PART 117—DRAWBRIDGE OPERATION REGULATIONS

■ 1. The authority citation for part 117 continues to read as follows:

Authority: 33 U.S.C. 499; 33 CFR 1.05–1; and Department of Homeland Security Delegation No. 0170.1.

■ 2. In § 117.400, add paragraph (c) to read as follows:

§ 117.400 Indiana Harbor Canal.

* * * * *

(c) The Indianapolis Boulevard Bridge, mile 2.59, at East Chicago, shall open on signal if at least twelve hours' notice is given.

M.J. Johnston.

Rear Admiral, U.S. Coast Guard, Commander, Ninth Coast Guard District.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 447

[CMS–2482–F2]

RIN 0938–AT82

Medicaid Program; 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), HHS.

ACTION: Final rule.

SUMMARY: This final rule will 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 (VBP) 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** to July 1, 2022. This final rule will also delay for 9 months the April 1, 2022 effective date of inclusion (hereinafter referred to as the inclusion date) of the 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 January 1, 2023. We requested public comment on the proposed delays of the applicable effective date and inclusion date and discuss the comments received in this final rule.

DATES: These regulations are effective on December 20, 2021.

FOR FURTHER INFORMATION CONTACT: Christine Hinds, (410) 786–4578.

SUPPLEMENTARY INFORMATION:

I. Background

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

In the ''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'' proposed rule that published in the May 28, 2021 **Federal Register** (86 FR 28742) (hereinafter referred to as the proposed rule), CMS made two proposals. First, CMS proposed 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) (hereinafter referred to as the December 31, 2020 final rule), for 6 months to July 1, 2022. Second, CMS proposed 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 based on public comments.

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

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. In the proposed rule, we proposed 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 prices connected to a VBP arrangement, to July 1, 2022, and sought public comment on the proposed delay. As discussed in the proposed rule, we believed 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 patient access and quality of care are protected. We sought 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 proposed delay, was 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 at least through 2021. 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 was most recently renewed on October 15, 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 Patient Protection and Affordable Care Act (Pub. L. 111–148, enacted March 23, 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 noted that we 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 developed 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 2022. However, because of other events that have transpired since the regulation was published on December 31, 2020, we explained in the proposed rule that we did not believe that certain aspects of the system necessary for states and manufacturers to operationalize the VBP multiple best price program would be transitioned at that time, making a January 1, 2022 effective date infeasible. We also noted that we believed 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. When the proposed rule was issued, we were concerned we could have a delay with operationalizing that part of the MDP system, which could mean we would not have the necessary CMS components in place by later this year to implement the program by January 1, 2022, and believed July 1, 2022, to be a more realistic target date. As noted in the proposed rule, 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 also stated that in the proposed rule that we understand that there was interest among patient and consumer groups, states, and manufacturers in the new multiple best price policy, and that we were 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 remain concerned that there are several challenges the states, providers, and manufacturers are facing during the PHE. These included those resulting from the passage of the ARP, including those relating to implementing expanded eligibility and mandatory benefit requirements under Medicaid (as described below). In summary, 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 explained in the proposed rule that 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. We also 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. Therefore, we proposed a delay to the effective date for amendatory instruction 10.a. (the multiple best price approach) of 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. Again, by delaying the effective date of the amendment permitting multiple best price reporting for 6 months, the amendatory instruction 10.a would be effective beginning July 1, 2022. In the proposed rule, CMS also stated it expects to issue additional guidance before that time on operational and policy aspects of the new VBP program, including specifications relating to beneficiary protections.

C. Proposed Delay of Inclusion Date of U.S. Territories 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 effective 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 Social Security Act (the Act). 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'' 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 effective date for including 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 amending the regulatory definitions of ''States'' and ''United States'' to include the U.S. territories to 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 proposed to amend 42 CFR 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 sought public comment on the proposed delay. In the alternative, we proposed to finalize an earlier inclusion date, but no earlier than January 1, 2023, based on public comments received. We explained in the proposed rule that 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 sought public comments on the proposal.

