de: 4120-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 433, 438, 447, and 456

[CMS-2482-P2]

RIN 0938-AT82

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: Delay of Effective Date for Provision Relating to Manufacturer Reporting of Multiple Best Prices Connected to a Value Based Purchasing Arrangement; Delay of Inclusion of Territories in Definition of States and United States

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: This proposed rule proposes to delay for 6 months the January 1, 2022 effective date for amendatory instruction 10.a., which addresses the reporting by manufacturers of multiple best prices connected to a value based purchasing arrangement, of the final rule entitled, "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", published in the December 31, 2020 **Federal Register**. This proposed rule also proposes to delay for 2 years the April 1, 2022 effective date of inclusion (inclusion date) for U.S. territories (American Samoa, Northern Mariana Islands, Guam, Puerto Rico, and the Virgin Islands) in the amended regulatory definitions of "States" and "United States" for purposes of the Medicaid Drug Rebate Program (MDRP), adopted in the interim final rule with comment period entitled, "Medicaid Program;

Covered Outpatient Drug; Further Delay of Inclusion of Territories in Definitions of States and United States", published in the November 25, 2019 **Federal Register** to April 1, 2024. In the alternative, we are proposing to finalize an inclusion date that may be earlier than April 1, 2024, but not before January 1, 2023, based on public comments received. We are requesting public comment on the proposed delays of applicable effective date and inclusion date discussed in greater detail below.

DATES: To be assured consideration, comments on the proposals must be received at one of the addresses provided below by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE **FEDERAL REGISTER**].

ADDRESSES: In commenting, please refer to file code CMS-2482-P2.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. Electronically. You may submit electronic comments on this regulation to **http://www.regulations.gov**. Follow the "Submit a comment" instructions.

2. By regular mail. You may mail written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-2482-P2,

P.O. Box 8016,

Baltimore, MD 21244-8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-2482-P2,

Mail Stop C4-26-05,

7500 Security Boulevard,

Baltimore, MD 21244-1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Christine Hinds, (410) 786-4578; Wendy Tuttle, (410) 786-8690.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the applicable comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the applicable comment period on the following website as soon as possible after they have been received: http://www.regulations.gov. Follow the search instructions on that Web site to view public comments. CMS will not post on Regulations.gov public comments that make threats to individuals or institutions or suggest that the individual will take actions to harm the individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

I. Background

A. Proposed Delays in Effective and Inclusion Dates of Certain Regulation Provisions

CMS is proposing to delay the January 1, 2022 effective date for amendatory instruction 10.a. of the final rule entitled, "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" (85 FR 87000), for 6 months to July 1, 2022, and to delay the April 1, 2022,

inclusion date in the amended regulatory definitions of "States" and "United States", adopted in the interim final rule with comment period entitled "Medicaid Program; Covered Outpatient Drugs; Further Delay of Inclusion of Territories in Definitions of States and United States" (84 FR 64783), for 2 years until April 1, 2024, or in the alternative, to a date earlier than April 1, 2024, but not before January 1, 2023.

B. Proposed Delay of Effective Date of Amendatory Instruction 10.a.

On December 31, 2020, we published a final rule in the **Federal Register** entitled "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"[1] (85 FR 87000) (hereinafter referred to as the December 31, 2020 final rule). The December 31, 2020 final rule advanced CMS' efforts to support state flexibility to enter into innovative value-based purchasing (VBP) arrangements with drug manufacturers for new and innovative, and often costly therapies, such as gene therapies, and codified new approaches required by section 1004 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (SUPPORT Act) (Pub. L. 115-271, enacted October 24, 2018) and the existing Medicaid DUR program to improve the clinical use of opioids and reduce the potential for abuse in Medicaid patients. In addition, it codified in regulation several changes made in recent legislation and clarified other provisions of regulations relating to the Medicaid Drug Rebate Program (MDRP).

