From: CMS MDROperations
To: CMS MDROperations
Cc: CMS MDROperations

Subject: (Manufacturers - Invoice Contacts) Final Revisions to Various Medicaid Drug Rebate Program (MDRP)-Related File

Formats

Date: Thursday, June 18, 2020 11:23:41 AM

Attachments: (Manufacturers) Upcoming Changes to Various Medicaid Drug Rebate Program (MDRP)-Related File Formats.msg

MDP CMS Form-304 Reconciliation of State Invoice (ROSI) Electronic Format 07.2021.pdf MDP CMS Form-304 Reconciliation of State Invoice (ROSI) Instructions 07.2021.pdf

MDP CMS Form-304a Prior Quarter Adjustment Statement (PQAS) Electronic Format 07.2021.pdf MDP CMS Form-304a Prior Quarter Adjustment Statement (PQAS) Instructions 07.2021.pdf

MDP CMS-R-144 State Invoice Record Format 07.2021.pdf
MDP CMS-R-144 State Invoice Data Definitions 07.2021.pdf
MDP CMS Form-367a Quarterly Pricing 07.2021.pdf
MDP CMS Form-367b Monthly Pricing 07.2021.pdf
MDP CMS Form-367c Product Data 07.2021.pdf

Importance: High

Dear Manufacturer Technical and <u>Invoice</u> Contacts:

As mentioned in our March 9, 2020, email (attached, less original attachments to avoid confusion with updated documents attached in this email), CMS is building a new system, the Medicaid Drug Programs (MDP) system, which will contain modules for several Medicaid pharmacy programs, including the MDRP. Additional details regarding the MDP system, which will eventually replace the existing Drug Data Reporting for Medicaid (DDR) system for all manufacturer MDRP product and price reporting, will be forthcoming.

In our March 9, 2020, email, we provided draft versions of six revised MDRP-related File Formats, which included increased lengths for several pricing fields to correspond to field length increases CMS will be implementing in MDP. Two of the revised file formats attached to our March communication (i.e., the formats for the Reconciliation of State Invoice (ROSI) and Prior Quarter Adjustment Statement (PQAS)) also included the addition of several new fields. However, upon further review, we have decided against implementing those new fields at this time, and plan to introduce them at a later date.

The implementation date is July 1, 2021, for both manufacturers and states to begin utilizing the new file formats, pending approval of the PRA packages.

- The revised 367a form (Quarterly Pricing) should be used by manufacturers for all quarterly pricing submissions (regardless of the quarter/year combination) beginning July 1, 2021.
- The revised 367b form (Monthly Pricing) should be used by manufacturers for all monthly pricing submissions (regardless of the month/year combination) beginning July 1, 2021.
- The revised 367c form (Product data) should be used by manufacturers for all product data submissions beginning July 1, 2021.
- The revised 304 and 304a forms (ROSI/PQAS) should be used for all ROSI/PQAS transmissions (regardless of the quarter/year combination) beginning July 1, 2021.
- The revised quarterly URA file will be used by CMS beginning with the 2Q2021 file that will be sent to the states in early August 2021 (this will be the first one we'll send after the July 1st implementation date of all the other forms).
- The revised quarterly UROA file will be used by CMS beginning with the 2Q2021 file that will be sent to the states in early August 2021 (again, this will be the first one we'll send after the July 1st implementation date of the other forms).

• The revised R-144 form (SDUD and state invoice) should be used by states for all SDUD submissions/invoices (regardless of quarter/year combination) beginning July 1, 2021.

To provide manufacturers with as much time as possible to incorporate these changes into their Medicaid pharmacy systems, we are attaching FINAL versions of the following revised file formats and associated data definitions:

- MDP CMS Form-304 Reconciliation of State Invoice (ROSI)_Electronic Format_07.2021
- MDP CMS Form-304 Reconciliation of State Invoice (ROSI)_Instructions_07.2021
- MDP CMS Form-304a Prior Quarter Adjustment Statement (PQAS)_Electronic Format 07.2021
- MDP CMS Form-304a Prior Quarter Adjustment Statement (PQAS)_Instructions_07.2021
- MDP CMS R-144 State Invoice_Record Format_07.2021 (i.e., the State Invoice and State Drug Utilization Data File Format)
- MDP CMS R-144 State Invoice_Data Definitions_07.2021
- MDP CMS Form-367a Quarterly Pricing_07.2021
- MDP CMS Form-367b Monthly Pricing 07.2021
- MDP CMS Form-367c Product Data_07.2021

Please note that the attached file formats specify both Comma Separated Value (.CSV) and Text (.TXT) options for electronic file submission. While manufacturers and states currently upload MDRP-related data in Text file (.TXT) format, with fixed record specifications and field lengths for every data field collected, MDP will provide both .CSV and .TXT options for file uploads. Therefore, the attached documents reflect the reporting formats for each file type.

As we move closer to the implementation of MDP, we will provide additional communications regarding the new system. In the meantime, we strongly encourage you to begin planning for any updates that may be necessary to your Medicaid pharmacy systems in order to accommodate the attached changes as early as July 1, 2021.

Please direct any questions regarding MDP or the revised file formats to MDROperations@cms.hhs.gov.

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.