As discussed in the proposed rule, 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 proposed an inclusion date beginning April 1, 2024. In the alternative, we proposed 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 explained in the proposed rule that 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, 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 proposed delay in inclusion date would also benefit those territories that choose not to participate in the MDRP, which would be required to use human and financial resources that are currently focused on responding to the PHE 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, as explained in the proposed rule, 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 will 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 stated 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 AMP and best price. The inclusion of these prices in AMP and best price could 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 previously in the proposed rule, 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 effective date of the inclusion of the 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 proposed 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 proposed to finalize an inclusion date that may be earlier than April 1, 2024, but before January 1, 2023, based on public comments received. We specifically requested comments 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 requested 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 proposed to be April 1, 2024, or possibly earlier, but no earlier than January 1, 2023 based on public comments.

II. Response to Public Comments and Provisions of the Final Rule

In response to the proposed rule, we received 29 public comments.

A. Delay of Effective Date of Amendatory Instruction 10.a. (§ 447.505(a))

The following is a summary of the comments received and our responses on proposed delay of effective date of amendatory instruction 10.a., which addresses the reporting by manufacturers of multiple best prices connected to value based purchasing (VBP) arrangements.

Comment: Several commenters supported the proposal to delay for 6 months the January 1, 2022 effective date for amendatory instruction 10.a. of the December 31, 2020 final rule, which addresses the reporting by manufacturers of multiple best prices connected to a VBP arrangement. These commenters supported the proposed delay because of both the time as well as the state and federal resources that have been taken up by the emergence of the pandemic, implementation of Medicaid expansion under the ARP, and the focus on development, production, and distribution of vaccination efforts related to controlling the spread of the COVID–19 virus. Some commenters indicated that they do not believe that states, providers, and CMS have the infrastructure in place at this time to be able to track the necessary data related to health outcomes to properly implement VBP arrangements. They believe that the proposed delay will allow for some of this work (for example, work associated with pandemic efforts and infrastructure work to collect adequate patient data with appropriate privacy protections) to be finished without compromising care for those who need it in the interim. The commenters also noted that the proposed delay will allow CMS, states, and manufacturers time to develop and test the new MDP system, and allow CMS to develop operational guidance to facilitate multiple best price reporting.

Response: We appreciate the support of the proposed delay of the effective date of amendatory instruction 10.a. to July 1, 2022, and continue to believe that the proposed delay is necessary for CMS, manufacturers, states, and providers to engage in the work necessary to facilitate the multiple best price reporting approach. As commenters noted, we are implementing a new MDP system and, as part of that new system, will include the necessary changes to address multiple best price reporting. The additional 6 months will give us time to upgrade our new MDP system to collect multiple best prices, as well as explore and test these changes with the manufacturers and states that have been anxious to commit to the multiple best price approach. We will also use this time to issue operational guidance for states and manufacturers on reporting and accessing the multiple best price information in the MDP system.

For commenters' concerns regarding infrastructure and data collection, while we plan to provide general operational guidance, we do not plan to issue guidance on how to operationalize, evaluate, or monitor *specific* VBP arrangements as each arrangement will have its own set of specific facts and circumstances associated with the arrangement, such as the drug, the anticipated outcomes, and population included in the arrangement. A ''one size fits all'' approach to operationalizing a VBP arrangement is not possible because of the many different arrangements on the marketplace (85 FR 87018).

Comment: A few commenters urged CMS to effectuate the multiple best price reporting option as established in the final rule, but no later than the proposed delay in effective date of July 1, 2022. Several commenters, while agreeing with the proposed delay, continue to believe that the multiple best price reporting flexibility is essential to ensuring that patients benefit from VBP arrangements. One commenter in particular was disappointed that CMS was considering the proposed 6 month delay in effective date, but understood that putting in place the necessary systems and modifications for a seamless adoption of this new program is challenging. This commenter encouraged CMS to work diligently to ensure the proposed effective date of July 1, 2022 was achievable. Another commenter indicated that any further delay in effective date, beyond the 6 months proposed, will result in substantial negative repercussions for patient access to therapies that address significant unmet need, especially for Medicaid beneficiaries, and therefore, should be a one-time delay.