The regulations included in the December 31, 2020 final rule went into effect on March 1, 2021, except for certain amendatory instructions, including instruction 10.a., which is effective on January 1, 2022. We are proposing to delay the January 1, 2022 effective date for amendatory instruction 10.a. of the December 31, 2020 final rule on manufacturer reporting of multiple best

[1] https://www.federalregister.gov/documents/2020/12/31/2020-28567/medicaid-program-establishing-minimum-standards-in-medicaid-state-drug-utilization-review-dur-and.

prices connected to a VBP arrangement, to July 1, 2022, and are seeking public comment on the proposed delay as outlined in section I.A. of this proposed rule. As discussed in greater detail in section II. of this proposed rule, we believe a delay of 6 months is warranted to assure that stakeholders have the ability to implement the new VBP policy in a manner that assures that patient access and quality of care is protected. We seek public comments on this proposed delay in the effective date, including the impact of this delay on affected beneficiaries. The primary reason for the original delay, and the new proposed delay, is to provide more time for CMS, states, and manufacturers to make the complex system changes necessary to implement the new best price and VBP program, and assure patient access and quality of care, given the current need to devote resources to the public health emergency (PHE) relating to COVID-19 that has been in effect, and will likely remain in effect through 2021.

C. Proposed Delay of Inclusion Date in Amended Regulatory Definitions of "States" and "United States"

The Covered Outpatient Drug (COD) final rule, published in the February 1, 2016 **Federal Register** (81 FR 5170), amended the regulatory definitions of "States" and "United States" to include the U.S. territories (American Samoa, Northern Mariana Islands, Guam, Puerto Rico, and the Virgin Islands) for the purposes of the MDRP with a delayed inclusion date of April 1, 2017. We stated in the preamble to the final rule that U.S. territories may use existing waiver authority to elect not to participate in the MDRP consistent with the statutory waiver standards. Specifically, the Northern Mariana Islands and American Samoa may seek to opt out of participation under the broad waiver that has been granted to them in accordance with section 1902(j) of the Act. The territories of Puerto Rico, the Virgin Islands, and Guam may use waiver authority under section 1115 of the Act to waive section 1902(a)(54) of the Act, which requires state compliance with the applicable requirements of section 1927 of the Act (81 FR 5203 through 5204).

The change to the definition of "States" and "United States" under the COD final rule to

include the territories would also impact the quarterly calculation of average manufacturer price (AMP) and best price by manufacturers. That is, the change requires manufacturers to include prices paid by entities in the U.S. territories in the same manner in which they include prices paid by entities located in one of the 50 states and District of Columbia (81 FR 5224) in AMP and best price. It requires manufacturers to include eligible sales and associated discounts, rebates, and other financial transactions that take place in the U.S. territories in their calculations of AMP and best price once the revised definitions of "States" and "United States" take effect, regardless of whether the U.S. territories seek to waive participation in the MDRP.

Once the COD final rule became effective, CMS began discussions with the territories regarding their participation in the MDRP. Based on those discussions, it became evident that interested territories would not be ready to participate in the MDRP by April 1, 2017. Stakeholders also reiterated the concerns in the comments to the COD final rule (81 FR 5224) that drug manufacturers will likely need to increase drug prices paid by U.S. territory Medicaid programs once the territories are included in the definitions of "States" and "United States" in order to avoid setting a new, lower best price. That is because if prices for drugs in the territories are lower than those in the states, then those prices could become the Medicaid best price for that drug in the entire Medicaid program. The manufacturers may then increase their drug prices in the territories to avoid this outcome, and an increase in drug prices in the territories could result in an increase in territory Medicaid drug spending without the offsetting benefit of receiving Medicaid rebates. Furthermore, the increase in Medicaid drug spending could adversely impact the availability of drugs to patients in the territories because of their Medicaid funding cap.

As a result of these initial and subsequent discussions on preparedness, the potential for increased Medicaid drug prices in certain territories, and later, due to additional impacts of natural disasters in several of the territories, CMS issued two interim final rules with comment period (IFC) to further delay the inclusion date for the U.S. territories in the regulatory definitions of "States" and "United States" for purposes of the MDRP. The first, the "Medicaid

Program; Covered Outpatient Drug; Delay in Change in Definitions of States and United States" IFC, was issued on November 15, 2016, amending the regulatory definitions of "States" and "United States" to include the U.S. territories beginning April 1, 2020, rather than to April 1, 2017 (81 FR 80003). The second, the "Medicaid Program; Covered Outpatient Drug; Further Delay of Inclusion of Territories in Definitions of States and United States" IFC, was published on November 25, 2019, and further delayed the inclusion date for the regulatory definitions of "States" and "United States" to include the U.S. territories beginning April 1, 2022, rather than April 1, 2020 (84 FR 64783).

