From: CMS MDROperations

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Cc: CMS MDROperations; CMS MDROperations

Subject: (States) Corrected Attachment: Upcoming Changes to Various Medicaid Drug Rebate Program (MDRP)-Related

File Formats

Date:Monday, March 9, 2020 3:03:44 PMAttachments:ROSI Electronic Format for CMS-304.pdf

POAS Electronic Format for CMS-304a.pdf

Importance: High

Good afternoon,

It was brought to our attention that there were two PQAS File Formats included in the original email and the ROSI File Format was not included. Both the ROSI/PQAS File Formats are attached.

Thank you,

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.

From: CMS MDROperations

Sent: Monday, March 9, 2020 12:46 PM

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Cc: CMS MDROperations <MDROperations@cms.hhs.gov>

Subject: (States) Upcoming Changes to Various Medicaid Drug Rebate Program (MDRP)-Related File

Formats

Importance: High

Dear State Technical Contact:

As you know, over the last few years, several high cost drugs have been introduced to the market. Due to field size limitations on existing MDRP-related file formats (e.g., the State Invoice, the Reconciliation of State Invoice (ROSI), the Prior Quarter Adjustment Statement (PQAS), etc.), these drugs have been excluded from standard MDRP data transmissions, and handled via alternative, manual processes instead. For example, rather than being transmitted as part of the standard quarterly rebate files, the Unit Rebate Amounts (URAs) and Unit Rebate Offset Amounts (UROAs) for these drugs have been added to supplemental URA/UROA files that are manually created each quarter and then posted in the Drug Data Reporting for Medicaid (DDR) system.

Concurrent to this rise in the number of high cost drugs, CMS has been building a new system, the Medicaid Drug Programs (MDP) system, which will contain modules for several Medicaid pharmacy programs, including the MDRP. In response to numerous requests to address the field length problem imposed by the rise in the number of high cost drugs, CMS has incorporated increased field lengths for all pricing, dollar, and unit values within MDP. Further, to ensure consistency between MDP and the file formats that are regularly utilized as part of the MDRP data transmission process, CMS has also revised those file formats accordingly. In addition to the increased field sizes, some of the file formats (e.g., the ROSI and PQAS) are also being modified to streamline and modernize the data fields included on the forms.

At this time, we do not have a definitive implementation date for either the new MDP system or the revised file formats; however, implementation of both could occur as early as January 2021. Therefore, to provide the states with as much time as possible to incorporate these changes into their Medicaid pharmacy systems, we are attaching DRAFT copies of the following revised file formats and associated data definitions:

- CMS R-144 File Format (i.e., the State Invoice and State Drug Utilization Data File Format)
- CMS-R-144 Data Definitions
- CMS-304 File Format (i.e., the ROSI File Format)
- CMS-304 Data Definitions
- CMS-304a File Format (i.e., the PQAS File Format)
- CMS-304a Data Definitions
- Quarterly URA File Format
- Quarterly URA Data Definitions
- Quarterly UROA File Format

• Quarterly UROA Data Definitions

As we move closer to the implementation of MDP, we will provide additional communications regarding the new system and the revised file formats. 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 January 1, 2021. To that end, please feel free to share this communication with your fiscal intermediary, as appropriate.

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.