Response: This delay rule allows states additional time to ensure patient access by Medicaid beneficiaries to certain higher cost therapies. We will continue to assess system readiness for states, manufacturers and CMS to ensure the reporting by manufacturers of multiple best prices connected to a VBP arrangement can be effectuated in

the timeframe established in this delay rule, and we may consider further delays in future rulemaking if systems are not ready.

Comment: Several commenters provided input as to how CMS, states, and manufacturers should utilize the time associated with the proposed 6 month delay in effective date. One commenter encouraged CMS to utilize the proposed 6 month delay to issue subregulatory guidance regarding whether an arrangement would qualify as a VBP arrangement if a State Medicaid Agency is not able to access the same type of patient and outcomes data utilized in the commercial contract that resulted in the multiple best price. In other words, the commenter questioned if the state and the manufacturer will be allowed to modify the commercial sector agreement to better fit the Medicaid population, and how manufacturers will report multiple best prices when multiple commercial and/or state agencies enter into similar contracts but have different outcomes, resulting in different rebates and multiple best prices.

Response: We appreciate the commenters' recommendations for how CMS, states, and manufacturers should utilize the time associated with the proposed 6 month delay in effective date; however, these comments and recommendations are outside of the scope of this rulemaking. We note, however, that CMS plans to provide further operational guidance for states and manufacturers in the near future regarding the implementation of the multiple best price reporting.

Comment: A few commenters requested that CMS take this additional time to consult with Medicaid agencies and other stakeholders to ensure the necessary systems and technology needed to facilitate the collection and reporting of patient clinical outcomes are in place. The commenters further commented that CMS should encourage and incentivize consistency (for example, standard data reporting requirements) in these systems across states.

Response: We agree with the commenters, and as noted in the December 31, 2020 final rule, we plan to develop operational guidance regarding the final policy permitting multiple best price reporting. To that end, we have been available to manufacturers, states, and other stakeholders to discuss what is needed in MDP systems to effectuate the reporting of multiple best prices and intend to issue operational guidance associated with the MDP system changes. We expect to also provide states with guidance regarding existing Medicaid access and beneficiary protections when engaging in VBP arrangements.

With respect to the standardization of reporting systems across states, we understand that such systems would benefit states, patients, and manufacturers, as it would facilitate implementation of VBP programs, and avoid duplication of efforts. Since the MDP systems operated by CMS will not be collecting patient-specific or outcomes data associated with VBP arrangements, we will not be encouraging or providing incentives to standardized data collection reporting associated with VBP arrangements as part of the MDP system. However, we expect that states, working with their supplemental rebate contractors or other VBP vendors, as well as manufacturers, will attempt to create standardized reporting templates and formats that may become industry standards over time.

Comment: A few commenters indicated their appreciation of CMS' December 31, 2020 final rule to enhance flexibility in creating VBP arrangements; however, the commenters do not believe a 6 month delay in the effective date allows CMS sufficient time to adequately address the operational complexities and other legal hurdles (giving examples such as the federal Anti-Kickback Statute or Medicare Part B requirements) that impede adoption of VBP arrangements in a timely fashion. Therefore, the commenters stated that to leverage the full benefit of VBP arrangements, additional flexibilities and clarity are needed that cannot be provided via subregulatory guidance and urged CMS to withdraw the December 31, 2020 final rule and issue a revised proposed rule, or reopen the December 31, 2020 final rule for further public comment. A commenter indicated that while they appreciate CMS' interest in and effort to modernize the MDRP to support innovation that advances high value, patient-centered care through VBP arrangements, the final VBP multiple best price policy lacks clarity and does not consider a full range of operational hurdles. The commenter also indicated that the changes to the MDRP alone are not sufficient to reduce current barriers to VBP arrangements in the commercial market, and therefore, CMS must address the Anti-Kickback Statute (AKS), impact to Average Sales Price (ASP), and other government price reporting barriers to realize the full potential of VBP arrangements.