For similar reasons, in addition to ensuring continued beneficiary access and quality of care protections, we are proposing to amend § 447.502 to delay the April 1, 2022 inclusion date for the amended regulatory definitions of "States" and "United States" to April 1, 2024, and are seeking public comment on the proposed delay as outlined in section I.A. of this proposed rule. As discussed in greater detail in section II. of this proposed rule, we believe an additional delay of 2 years may be warranted because it would allow the territories to focus their human and financial resources on ensuring the health and well-being of their beneficiaries during this PHE, rather than having to divert those resources to the development of systems required to participate in the MDRP, which can take several years to implement from start to finish, and seek public comments on this proposal. However, if we determine based on public comments received from interested parties that the territories that want to participate in MDRP can do so sooner than April 1, 2024, and those that do not want to participate are able to complete the necessary waiver process, then we are proposing in the alternative to finalize a date that is sooner than April 1, 2024, but not earlier than January 1, 2023.

II. Proposed Delay in Effective and Inclusion Dates of Certain Regulation Provisions Due to Ongoing Public Health Emergency (PHE)

On April 21, 2021, the Secretary of Health and Human Services (the Secretary) renewed the PHE initially declared on January 31, 2020, to continue giving CMS programs (including

Medicaid) flexibility to support beneficiaries during the COVID-19 pandemic. This PHE is expected to last through 2021. In response to the PHE, CMS put in place its own pandemic plan (https://www.cms.gov/files/document/covid-pandemic-plan.pdf) to address the needs of its stakeholders, as well as the beneficiaries of its various programs including Medicaid. As part of that plan, CMS provided that it may approve waivers, amendments, and flexibilities for U.S. states, including the District of Columbia, and U.S. territories to allow Medicaid and CHIP programs to adapt their operations as necessary to respond to the pandemic. The pandemic plan also provided that it may make adjustments to the agency's value-based payment initiatives to allow health providers, healthcare facilities, Medicare Advantage and Part D plans, and States to focus on providing needed care to beneficiaries. In addition to the flexibilities granted to states under the PHE, the President signed into law on March 11, 2021 the American Rescue Plan Act of 2021 (ARP) (Pub. L. 117-2) to address the health care and economic needs of the country during the pandemic. This law is one of the most significant expansions of Medicaid since enactment of the Affordable Care Act of 2010, and includes several new mandatory benefit requirements on states that will take time to implement.

We acknowledged in the December 31, 2020 final rule that the changes to the reporting of multiple best prices by manufacturers under the MDRP (a VBP policy) adopted under the amendatory instruction 10.a would require additional time to provide operational guidance and complex system changes to implement. Thus, we delayed the effective date of the VBP provision until January 1, 2022. States that opt to participate in VBP models offered by manufacturers under the multiple best price approach must ensure that beneficiaries have appropriate access to care under such arrangements by developing systems and methods to track beneficiaries and their outcomes, retrieving and evaluating the patient-specific outcomes data, and securing the cooperation of providers and beneficiaries to enter into some of the more complex outcome-based arrangements offered by the manufacturers. Thus, there will be requirements on states to develop significant capabilities to build an infrastructure that will be able to implement VBP.

We also want to be sure that our own technology infrastructure will be ready to receive multiple VBP offers from manufacturers that will report them to CMS, and subsequently report them to states. We are currently developing a new Medicaid Drug Program (MDP) system. This MDP system will replace CMS' current legacy system with certain aspects of the system expected to be transitioned in the summer of 2021. However, because of other events that have transpired since the regulation was published in December 2020, we do not believe that certain aspects of the system necessary for states and manufacturers to operationalize the VBP multiple best price program will be transitioned at that time, making a January 1, 2022 infeasible. We believe that it is important to have a technically up-to-date system that is ready to support the data requirements necessary for states and manufacturers to operationalize the VBP multiple best price program. However, we may have a delay with operationalizing that part of the MDP system by July 2021, which may mean we will not have the necessary CMS components in place by later this year to implement the program by January 1, 2022, and believe July 1, 2022, is a realistic target date.

