

Best Practices Guidance for Effective Review of BPD Disputes Sent to Medicaid by IRS

Based on the BPD disputes received through IRS to date, the following information is offered for those manufacturers that seek review of BPD disputes of Medicaid sales amounts:

- 1. Begin Reviewing State Utilization Data Early:** Manufacturers should email states and copy Medicaid (MedicaidBPD@cms.hhs.gov) regarding issues with the current BPD year's utilization data (i.e., 2016) as soon as they become aware of them. Don't wait until the IRS opens the current year's BPD disputes to report utilization overstatements and understatements to states and CMS for the first time.
- 2. Use Appropriate Supporting Documentation to Dispute:** Manufacturers should use state-sourced data to dispute utilization numbers from states, where the dispute is that the Medicaid sales amount was calculated as too high or too low based on the state's reported utilization. For example, supporting documentation such as state invoices or emails exchanged between manufacturers and states showing agreement on unit changes would be considered responsive BPD dispute data. A manufacturer's ROSI/PQAS could also be considered responsive if it contains a clear state response indicating agreement with the manufacturer. Supporting documentation such as manufacturer data unrelated to rebates would generally not be considered responsive for purposes of defending a dispute. Further, if CMCS receives disputes from the same manufacturer that include instances of both over and underpayment, responsive supporting documentation should be provided for both instances.
- 3. Contact CMS Regarding Unit Rebate Amount (URA) Inaccuracies ASAP:** Manufacturers should contact CMS as soon as possible if they believe a URA calculated by CMS is inaccurate. We request that manufacturers do not wait until the IRS opens the current year's BPD dispute window to report potential URA issues to CMS for the first time. For line extension drugs, a manufacturer's supporting documentation should include the ROSI/PQAS with the labeler-calculated URA, along with confirmation from several states that the labeler-reported URA is what was paid.
- 4. Be Proactive in Addressing Unit of Measure Issues:** Manufacturers should communicate with states about drugs that require unit of measure conversions to facilitate correct rebate billing. If a manufacturer submits a BPD dispute on an NDC that many/all states bill incorrectly, but the manufacturer has allowed the states' incorrect units to remain publicly posted on Medicaid.gov without ever notifying CMS of the problem, it is unlikely that Medicaid will be able to fix this during the IRS's BPD dispute time frame. As a result, manufacturers are strongly encouraged to be proactive and contact CMCS in a timely manner if a state will not fix their data or respond to repeated efforts to correct a unit of measure issue. Further, should a manufacturer dispute a Medicaid sales amount on the basis of a unit of measure discrepancy, the manufacturer is encouraged to include documentation of any attempts at preventing such disputes with states.

5. **Consult with All Appropriate Manufacturer Contacts:** If the MDRP Technical Contact for the labeler code is not also the BPD contact engaging in disputes, manufacturers should ensure that disputes are appropriately based on rebate data. Further, communication between both contacts can help to ensure that the rebate data is understood by the manufacturer's BPD contact.
6. **Use Proper Dispute Format:** Manufacturers should include one unit total for Fee for Service (FFS) and one unit total for Managed Care Organization (MCO) per NDC per quarter per state for all federal Medicaid disputes. Dispute submissions should not include multiple unit totals for the same NDC/quarter from separate state invoices (e.g., one unit total for FFS physician-administered drugs and one unit total for retail pharmacy FFS drugs for the same state and NDC/quarter).
7. **Report Partial Unit Agreements to CMS on a Timely Basis:** In the event a manufacturer and state have agreed to a partial reduction or adjustment in the disputed units of an NDC for a quarter(s), the manufacturer should provide information to the state and to CMS on the partial agreement if they see that the state hasn't transmitted that agreed-upon change in utilization data to CMS Medicaid. Manufacturers shouldn't wait until the IRS opens the current year's BPD dispute window to report such expected utilization changes.