Establishing Minimum Standards in Medicaid State Drug Utilization Review and Supporting Value-Based Purchasing for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third-Party Liability Requirements (CMS-2482-F)

Final Rule Summary

On December 22, 2020, the Centers for Medicare & Medicaid Services (CMS) placed on public display a final rule that makes a number of changes to Medicaid drug rebate, drug utilization review, and third-party liability regulations.[1] It is scheduled to be published in the *Federal Register (FR)* on December 31, 2020.

The final rule makes changes to amend Medicaid's best price definition to promote value-based purchasing (VBP) arrangements; implement statutory changes made by the Continuing Appropriations Act, 2020 and Health Extenders Act of 2019 to prohibit manufacturers from including authorized generics in average manufacturer prices (AMPs); amend certain drug rebate definitions to implement provisions of the Bipartisan Budget Act (BBA) of 2018, the Medicaid Services Investment and Accountability Act of 2019, and the Affordable Care Act (ACA); and codify provisions of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (the SUPPORT Act) to establish mandatory minimum standards for drug utilization review to reduce opioid fraud, misuse and abuse.

Unless otherwise specified, the regulations are effective on March 1, 2021. In recognition of operational challenges, CMS extended the timeline for implementing certain policies. Policies to encourage VBP, to change certain definitions, and to establish new data reporting requirements will be effective January 1, 2022. Changes to the clarify when manufacturer-offered patient assistance programs may be included in best price are effective January 1, 2023.

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[1] Federal Register :: Public Inspection: Medicaid Program: Establishing Minimum Standards in Medicaid State Drug Utilization Review and Supporting Value-Based Purchasing for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability Requirements.

I. Provisions of the Final Regulation

CMS finalizes provisions to:

- Permit manufacturers to submit multiple best prices under certain circumstances to promote the ability of state Medicaid programs to enter into VBP arrangements with pharmaceutical manufacturers and to promote manufacturers' ability to enter into such arrangements with other payers;
- Prohibit manufacturers from including sales of authorized generics in the calculation of average manufacturer price (AMP);
- Implement minimum drug utilization review standards with respect to opioid use, misuse and abuse;
- Require states to reject certain claims for prenatal services when a third-party payer is responsible, extend the timeline for paying claims related to medical support enforcement services, and pay claims for pediatric preventive services without regard to third-party liability;
- Codify a definition of a "line extension" drug that expands the universe of drugs subject to the ACA alternative rebate formula;
- Clarify definitions and other rules related to the obligation to make rebate payments with respect to state supplemental rebate agreements and where drug manufacturers provide patients with assistance towards a drug's cost;
- Codify requirements for additional rebates for certain drugs whose prices increase at a rate that exceeds inflation; and
- Amend state drug utilization data reporting requirements and to establish new state reporting requirements related to VBP arrangements.

Commenters raised general concerns about the impact of the rule on future drug development and on the burden the rule will place on Medicaid providers. CMS does not agree with those concerns but does recognize that it may take some additional time to make the operational and administrative changes required by a number of provisions of the rule. In response CMS extends the timeline for implementing several provisions. Policies to encourage VBP, to change certain definitions, and to establish new data reporting requirements will be effective January 1, 2022. Changes to the clarify when manufacturer-offered patient assistance programs may be included in best price are effective January 1, 2023.

A. Third Party Liability: Payment of Claims (§433.139)

State Medicaid programs, as the payer of last resort, must comply with certain requirements related to third party liability (TPL). TPL statute and regulations ensure that Medicaid programs take all reasonable measures to identify and seek payment from liable third parties before paying claims.

The BBA 2018 requires a state to reject a claim for prenatal care for pregnant women including for labor and delivery services and post-partum care when it has determined that there is a legally liable third party responsible for payment for those services. Prior law and regulations had

permitted states to first pay claims for labor, delivery, and post-partum care and then seek reimbursement from the responsible third party. To codify the BBA 2018 requirement in regulations, CMS eliminates §433.139(b)(2) which permitted states to "pay and chase" those claims. In addition, a technical change is made to §433.139(b)(3)(i) to eliminate a reference to prenatal care for pregnant women consistent with the BBA 2018 provision.