Furthermore, the demands on researching, producing, and distributing COVID-19 drug treatments and vaccines have likely diverted some manufacturer financial and human resources from developing and implementing system changes that would be required to enter multiple best price offers in the MDP system.

We understand that there is interest among patient and consumer groups, states, and manufacturers in the new multiple best price policy, and we are committed to implementing the VBP multiple best price policy in a manner that assures that Medicaid beneficiaries have access to medications and therapies that are appropriately administered and monitored. However, we are concerned that there are several challenges the states, providers, and manufacturers are facing during the PHE. These include, in addition to those resulting from the passage of the ARP, those relating to implementing expanded eligibility and mandatory benefit requirements under Medicaid (as described below). In sum, states, providers and manufacturers, as well as CMS,

will need additional time to operationalize the multiple best prices policy under amendatory instruction 10.a.

Therefore, given the possible delay in the MDP system and the recent developments around the PHE and ARP, we believe more time is critical to permit CMS and our partners - states, providers, and manufacturers - to successfully implement the multiple best prices approach so that Medicaid patients benefit from these programs to full extent possible. Specifically, CMS and all the parties involved with the multiple best prices policies will want to make sure Medicaid patients receive the drug therapies under the VBP approach that are prescribed for them in a timely manner; that the VBP program does not create unnecessary barriers or requirements on the patient to access the drug; that they receive appropriately scheduled doses of a therapy if the patient treatment under the VBP arrangement is based on multiple doses; and that patient outcomes are tracked so that optimal patient care is provided; and, the states can obtain any additional discounts due to them from manufacturers under the VBP arrangement. At this time, we believe it is in the best interest of the Medicaid program and Medicaid beneficiaries, in particular, that states prioritize the Medicaid eligibility and benefit requirements under the ARP (for example, expanded optional Medicaid coverage for postpartum women, expansion of COVID-19 testing and treatment services, and expansion of vaccine administration to limited benefit groups), resulting from enactment of the ARP to address beneficiary needs during the COVID-19 pandemic, and therefore, propose a delay to the effective date for amendatory instruction 10.a. (the multiple best price approach) by 6 months (effective July 1, 2022). By allowing more time to address the needs of Medicaid beneficiaries during the PHE, states, CMS, providers, and manufacturers will also have more time to put in place appropriate beneficiary protections as part of the multiple best price approach.

Therefore, we propose to delay the amendment associated with multiple best price requirements for 6 months, which if finalized, would make amendatory instruction 10.a effective beginning July 1, 2022. We also expect to issue additional guidance before that time on

operational and policy aspects of the new VBP program, including specifications relating to beneficiary protections.

For the same reasons discussed above, we believe that in light of the pandemic and the resource demands stemming from the PHE (including those established under the ARP) on the Medicaid program and its beneficiaries, it is imperative that the territories prioritize the Medicaid eligibility and mandatory benefit requirements brought about by the ARP to address beneficiary needs during the COVID-19. Therefore, we believe that a further delay in the inclusion date of the U.S. territories in the regulatory definitions of "States" and "United States" is warranted and are proposing that they be included in those definitions beginning April 1, 2024. In the alternative, we are proposing to finalize an inclusion date that may be earlier than April 1, 2024, but not before January 1, 2023, based on public comments received.

By delaying the inclusion date to April 1, 2024, or in the alternative, a date earlier than April 1, 2024, but not before January 1, 2023, we are allowing the territories additional time to develop needed systems and policy changes, in order to avoid unintended increases in drug costs and access concerns. The needed systems must be capable of collecting, reporting, validating, and tracking drug utilization on an ongoing basis. In addition, they require extensive advance planning and budgeting.

The delay in inclusion date would also benefit those territories that choose not to participate in the MDRP, and therefore, would be required to use human and financial resources to complete the section 1115 and section 1902(j) waiver applications that are required to waive out of MDRP participation should the current April 1, 2022 date remain in effect.