Another commenter expressed concerns regarding how the final rule on VBP arrangements could be gamed by manufacturers. The commenter suggested and encouraged CMS withdraw the December 31, 2020 final regulation, prohibit manufacturers from reporting multiple best prices, limit outcomes-based arrangements under a bundled approach, and clarify requirements regarding stacking discounts. The commenter expressed concern that CMS' VBP regulations, as finalized in the December 31, 2020 final rule, are not related to the Medicaid program and instead are designed to encourage specific types of contracting in the commercial market. This commenter suggested that the VBP regulations change Medicaid program requirements to achieve a goal outside of the Medicaid program and asserted that it is not appropriate to harm the Medicaid program to promote commercial contracting flexibility.

Response: The proposed rule only proposed a delay in effective date related to the VBP multiple best price reporting policy finalized in the December 31, 2020 final rule. The underlying policy itself was not a subject of the proposed rule open to public comment. Thus, comments related to the underlying policy are outside the scope of this rulemaking. At this time, we believe the 6 month delay beyond the initial delay in inclusion date from the COD final rule will be adequate for manufacturers to provide the data necessary to report multiple best prices in MDP system. Any other legal requirements that manufacturers may be subject to, such as the federal anti-kickback statute or Medicare Part B requirements, are outside of the scope of this rulemaking. However, we do intend to issue additional guidance on the interaction between VBP and Medicare Part B ASP calculations.

Comment: Some commenters continue to request additional clarity on whether, and to what extent, new VBP arrangements run afoul of the federal anti-kickback statute. The commenters indicate that CMS should work to remove barriers imposed by AKS that limit or prevent adoption of VBP arrangements.

Response: While we appreciate the comments received, these issues are outside the scope of this rulemaking. As noted above, the underlying policy regarding VBP arrangements was not a subject of the proposed rule open to public comment. Rather, the proposed rule specifically proposed a 6 month delay to the effective date for the policy permitting manufacturers to report multiple best prices related to a VBP arrangement. Questions regarding these

issues should be directed to the Office of the Inspector General (OIG).

Comment: A couple of commenters reiterated their comments provided on the ''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'' proposed rule that appeared in the June 19, 2020 **Federal Register** (85 FR 37256), including comments regarding the drug utilization review requirements.

Response: The DUR requirements set forth in the December 31, 2020 final rule were not a subject of this proposed rule and were not impacted by the proposed delay.

After consideration of the comments received regarding the proposed delay to amendatory instruction 10.a. of the December 31, 2020 final rule, we are finalizing the proposed July 1, 2022 effective date.

B. Delay of Inclusion Date of U.S. Territories in Amended Regulatory Definitions of ''States'' and ''United States'' (§ 447.502)

The following is a summary of the comments received and our responses on the proposed delay of the inclusion date for the U.S. territories in the definition of ''States'' and ''United States'' at § 447.502 to April 1, 2024, or, alternatively, a date that is earlier than April 1, 2024, but not before January 1, 2023 based on public comments received.

Comment: Several commenters supported the proposed delay of the April 1, 2022 inclusion date to April 1, 2024, or, alternatively, to a date earlier than April 1, 2024, but not before January 1, 2023 based on public comments. These commenters supported the proposed delay because of the territories' current need to focus on the PHE relating to COVID–19 and the time needed to prepare for the technology infrastructure changes necessary to support participation in the MDRP. The commenters also noted concern that manufacturers may increase their drug prices in the territories as a result of their participation in the MDRP. One commenter specifically noted concern as to whether the territories would be capable of participating in the MDRP prior to April 1, 2024.