CMS also modifies regulations at §433.139(b)(3)(ii)(B) to be consistent with another statutory provision. Section 202(a)(2) of the Bipartisan Budget Act of 2013 allowed states 100 days (instead of 30 days) to pay claims related to medical support enforcement services. Medical support is a form of child support that is often provided through an absent parent's employers' health insurance plan.

Additionally, effective October 1, 2019, BBA 2018 requires a state to make payments without regard to third party liability for pediatric preventive services unless the state has made a determination related to cost-effectiveness and access to care that warrants cost avoidance. CMS codifies this provision at §433.139(b)(3)(i).

All of those changes are finalized as proposed. In response to a commenter's request for clarification as to whether the 100-day period permitted to pay claims related to medical support enforcement applies to both preventive pediatric services as well as medical support enforcement, CMS clarifies that it does not apply to preventive pediatric services. In addition, CMS clarifies that states have the flexibility to allow up to 100 days to pay claims related to medical support enforcement and directs readers to its November 14, 2019 guidance on this matter.[2]

B. Value-Based Purchasing (VBP) Arrangements

CMS released a state and manufacturer notice on July 14, 2016 (State Release 176 and Manufacturer Release 99)[3] to inform states and manufacturers about how to seek assistance from CMS in establishing VBP arrangements that address high-cost drug treatments and about how such arrangements might affect a manufacturer's best price and Medicaid drug rebate obligations. Despite this assistance, CMS notes that some manufacturers continue to hesitate to offer VBP arrangements to Medicaid and other payers. Those manufacturers are concerned that Medicaid statute and regulations have not specifically addressed the purchase or discounting of drugs based on evidence or outcomes-based measures.

In particular, because rebates for single source or innovator multiple source drugs are calculated based on the reported best price, a VBP arrangement that reduces the price of a drug treatment based on a poor outcome could have the impact of resetting the best price for all rebates for that drug product, prompting significantly higher rebates owed by its manufacturer.

[2] https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/cib111419.pdf.
[3] Available at https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Prescription-Drugs/Downloads/Rx-Releases/State-Releases/state-rel-176.pdf and https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Prescription-Drugs/Downloads/Rx-Releases/MFR-Releases/mfr-rel-099.pdf .

CMS finalizes a series of regulatory changes that address the burdens that CMS sees as preventing manufacturers from entering into VBP arrangements with commercial payers and states. Foremost among them, CMS will permit manufacturers to report multiple best prices when a VBP arrangement is offered to all states. The provisions are finalized with several changes as described below including to delay their effective date.

Responses to Comments. Some commenters were supportive of policies that encourage VBP arrangements. Other commenters raised concerns about unintended consequences, lack of understanding about how VBP arrangements can actually meet the objective of increasing therapeutic value while reducing costs, reducing Medicaid drug rebates, and the timing of the final rules. Other commenters questioned how states would become aware of a manufacturer offering a VBP arrangement to states, and about other related operational details. CMS replied that it expects to address those issues in the future through operational guidance.

Final Rule. In response to concerns about the operational challenges of changing best price reporting, in the final rule, CMS delays the effective date of permitting manufacturers to report multiple best prices under a VBP arrangement until January 2, 2022. In addition, CMS notes that it is developing a new Medicaid Drug Program reporting system that it expects will be fully functional in July of 2021.

Specifically, CMS finalizes, with a number of changes as described below, the following new definitions in §447.502:

Definition of Value-Based Purchasing Arrangement. CMS defines such an arrangement or agreement as one intended to align pricing and/or payments to an observed or expected therapeutic or clinical value in a *select* population [the word "select" is added and the parenthetical "outcomes relative to costs" is removed] and includes, but is not limited to: (1) Evidence-based measures, which substantially link the cost of a drug to existing evidence of effectiveness and potential value for specific uses of that product; and/or [instead of "and"] (2) Outcomes-based measures, which substantially link payment for the drug to that of the drug's actual performance in patient or a population, or a reduction in other medical expenses.

