

Disabled and Elderly Health Programs Group

May 20, 2022

MEDICAID DRUG REBATE PROGRAM NOTICE

Release No. 190

For State Technical Contacts

This notice provides information for states regarding a new requirement for certification of State Drug Utilization Data (SDUD) and the system to be used for certification.

New Requirement for Certification of State Drug Utilization Data (SDUD)

In accordance with section 1927(b)(2)(A) of the Social Security Act (the Act), states are required to submit all Medicaid SDUD to the Centers for Medicare & Medicaid Services (CMS) within 60 days of the end of each quarter. This data includes information on physician administered drug utilization, managed care organization (MCO) drug utilization, and drugs paid as fee-for service (FFS) claims.

To hold states accountable for their data integrity, and to mitigate the effects of transmitting inaccurate and untimely SDUD, CMS amended the Code of Federal Regulations at 42 CFR §447.511(d) to specify that the state data must be certified, and added §447.511(e), which specifies the state data certification language that must be included in the submission. These updated regulatory requirements went into effect on January 1, 2022.

Through this technical bulletin CMS is informing states that the Medicaid Drug Programs (MDP) system for the *State Utilization* module is still being updated to accommodate this requirement for state certification, and will not be available until July 1, 2022. Once this module is available, states will be expected to officially certify their first quarter 2022 SDUD submission and make any edits made to prior quarter data that were submitted since January 1, 2022. This certification will take place directly within the MDP system. Please note that at this time, only the State Medicaid Drug Rebate Program (MDRP) contact role is able to certify the SDUD. However, we do intend to expand the state certification capability to other state user roles at a future date. As we get closer to the July 1, 2022 SDUD Certification implementation date, CMS will provide further detailed operational instructions to all state MDRP contacts and state technical contacts.

It is important that SDUD that is submitted to CMS and certified by the state be credible and reliable because the data are made public, and multiple stakeholders use the data for various purposes. SDUD are used to calculate the Medicaid portion of the IRS' Branded Prescription Drug (BPD) Fee. If the data are understated or overstated, then the fee could also be understated or overstated. Additionally, SDUD are shared with government oversight agencies to assist in numerous studies and audits, and is so used by numerous research facilities. To enhance the credibility of the data, we urge states to do the following before submitting the

data:

- Determine if any applicable conversion factors from the invoice data have been applied to the SDUD files.
- Determine if the units modified during the dispute review process have been applied to the SDUD.
- Determine if the units modified during a claim adjustment have been submitted.

For additional information on the amended regulation, please refer to “Section G. State Drug Utilization Data (SDUD) Reported to MDRP,” of *CMS-2482-F Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements*, posted in the Federal Register at: <https://www.federalregister.gov/documents/2020/12/31/2020-28567/medicaid-program-establishing-minimum-standards-in-medicaid-state-drug-utilization-review-dur-and>.

If you have any questions regarding this topic, please contact MDRUtilization@cms.hhs.gov.

Sincerely,

/s/

Alissa Mooney DeBoy
Director
Disabled and Elderly Health Programs Group