Another commenter supported the proposed delay, given the various programs and processes that a state has to put in place to effectively and efficiently participate in the MDRP, such as establishing a drug manufacturer rebate billing mechanism, a state drug utilization reporting mechanism, a process to assure that all drugs of a manufacturer that sign a rebate agreement with the Secretary of HHS are covered, a dispute resolution process, and a Drug Utilization Review (DUR) program.

Another commenter supported a proposed delay of the April 1, 2022 inclusion date and suggested October 1, 2023 as an alternative inclusion date. The commenter stated that an October 1, 2023 inclusion date would provide an additional eighteen months beyond April 1, 2022 before the territories are included in the amended regulatory definitions of ''States'' and ''United States'', and believed that an October 1, 2023 inclusion date is justified because some interested territories have requested more time to prepare for MDRP participation and suggested potential policy changes to address increases in drug prices. In addition, the commenter indicated that the territories and manufacturers will need this additional time because their resources continue to be diverted to the COVID–19 pandemic response.

Another commenter found it difficult to envision territories having the infrastructure or funding in place to fully transition to the MDRP given the PHE. The commenter also noted that even if a territory was prepared to make this transition, the providers, including hospitals and others across the healthcare marketplace that prescribe and provide prescription drugs, would need to update their systems, resulting in significant confusion and patient access barriers. The commenter believed further guidance is necessary to prepare the territories for this transition, as well as the providers of care within those programs. The commenter restated these reasons for prior delays in implementing this requirement as rationale for reversing the 2016 COD final rule including territories in the definition of ''States'' and ''United States.''

Other commenters indicated that they did not support the proposed delay because one territory in particular, Puerto Rico, has made significant efforts to prepare for participation in the program. The commenter indicated that the proposed delay would be financially harmful to that territory because it has already written a request for proposal (RFP) to procure a vendor to manage participation in the MDRP, which has an expected launch date of July 1, 2022, and a delay would result in the need for multiple modifications to the territory's RFP. The commenter also noted that the territory has undertaken a significant amount of budgeting and financial forecasting as part of their efforts, which indicated that there would be a financial loss as a result of unrealized federal rebates for both brand and generic drugs if there is a delay beyond the territory's FY 2023, which runs from July 2022 through June 2023.

Response: In proposing this delay, and in finalizing a new inclusion date of January 1, 2023, we considered all public comments received, the needs of all the stakeholders, including territories and manufacturers, while considering the impact that the delay could have on access to necessary and affordable medications for the citizens of the territories, both those that would and would not participate in MDRP.

To balance the willingness of territories that want to participate, while accommodating the time to prepare waivers for those that do not, we have determined that the January 1, 2023 date, which falls within the scope of the alternative proposal, is appropriate.

Based on the information available to us at this time, we believe that of the five territories, only two will make efforts to participate in MDRP, regardless of the ultimate inclusion date, and the others will require additional time to request the applicable waivers. Of the two territories that we anticipate will make efforts to participate in MDRP, only one (Puerto Rico) has definitively indicated that they are ready and will be able to participate in MDRP as early as July 1, 2022, while the other (U.S. Virgin Islands) has previously expressed interest, but may or may not have decided whether to participate by January 1, 2023.

Those territories that do not participate will need time to prepare to waive out of the program through the appropriate Medicaid waiver mechanism.

To accommodate the resource needs of the territories during the PHE, we believe a January 1, 2023 inclusion date gives Puerto Rico the ability to participate sooner than the April 1, 2024 inclusion date, while giving the other territories a firm deadline to make a final decision to participate or waive out of the program. The timeline also recognizes the work done to date by Puerto Rico to prepare to participate in the program. Therefore, the new inclusion date for U.S. Territories in the amended regulatory definitions of ''States'' and ''United States'' for purpose of the Medicaid Drug Rebate Program will be January 1, 2023, which is the earliest new inclusion date that we could have finalized given our proposals in the proposed regulation.