Response to Comments. CMS received a large number of recommended and requested changes to the definition of value-based purchasing arrangement including requests for additional detail and guardrails to ensure VBPs provide value for a drug, to requests to further define evidence-based and outcomes-based measures.

CMS, in declining to add definitions of evidence- or outcome-based measures, states that additional clarification will unnecessarily limit the potential for VBP arrangements using such measures. It identifies some examples of evidence- or outcome-based measures including the absence of disease over time, reducing medical spending, improving activities of daily living, etc. It states that an example of an evidence-based measure is a situation where a manufacturer may use documented evidence that its cancer drug results in complete remission for 80 percent in a population and an example of an outcome-based measure is whether or not a patient reaches an agreed upon clinical outcome. Other commenters suggested various types and considerations for selecting outcome-based measures, and that VBP arrangements be evaluated with outcomes-

based measures that were not included in clinical trials. CMS appreciates the suggestions but declines to incorporate the recommendations.

In response to a commenter requesting that CMS clarify that outcomes-based measures based on quality of life or age are discriminatory, CMS reminds readers that in accordance with section 504 of the Rehabilitation Act, the Americans with Disabilities Act, the Age Discrimination Act and section 1557 of the ACA, measures cannot discriminate on the basis of disability or age.

CMS had requested comment on whether it should further define the term "substantially" with respect to linking evidence or outcomes to the cost of a drug. It declines, however, to define the term at this time and instead states that it expects information about the link between the evidence or outcome-based measures to cost to be defined in the VBP arrangement itself and that manufacturers will be expected to maintain records of how the measures link to payment or cost. It may, however, provide examples in future guidance. CMS notes that VBP arrangements offered before the effective date of the VBP definition in this rule may need to be restructured to meet the new definition.

Commenters suggested additional measures of the value of a drug and that measures should be person-centered. CMS notes that manufacturers may consider some of those measures, but declines to incorporate them in the regulatory text. With respect to recommendations regarding transparency and oversight, CMS states that states and manufacturers may want to consider some of those suggestions in their negotiations and notes that state programs with VBP arrangements will be required to report on a quarterly basis certain information about the program as described in greater detail below.

In response to those commenters raising concerns that VBP arrangements could limit Medicaid enrollees' access to medically necessary drugs, CMS states that nothing in this rule changes Medicaid drug coverage requirements under existing law and regulations.

CMS clarifies that manufacturers must include the full price of a drug in the quarter in which it is sold in the determination of AMP. In addition, under VBP outcome-based arrangements, where an outcome may not be observed for an extended period of time, states would report outcomes data to manufacturers when available and revisions to an initial drug rebate payment may need to be made via a prior period adjustment based on that outcome.

Some commenters requested that CMS include other innovative payment arrangements, such as payment-over-time, subscription arrangements, or warranty type models under the definition of VBP arrangements. CMS states that many of those arrangements are simply payment schedules negotiated between manufacturers and payers. If such an arrangement included a value-based component it would be considered a VBP arrangement. CMS also states that a premium paid by a manufacturer to a third party reduces the price of a drug and therefore should be included in best price reporting. CMS also clarifies that Medicaid MCOs may enter into their own VBP arrangements with manufacturers but the prices under those arrangements are not exempt from best price.

Final rule. CMS maintains a broad definition of VBP arrangements despite many comments requesting additional detail and definitions of terms. It adds the word "select" to the definition to clarify that VBP arrangements are specific to select population groups using the drug therapy. It adds "and/or" between the two measures in the definition to clarify that either evidence-based or outcome-based measures could be used in a VBP arrangement. It removes the phrase in parentheses "that is, outcomes relative to costs" stating that since outcomes measures are already a part of the definition, the phrase was redundant.

Definition of Bundled Sale. Under existing rules, bundled sales are defined (at §447.502) as any arrangement under which the rebate, discount, or other price concession is conditioned upon the purchase of the same drug, drugs of different types or another product or some other performance requirement (for example, the achievement of market share, inclusion or tier placement on a formulary), or where the resulting discounts or other price concessions are greater than those which would have been available had the bundled drugs been purchased separately or outside the bundled arrangement.

