

Sent: Tuesday, June 15, 2021 3:15 PM
Subject: (State Technical & Rebate Contacts) Additional Clarification on the State Drug Utilization Data (SDUD) Delete Flag and Implementation Plans for MDP
Attachments: [4Qtr2020URA_Testfile.txt](#); [4Qtr2020UROA_Testfile.txt](#)
Importance: High
Follow Up Flag: Follow up
Flag Status: Flagged

Dear State Technical and Rebate Contacts:

For over a year, we have been communicating with states and manufacturers regarding the implementation date of the new Medicaid Drug Programs (MDP) system. We have several important updates to share with you in regards to the implementation of MDP.

Clarification on the Delete Flag

On April 19, 2021, we sent you an email regarding the upcoming implementation of the MDP CMS R-144 *Delete Flag* (which is applicable only to the SDUD submission and not the State Invoice). Since then we have received several state questions about how the delete flag will work. We hope the following information will clarify the difference between the existing way you delete records and the new way that you will delete them in MDP.

Under the current electronic file transfer (EFT) system, in order to adjust an national drug code (NDCs) quarterly utilization units to zero (e.g., due to a reversal), a state must delete the existing utilization record by submitting an adjustment record that contains a value of zero in ALL the following fields:

- Units Reimbursed
- Rebate Amount Claimed
- Number of Prescriptions
- Medicaid Amount Reimbursed
- Non-Medicaid Amount Reimbursed
- Total Amount Reimbursed

When a record is deleted in this way, the utilization is removed from our system and no longer shows in Drug Data Reporting for Medicaid system (DDR).

It is our understanding that when reversing claims, states generally do not delete utilization records from their systems; instead, they adjust those utilization records to zero. Therefore, in our new MDP system, data can be submitted to adjust the NDC's units to zero rather than forcing the NDC record to be deleted. These and other adjustments can be made either online or via file transfer.

To account for records that may have been submitted in error (i.e., the records are invalid and require removal rather than adjustment), MDP will allow records to be deleted either online, by clicking a "Delete" button, or via file transfer, by adding a delete flag. Please be advised that when deleting records via file transfer, you should simply add a "D" to the Filler field of an existing record as records submitted with both a "D" and zeroed-out fields will reject.

Delay in Manufacturer use of MDP

Due to unforeseen circumstances, CMS has delayed the implementation of MDP for manufacturers until after the production of the third quarter 2021 rebate file. The third quarter rebate cycle will be completed around November 5, 2021. In the interim, manufacturers will continue to report product and pricing data via the Drug Data Reporting for

Medicaid (DDR) system and will continue to use existing file formats to report data to CMS. The current manufacturer file formats will continued to be used for manufacturer submitted data to CMS until MDP is available for manufacturer reporting of data.

The implementation date for states to begin using MDP to submit SDUD to CMS has not changed. States are still required to update their systems and be prepared to submit their second quarter 2021 (2Q2021) SDUD files to CMS using the new file formats in August 2021. More details on the transition to MDP for states will be forthcoming in the next two months.

With the state and manufacturer MDP system implementation dates now four months apart, we suggest that manufacturers and states work closely together to establish agreed upon field lengths in order to ensure that the Reconciliation of State Invoice (ROSI), the Prior Quarter Adjustment Statement (PQAS) and the State Invoice are able to be sent and received without interruption during this interim period. Please note that the updated file formats for the ROSI, PQAS and State Invoice have been approved through the Paperwork Reduction Action (PRA) process with the Office of Management and Budget (OMB). As such, we are requesting that manufacturers consider utilizing the new file formats for the ROSI and the PQAS and that states begin using the new file format for the State Invoice beginning with the 2Q2021 rebate cycle.

Sample URA and UROA files

CMS will be sending the 2Q2021 Unit Rebate Amount (URA) and Unit Rebate Offset Amount (UROA) files to the states using the new file formats. Since many states have requested sample URA and UROA files in the new file format, attached to this email are sample files that contain scrubbed test data that states can use to test uploading the files with the new file formats into their internal state systems.

Sincerely,
CMS MDR Operations

The information in this response is limited to and based upon the facts described in this email and any attachments provided and our understanding of the facts as described in the emails and attachments submitted. If a subsequent review by CMS, by the Office of Inspector General, or another authorized government agency determines or reveals that additional adjustments or revisions are necessary, the manufacturer is responsible for complying with that determination. This response cannot be considered an advisory opinion under section 1128D(b) of the Social Security Act, since only the Inspector General of the U.S. Department of Health and Human Services has been authorized to issue advisory opinions relating to health care fraud and abuse under that section. This response should not be interpreted as acquiescence by the Government to the arrangements described herein. Further, this response is not a release of any liability.