Moreover, should the amended regulatory definitions of "States" and "United States" go into effect on April 1, 2022, all manufacturers' sales to the territories and prices paid would be included in the AMP and best price calculations at that time, regardless of whether the territory is participating in the MDRP. As discussed in the COD final rule (81 FR 5224), we heard from various stakeholders who expressed concerns that drug manufacturers would likely be prompted

to increase drug prices, including prices paid by the U.S. territory Medicaid programs, once the territories are included in the definitions of "States" and "United States." This is because, as currently drafted, section 1927 of the Act requires that eligible sales of drugs within the United States be included in the drug manufacturers calculation of Average Manufacturer Price (AMP) and best price. The inclusion of these prices in AMP and best price would result in the territories that receive a waiver realizing an increase in their Medicaid drug costs without the offsetting benefit of receiving Medicaid rebates. Furthermore, the increase in Medicaid costs could adversely affect territories because of their Medicaid funding cap. As noted above, that could result in an increase in drug prices in the territories, making drugs less affordable, and making it more difficult for the territories to address their own public health needs during the PHE. We believe this provides further rationale for delaying the inclusion date of territories in the regulatory definitions of "States" and "United States." It will ensure that during this PHE, which has the potential to extend into 2022, those territories that opt to waive participation from the MDRP will not face the additional financial burdens associated with increased Medicaid drug costs from drug manufacturers increasing drug prices to the territories.

We are proposing a new inclusion date of April 1, 2024 for the amended regulatory definitions of "States" and "United States" to include the U.S. territories for purposes of the MDRP. In the alternative, we are proposing to finalize an inclusion date that may be earlier than April 1, 2024, but not before January 1, 2023, based on public comments received. Thus, we are specifically requesting comments from all interested parties on whether April 1, 2024, or an earlier inclusion date, but not earlier than January 1, 2023, would be more appropriate for the amended regulatory definitions. More specifically, we are requesting public comments that will assist us in understanding all relevant concerns related to establishing a new inclusion date, including whether territories are ready to participate in the MDRP, and whether CMS is able to execute appropriate and necessary waivers for territories that do not want to participate. In any case, manufacturers would be required to include their sales to the territories in their AMP and

best price calculations based on the inclusion date finalized in a final rule, which we are proposing to be April 1, 2024, or possibly earlier, but no earlier than January 1, 2023 based on public comments.

Therefore, we are requesting comment on our proposal to amend § 447.502 to delay the inclusion date for the the U.S. territories into the regulatory definitions of "States" and "United States" until April 1, 2024. We are also requesting comments on an alternative proposal, which is to finalize an inclusion date that may be earlier than April 1, 2024, but not before January 1, 2023, based on public comments received.

III. Response to Comments

Because of the significant number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble for each applicable comment period, and, if and when we proceed with a subsequent document, we will respond to the applicable comments in the preamble to that document, as appropriate.

I, Elizabeth Richter, Acting Administrator of the Centers for Medicare & Medicaid Services, approved this document on May 18, 2021.

List of Subjects in 42 CFR Part 447

Accounting, Administrative practice and procedure, Drugs, Grant programs-health, Health facilities, Health professions, Medicaid, Reporting and recordkeeping requirements, Rural areas.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 447—PAYMENT FOR SERVICES

1. The authority citation for part 447 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1396r-8.

2. Amend § 447.502 by revising the definitions of "States" and "United States" to read as follows:

§ 447.502 Definitions.

* * * * *

States means the 50 States and the District of Columbia and, beginning April 1, 2024, also includes the Commonwealth of Puerto Rico, the Virgin Islands of the United States, Guam, the Commonwealth of the Northern Mariana Islands, and American Samoa.

United States means the 50 States and the District of Columbia and, beginning April 1, 2024, also includes the Commonwealth of Puerto Rico, the Virgin Islands of the United States, Guam, the Commonwealth of the Northern Mariana Islands, and American Samoa.

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Dated: May 21, 2021.

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Xavier Becerra,

Secretary,

Department of Health and Human Services.

[FR Doc. 2021-11160 Filed: 5/26/2021 4:15 pm; Publication Date: 5/28/2021]