CMS notes that manufacturers have had to make reasonable assumptions about how to report best price when discounts or rebates are provided as part of a VBP arrangement for drugs purchased as part of a bundled sale. Some manufacturers have allocated those discounts proportionately across all of the drugs or products in the bundle. CMS finds this approach to be reasonable and modifies the definition of bundled sales to incorporate that approach.

CMS finalizes its proposal to revise the definition of bundled sales to include VBP arrangements with one change to omit redundant language. The revised definition would permit the discounts resulting from a VBP contingent arrangement to be allocated proportionally to the total dollar value of the units of all drugs or products sold under the bundled arrangement. This would prevent the discounted price of a single unit or a few units paid under a VBP arrangement because of low performance from resulting in resetting rebates for all units of that drug to that discounted price.

Definition of Best Price (§447.505(a)). CMS explains that the statutory definition of best price and prior regulations implementing that definition have interpreted that price to be the lowest price at which a manufacturer sells a covered drug – that is the *single* lowest price available per dosage form and strength of a drug. As noted above, this interpretation has the impact of raising the rebates that a manufacturer must pay when, under a VBP arrangement, a drug's price is reduced based on a poor outcome.

CMS proposed to change its interpretation of "best price" to recognize that multiple prices could be made available by the manufacturer for a particular drug based on the drug's performance, such as under VBP arrangements that use evidence or outcomes-based measures, in a quarter. It explains that it has in the past allowed for different best prices available in various pricing structures – such as under capitated arrangements. CMS finalizes as proposed to recognize VBP arrangements as different pricing structures and permit multiple best prices to be reported including the price points available under VBP arrangements. Specifically, the definition of best price is amended, as proposed, to permit a manufacturer offering a VBP arrangement to all states

to submit the lowest price available at varying best price points for a single dosage form and strength as a result of that VBP.

CMS provides as an example that under a VBP, the manufacturer would report a single best price for sales of a drug in a quarter. In addition, the manufacturer would report a distinct set of "best prices" that would be available based on the range of evidence-based or outcomes measures for that drug that are possible under the VBP arrangement. The rebate due to the state for a patient who is included in the VBP arrangement would be specific to that patient's outcome, as that price is the lowest price available from the manufacturer based on that patient's outcome. For all other patients, the rebate would be calculated based on the lowest price available absent a VBP arrangement.

In addition, under existing rules, a manufacturer is required to adjust the average manufacturer price (AMP) for a rebate period for any discounts, rebates or adjustments that subsequently change the AMP (unless specifically excluded from AMP). CMS finalizes as proposed to add parallel language to the definition of best price requirements at §447.505(d)(3).

Response to Comment. Commenters offered alternative approaches for best price and multiple best price reporting which CMS states it may consider in future rulemaking. Among the concerns expressed by commenters was that the policy would reduce Medicaid rebates and that the proposal does not limit the number of VBP arrangements or pricing tiers within those arrangements that a manufacturer could create, fearing that such segmentation would weaken best price protection for state Medicaid programs.

CMS clarifies that states are not required to participate in such arrangements and that if they choose not to participate, then rebates would remain calculated based on the non-VBP best price reported by the manufacturer. As such, rebates in non-participating states will not be impacted by the provisions. Further, manufacturers are only permitted to report multiple best prices if they make available to all states the VBP arrangements or arrangements being offered in the commercial market.

In response to operational concerns, CMS indicates that it will provide additional technical and operational guidance. In addition, as noted above, CMS will delay the effective dates of the revised definitions until January 1, 2022. In response to concerns that states may not be aware of commercial VBP arrangements, CMS states that it will share multiple best prices with states and will address such communications to states in forthcoming operational guidance. CMS notes, however, that it will not be involved in the approval or review of specifics of any VBP arrangements by manufacturers to commercial payers and it does not intend to audit how multiple best prices are reported or how patient-specific outcomes are determined.

