

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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Center for Medicaid and CHIP Services

February 10, 2023

MEDICAID DRUG REBATE PROGRAM NOTICE

Release No. 191

For States

Important Medicaid Drug Rebate Program Reminders for States

This state program notice provides two reminders to states of actions that are upcoming: (1) to report certain data about their value-based purchasing arrangements under a Centers for Medicare & Medicaid Services (CMS) authorized supplemental rebate agreement, and (2) to certify their state drug utilization data.

State Data Report on CMS-Authorized Supplemental Rebate Agreements with Value-Based Purchasing Arrangements – DUE NO LATER THAN March 1, 2023

Effective January 1, 2023, information on calendar year (CY) 2022 value-based purchasing (VBP) arrangements under a CMS-authorized supplemental rebate agreement (SRA) are due to CMS. These reports must be submitted within 60 days after the end of CY 2022, or by March 1, 2023.

On December 30, 2020, CMS finalized a policy in *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* (CMS-2482-F). The final rule added 42 CFR § 447.518(d)(2), which requires a state participating in a VBP agreement(s) with a manufacturer approved under a CMS-authorized SRA to report to us the data described in the § 447.518(d)(3) within 60 days of the end of each calendar year. Specifically, § 447.518(d)(3) requires that within 60 days of the end of each year, the state must submit all of the following data, including cumulative data to date:

- State,
- National drug code(s) for drugs covered under the CMS-authorized VBP SRA,
- Product's Food and Drug Administration (FDA) list name,
- Number of prescriptions,
- Cost to the state to administer the CMS-authorized VBP SRA (for example, systems changes, tracking outcomes, etc.), and
- Total savings generated by the supplemental rebate due to the CMS-authorized

VBP SRA.

CMS published the format states will use to report the required data as part of the Paperwork Reduction Act (PRA) package CMS-10722 on June 11, 2021. States may access the downloadable workbook that includes the PRA Disclosure statement, data reporting format and data definitions at <https://omb.report/icr/202106-0938-006/doc/112336601>.

States should mail their reports to our drug policy mailbox (RxDrugPolicy@cms.hhs.gov) with the subject line “Annual Report on VBP SRA”. CMS notes that this reporting only applies to states that enter into VBP arrangements with manufacturers under CMS-authorized SRAs.

If you have further questions regarding the state data reporting, please send your inquiries to the CMS Rx DRUG Policy email box at RxDrugPolicy@cms.hhs.gov.

Requirement for Certification of State Drug Utilization Data (SDUD)

The State Drug Utilization Data (SDUD) certification module has been available in the Medicaid Drug Product (MDP) system since August 2022. As a reminder, states must certify all newly submitted or revised SDUD records submitted after January 1, 2022. This includes fourth quarter (4Q) 2021 and first quarter (1Q) 2022 SDUD submissions as these data were submitted after the January 1, 2022 effective date of the certification requirement.

CMS reminds all State and Technical Medicaid Drug Rebate Program (MDRP) contacts that the certification of SDUD is not an option. States are expected to review and certify their data after each quarter’s SDUD submission. In addition to the current quarter, if changes were made to prior periods, then that data will need to also be reviewed/recertified.

If you need assistance with the certification module within MDP, there are several resources available to you. There is a demonstration video that is posted to the MDP Bulletin page, which may also be accessed via this link: [SDUD Certification](#). Additionally, the MDP User Manual is available for download within MDP, and provides screenshots and detailed instructions for maneuvering through the SDUD screens, including the new Certification module.

Specific questions regarding SDUD certification should be directed to MDRUtilizaton@cms.hhs.gov.

Sincerely,

/s/

Alissa Mooney DeBoy
Director
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