

Section 7: Invoice Process

Within 60 days of the end of a calendar quarter, states are required to send rebate invoices to each labeler Invoice Contact for any rebate-eligible drugs the states paid for during that quarter. The established invoice format is the Office of Management and Budget (OMB) approved Form CMS-R-144. Form CMS-R-144 includes various data fields for each drug and requires states to separately identify Fee-For-Service (FFS) units from managed care organization (MCO) units. States may choose to include both FFS and MCO units on one invoice, or they may opt to submit one invoice containing all FFS units and a second invoice containing MCO units. In addition, states may opt to send invoices in a paper or electronic format; however, each invoice should be made available in paper format for those labelers that cannot utilize an electronic format. Please note that CMS does not have the authority to mandate electronic submission of invoices. For each NDC, the state's invoice will report the following information:

1. Record ID
2. State Code
3. Period Covered
4. Labeler Code
5. Product Code
6. Package Size Code
7. Drug Name
8. Unit Rebate Amount
9. Units Reimbursed
10. Rebate Amount Claimed
11. Number of Prescriptions
12. Medicaid Amount Reimbursed
13. Non-Medicaid Amount Reimbursed
14. Total Amount Reimbursed
15. Correction Flag

For various reasons, the quarterly CMS files sometimes contain zero URAs and states should include each zero URA on their invoices to labelers. Labelers are responsible for calculating a URA for all zero URAs on the invoice, multiplying the URA by the number of units reported by the state, and sending a rebate payment with updated totals along with the ROSI, Form CMS-304. The next quarterly CMS files should contain a valid (i.e., non-zero) URA for any NDC that had a zero URA on the previous files. In the event that a state does not receive a valid (i.e., non-zero) URA on the next quarterly CMS files, the state may contact the labeler directly to inform the labeler that its URA is missing. States may include CMS on that email. If the labeler does not indicate that it will correct the issue that resulted in the zero URA, the state should contact CMS at mdroperations@cms.hhs.gov.

States that wish to bill labelers for rebates for new drugs that are not included on the CMS file should ensure that such drugs are rebate-eligible prior to authorizing provider dispensing of these drugs. States may check DDR to determine whether a labeler has reported a product as a covered outpatient drug for inclusion in the MDR program.

All changes to URAs are reflected as PPAs on the quarterly files. While states may attach a PPA list to their quarterly invoice for informational purposes, they are not to include PPAs on the current quarter invoice as PPAs should appear on a separate invoice.

7.1 Alternate Invoice Process

Per the National Drug Rebate Agreement, in the rare event that CMS is unable to transmit quarterly URAs timely, states may send a list of NDCs and units in place of the standard invoice form (i.e., Form CMS-R-144). Labelers are responsible for paying these alternate invoices within 37 days of receipt, the same way they are with traditional invoices.

7.2 Quarterly Rebates Paid in Full

If a labeler's review of a quarterly state invoice determines that no disputes or adjustments are necessary and that the total quarterly rebate amount can be paid as reflected on the invoice, the labeler should pay the total invoiced amount in full with identifying documentation about the payment for the state's records. Such documentation may include, for example, the labeler code, the labeler name, the quarter and applicable federal program(s) covered by the payment, or any other such pertinent information that would help a state identify from whom the rebate payment is being sent and for which quarter and federal program the payment applies.

7.3 Unit Conversion Factor

When preparing quarterly invoices, please note that there may be some differences in the standards used by the MDR program compared to those used by pharmacies. In those instances where the reimbursement standard used by pharmacies may be different from the rebate standard, states should perform conversions prior to invoicing labelers. Alternatively, states may make the labeler aware of the conversion factor used and have the labeler perform the conversion prior to rebate payment. However, if the state chooses this option, they should notify the labeler in writing and should remain consistent in applying the conversion factor.

7.4 Tolerances

If the total invoice for an individual labeler code is \$50 or less for a calendar quarter, states may choose to forego sending an invoice to that labeler. However, if the \$50 tolerance is applied, CMS expects states to maintain documentation of the NDCs, applicable quarters, etc. In addition, states that apply this tolerance are expected to notify participating labelers of this practice.

7.5 Reconciliation of State Invoice (ROSI) (Form CMS-304)

In the event that labelers disagree with the utilization data submitted by states, or need to adjust the utilization billed on the current state invoice as agreed-upon, labelers are required to complete and submit a ROSI with their invoice payment. To keep the ROSI consistent with the information reported on the state invoice, Form CMS-304 also includes a "FFS/MCO Record ID" column. Labelers should use this column to separately identify each record as either FFS

utilization or MCO utilization when the ROSI is being submitted along with a state's quarterly rebate payment. The ROSI is used for both unit adjustments and disputes and CMS expects labelers to pay the portion of the invoice for which there is no disagreement with the state. If a labeler has not paid an invoice in full and has not properly completed the ROSI to account for all unpaid invoice units, the state should consider the labeler to be out of compliance with its rebate payment requirements. Therefore, states should track those outstanding rebates owed as late payments with interest due. Labelers that fail to comply with their rebate payment obligations may be subject to penalties, such as termination from the rebate program.

7.6 Prior Quarter Adjustment Statement (PQAS) (Form CMS-304a)

Once the current invoice cycle has passed, labelers may discover unit adjustments and/or disputes from a previous quarter. In these instances, labelers complete and submit a PQAS as official notification of the discrepancy. To keep the PQAS consistent with the information reported on the state invoice, Form CMS-304a also includes a "FFS/MCO Record ID" column. Labelers should use this column to separately identify each record as either FFS utilization or MCO utilization when the PQAS is being submitted along with state's quarterly rebate payment. Except for its use for prior quarter adjustments and disputes, the PQAS functions the same as the ROSI. Labelers that fail to comply with their rebate payment obligation may be subject to penalties, such as termination from the rebate program, etc.