With respect to the impact of multiple best prices on AMP, ASP, and 340B ceiling prices, CMS states that: (1) the 340B ceiling price will continue to reflect Medicaid drug rebates based on the non-VBP best price; (2) it does not expect the AMP to be impacted; (3) manufacturers should consider the impact of their VBP arrangements on payment amounts in other parts of Medicare.

Final rule. CMS clarifies that varying best price points can be reported only "*if a manufacturer offers a value-based purchasing arrangement (as defined at §447.502) to all states*" and delays the effective date of the revised definitions until January 1, 2022.

C. Amendments to Definitions to Reflect Statutory Changes

Innovator Multiple Source Drug. The Medicaid Services Investment and Accountability Act of 2019 made several changes to the statutory definition of an innovator multiple source drug to clarify that definition. CMS finalizes as proposed, to conform the regulatory definition at §447.502 with those changes.

Under the prior definition, an innovator multiple source drug is a "multiple source drug that was originally marketed under an original new drug application (NDA) approved by FDA, including an authorized generic drug."

To align the definition with the statutory changes, CMS eliminates the phrase "was originally marketed" from the first sentence of that definition so that an innovator multiple source drug is defined as "a multiple source drug, that is marketed under a new drug application (NDA) approved by the FDA….". CMS also eliminates the last sentence of the definition which had described what is meant by an "original NDA". The amendments were finalized as proposed.

Line Extension. The ACA established an alternative formula for calculating the rebate amount for a drug that is a "line extension" of a single source drug or innovator multiple source drug *that is an oral solid dosage form*.[4] CMS has in the past proposed but not finalized a definition of line extension and has directed manufacturers to rely on the statutory definition of a line extension and to use reasonable assumptions in determining whether a drug qualifies as a line extension.

At issue is how to apply the statutory phrase "that is an oral solid dosage form." It is unclear whether Congress intended for both the original drug and the line extension be an oral solid dosage form or whether only the original form of the drug must be in an oral solid dosage form.

CMS has found that manufacturers are interpreting the definition inconsistently and at times may be inappropriately limiting the universe of line extension drugs to avoid paying rebates. As a result, CMS finalizes, with one major change, to incorporate a definition of line extension and of new formulation at §447.502 to refer to "a drug that is a line extension of a single source drug or an innovator multiple source drug provided that the initial single source drug or innovator multiple source drug is an oral solid dosage form." This would expand the universe of line extension drugs to clearly include drugs that undergo a change from an oral solid dosage form to a different dosage form. The new definition would apply to rebate periods beginning January 1, 2022 instead of to rebate periods beginning on or after October 1, 2018 as proposed.

Commenters raised the concern that using a more expanded definition of line-extension drugs is contrary to Congressional intent and that Congress intended line-extension rebates to apply only

[4] 42 US Code 1396r-8(c)(2)(C)

in cases in which there were "slight alterations" of the previous drug. CMS disagrees and states that if that were the intent, Congress would have indicated that in the statutory language.

In addition, CMS finalized as proposed to exclude abuse deterrent formulations from the definition of "line extension" consistent with statute. Specifically, "line extension" is defined to mean a new formulation of a drug, not including an abuse-deterrent formulation of the drug (as determined by the Secretary).

New Formulation. CMS proposed a definition of "new formulation" to clarify when such drugs qualify as a line extension drug subject to the ACA rebates. It finalizes the definition with a number of significant changes.

It had proposed a new formulation to mean, for a drug, any change to the drug, provided that the new formulation contains at least one active ingredient in common with the initial brand name listed drug. The proposed definition would have also included the following sentence: "New formulations include, but are not limited to, extended-release formulations; changes in dosage form, strength, route of administration, ingredients, pharmacodynamics, or pharmacokinetic properties; changes in indication accompanied by marketing as a separately identifiable drug (for example, a different NDC); and combination drugs, such as a drug that is a combination of two or more drugs or a drug that is a combination of a drug and a device."

CMS finalizes a more abbreviated definition: A new formulation means "for a drug, a change to the drug, including but not limited to: an extended-release formulation or other change in release mechanism, a change in dosage form, strength, route of administration, or ingredients." It did not finalize the last sentence of the proposed definition that had included examples of new formulations largely in response to commenters' concerns described in more detail below.

