., field justification problems, inappropriate conversions, etc...)
- Rounding Problems or Incorrect Decimal Positions
- PHS Units Not Extracted from the Invoice
- Expired, Terminated, or Discontinued Drugs
- Units Dispensed Discrepancies – The units dispensed do not correlate with other reported utilization information.
- J-Code Disputes – This typically occurs when a state performs a J-code to NDC crosswalk for purposes of invoicing for rebate dollars and that crosswalk can not adequately identify down to the 11-digit NDC number.

6. 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.

7. Complete Resolution Statement

After you and the manufacturer have come to resolution with respect to the corrections and the final dollar amount due, you may prepare a resolution statement. This document should reiterate that both parties agree to the balances specified and number of units paid and/or dismissed. The appropriate state representative should sign the letter and a copy should be kept in each party's dispute resolution records.

8. Monitor Timely Receipt of Final Resolution

Once a resolution statement has been issued, payments should be made or credits should be taken within a reasonable time frame (e.g., the next rebate period). Any interest should be applied at the same time that the payment/credit is made/taken.

9. Post Resolution Payments and Document Resolution

After resolution payments/credits have been issued, you should continue working with the manufacturers, via ongoing discussions and information sharing, to post balances to zero. Once a zero balance has been posted, document the agreement in the files of both parties.

III. STEPS TO TAKE IF THE PROCESS IS UNSUCCESSFUL

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

If repeated attempts to resolve disputes fail, you should encourage the manufacturer(s) in question to attend a national dispute resolution meeting. These meetings, usually held twice a year, enable states to meet with several manufacturers 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.

2. Contact One of the CMS Regional Offices

If a manufacturer 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 manufacturer 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 manufacturer 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.

4. Request an Administrative Hearing

If you and a manufacturer have reached an impasse, you may request an administrative hearing; however, such a request should only be made if all other avenues have been unsuccessful. In lieu of a state hearing, both parties may agree to arbitration or mediation in an attempt to resolve the dispute. Should you and the manufacturer agree to resolve the dispute through mediation or arbitration rather than a state hearing, maintain documentation of the agreement in your records.

5. Hold a State Hearing

If all other options have been exhausted without success, a manufacturer may request that a state hearing be held to resolve the dispute(s). States are required to hold such hearings upon the request of the manufacturer. Please see Section V of the National Rebate Agreement for additional information on the state hearing process.