We note the suggestion for a delayed inclusion date of October 1, 2023 made by one of the commenters in light of the additional time needed and requested by some territories. we believe that further delay beyond January 1, 2023 negatively impacts the progress Puerto Rico has made to prepare to participate in the program (for example, Puerto Rico has already invested significantly in consulting costs and begun the request for proposal process for a system contractor). For example, Puerto Rico has indicated it could be ready to participate in the MDRP as early as July 1, 2022, and therefore, an effective date of October 1, 2023 would push back MDRP participation by over a year from that date for the territory that has the overwhelming majority of drug spending, and which stands to benefit most from participation in MDRP.

As for the commenter's request for additional guidance, the delay can be used to help any territory that plans on participating in the program more time to prepare its beneficiaries, pharmacies, and providers. That is because participation in the MDRP will increase the availability of medications that are available in participating territories, but the territories can also use various utilization management techniques, and providers and patients may need time to be educated on how these programs will work. Moreover, a territory participating in MDRP may need technical help from us on reporting its state drug utilization data, and, for example, assuring that all its physician administered drug claims also include National Drug Code (NDC) numbers. Like our state partners, we are available to guide territories that want to participate in MDRP to assure beneficiary access to drugs, as well as to properly invoice participating manufacturers for federal rebates.

Comment: A few commenters noted their general opposition to the expansion of the MDRP beyond the 50 states and DC to include the territories. One commenter remarked that at most, CMS should limit the expansion to only requiring that rebates be paid by the manufacturers to the territories, but not require manufacturers to include sales to the territories in calculation of their AMP or determination of their Best Price because of the enormous burden and compliance concerns that such an expansion would pose on the manufacturer.

A couple of commenters, while supporting the proposed delay of the participation of the territories in the MDRP to April 1, 2024, were still concerned with the decision to include the territories in the definition of ''States'' and ''United States'' in the first place, and urged CMS to address their prior comments requesting the agency to reverse its decision to add the territories to the Medicaid rebate program.

Response: We note that the definitions of ''States'' and ''United States'' at § 447.502 were amended to include the U.S. territories for purposes of the MDRP in the COD final rule with a delayed inclusion date. We did not propose to change the underlying policy, only to delay the inclusion date. As such, comments requesting that we revisit the underlying policy are outside the scope of this rulemaking.

After consideration of the comments received regarding the proposed delay of inclusion date for the U.S. territories in the definitions of ''States'' and ''United States'' at § 447.502, we are finalizing an inclusion date of January 1, 2023.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on October 27, 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 amends 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 January 1, 2023, 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 January 1, 2023, 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.

* * * * *

■ 3. Effective July 1, 2022, in paragraph (a), by revising the definition of ''Best price'' to read as follows:

§ 447.505 Determination of best price.

(a) * * *

Best price means, for a single source drug or innovator multiple source drug of a manufacturer (including the lowest price available to any entity for an authorized generic drug), the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity in the United States in any pricing structure (including capitated payments) in the same quarter for which the AMP is computed. If a manufacturer offers a value-based purchasing arrangement (as defined at § 447.502) to all states, the lowest price available from a manufacturer may include varying best price points for a single dosage form and strength as a result of that value based purchasing arrangement.

* * * * *

Dated: November 4, 2021.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2021–25009 Filed 11–17–21; 4:15 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 660

[Docket No. 211115–0231]

RIN 0648–BK56

Fisheries Off West Coast States; Coastal Pelagic Species Fisheries; Biennial Specifications; 2021–2022 and 2022–2023 Specifications for Pacific Mackerel

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Final rule.

SUMMARY: NMFS is implementing allowable catch levels including an overfishing limit, an allowable biological catch, and an annual catch limit for Pacific mackerel in the U.S. exclusive economic zone off the West Coast (California, Oregon and Washington) for the fishing seasons 2021–2022 and 2022–2023. This rule is finalized pursuant to the Coastal Pelagic Species Fishery Management Plan. The