Further, as noted above, the new definitions for line extensions, new formulations, and oral solid dosage forms are applicable to rebate periods beginning January 1, 2022 instead of to rebate periods beginning on or after October 1, 2018 as proposed.

- Combination Drugs. CMS had requested feedback on when a combination drug should or should not be included as a new formulation. While it did not receive comments on that question, it decided to modify the definition to not include new combinations of drugs, or of drugs and devices as a new formulation. It notes however, that all combination drugs are not necessarily excluded from the definition of a new formulation. It provides this example: "If an initial brand name listed drug is a combination of two or more drugs, and then a manufacturer begins selling a new formulation of that combination drug, then the new drug satisfies the definition of a new formulation and must be identified as a line extension. For example, consider two single-ingredient drugs, Alpha and Beta. A new combination of these two drugs, AlphaBeta, is not considered a new formulation for the purposes of the line extension alternative rebate calculation. However, a later developed new formulation of AlphaBeta, for example, AlphaBeta XR, is a new formulation with AlphaBeta representing the initial brand name listed drug."

- New Indications. In the "Medicaid Program; Covered Outpatient Drugs" proposed rule published in February 2012,[5] CMS proposed that a drug approved with a new indication for an already approved drug would be a line extension. CMS received comments opposing this interpretation. Some commenters believed that the proposal was not logical because a drug cannot be a line extension of itself, or that it is not possible to apply the alternative line extension calculation to rebate invoices for an NDC only for those claims that were prescribed for the newly approved indication. CMS had proposed to clarify that if, following the approval of a new indication, a manufacturer markets its drug in such a way that it is not a separately identifiable drug product, the alternative rebate calculation would not apply. However, if following the approval of a new indication the manufacturer markets the drug in such a way that it is a separately identifiable drug product, the alternative rebate calculation would apply. Thus, the proposed definition of new formulation would have included changes in indication accompanied by marketing as a separately identifiable drug (for example, a different NDC). CMS received new comments opposed to this policy that were consistent with the concerns raised in 2012. In response, it does not finalize its proposal to include new indications as line extensions subject to the line extension rebate.
- New Strengths. CMS clarifies in its definition of a new formulation that a new strength of a drug produced or distributed at a later time than the initial strength is included as a line extension and is subject to the line extension alternative rebate calculation. While it received a number of comments opposed to this interpretation, CMS finalizes the inclusion of new strengths in the line extension definition as proposed.
- Extended-Release Formulation. After considering comments, CMS concluded that using the terminology "pharmacodynamics or pharmacokinetics" incorporated a broader range of changes than intended and in the final rule incorporates simpler language to include in the definition of a new formulation a change in release mechanism, rather than changes in pharmacodynamics or pharmacokinetic properties as proposed.

Some commenters suggested additional modifications or additions to the definition of line extensions – for example to include non-oral drugs, biosimilars, or authorized generics; to add specificity around what is meant by the original drug; or to exclude certain drugs. CMS declines to make additional changes to incorporate those recommendations.

Oral Solid Dosage Form. CMS finalizes its proposal to add detail to the existing definition of oral solid dosage form at §447.502 to reduce confusion regarding the meaning or both "oral" and "solid." The prior definition included capsules, tablets, or similar drugs or products intended for oral use as defined in accordance with FDA regulation at 21 CFR 206.3. The final definition is "an orally administered dosage form that is not a liquid or gas as the drug enters the oral cavity." CMS clarifies that this includes a sublingual film and a drug that is orally inhaled. As noted above, the new definitions for line extensions, new formulations, and oral solid dosage forms are applicable to rebates periods beginning January 1, 2022 instead of to rebate periods beginning on or after October 1, 2018 as proposed.

[5] Federal Register (77 FR 5318, 5323 through 5324).

Multiple Source Drug. CMS finalizes proposed changes to the definition of a multiple source drug in §447.502 to be consistent with changes made in the Medicaid Services Investment and Accountability Act of 2019.[6] That legislation clarified the term as well as the term "single source drug" to eliminate confusion and to reduce the possibility that manufacturers are able to misreport drugs within those groups in order to reduce their required rebate payments.

The definition provides that "for a rebate period, a covered outpatient drug, including a drug product approved for marketing as a non-prescription drug that is regarded as a covered outpatient drug under section 1927(k)(4) of the Social Security Act[7], for which there is at least 1 other drug product which meets all of the following criteria: (1) Is rated as therapeutically equivalent (under the FDA's most recent publication of "Approved Drug Products with Therapeutic Equivalence Evaluations" which is available at http://www.accessdata.fda.gov/scripts/cder/ob/); and (2) Except as provided at section 1927(k)(7)(B) of the Act, is pharmaceutically equivalent and bioequivalent, as defined at section 1927(k)(7)(C) of the Act and as determined by FDA. (3) Is sold or marketed in the United States during the period."

It is different from the prior definition in that:

- It explicitly includes drug products approved for marketing as non-prescription drugs that are covered outpatient drugs;
- In describing therapeutic equivalents, it refers to FDA's *most recent* publication of "Approved Drug Products with Therapeutic Equivalence Evaluations" rather than simply identifying the name of the publication as in existing rules.
- In describing "pharmaceutically equivalent and bioequivalent", the proposed regulation refers to the definition of that phrase at section 1927(k)(7)(C) of the Act.

Single Source Drug. CMS finalizes as proposed, clarifications to the definition of a single source drug consistent with changes made by the Medicaid Services Investment and Accountability Act of 2019. A single source drug is defined as a covered outpatient drug, *including a drug product approved for marketing as a non-prescription drug that is regarded as a covered outpatient drug under section 1927(k)(4) of the Act*, which is produced or distributed under a new drug application approved by the FDA, including a drug product marketed by any cross-licensed producers or distributors operating under the new drug application unless the Secretary determines that a narrow exception applies, and includes a covered outpatient drug that is a biological product licensed, produced, or distributed under a biologics license application approved by the FDA.

The finalized definition differs from the prior definition in the following ways:

- It replaces "an original NDA approved by the FDA" with "a new drug application". CMS notes that the term "original NDA" is not a commonly understood term.
- It explicitly includes drug products approved for marketing as a non-prescription drug that are covered outpatient drugs.

[6] P.L. 116-16.
[7] Hereinafter referred to as "the Act".

- CMS inserts "unless the Secretary determines that a narrow exception applies (as described in §447.502 of title 42, Code of Federal Regulations or any successor regulation))" after "under the new drug application."
- It specifies that such term includes a covered outpatient drug that is a biological product.

CMS-authorized Supplemental Rebate Agreements. CMS finalizes as proposed to add a new definition to §447.502 to clarify the treatment of certain supplemental rebates paid to Medicaid MCOs. In particular, CMS has found that some manufacturers are excluding rebates paid directly to Medicaid MCOs from best price even when those rebates are not a result of a CMS-authorized supplemental rebate agreement and are not shared with the state and federal government. The new definition, which would prohibit such practices, defines a CMS-authorized Supplemental Rebate Agreement to be one that is approved through a State Plan Amendment (SPA) by CMS, which allows a state to enter into single and/or multi-state supplemental drug rebate arrangements that generate rebates at least as large as the rebates in the national rebate agreement with drug manufacturers. CMS-authorized supplemental rebates must be considered a reduction in the amount spent under the state program for medical assistance and are required to result in shared federal savings consistent with existing program guidance at https://www.medicaid.gov/federal-policy- guidance/downloads/smd091802.pdf.

D. Exclusion of Certain Manufacturer Sponsored Patient Assistance from Best Price

CMS describes concerns that some non-Medicaid plans and their pharmacy benefit managers are using manufacturer copay assistance and copay accumulator programs to subsidize the health plan's payment for drug products rather than enrollee's costs. CMS has become aware that sometimes copay assistance is used to delay the consumer's deductible from applying rather than accruing towards the deductible. If such copay assistance is excluded from best price reporting, it is a violation of existing rules in §447.505(c) and has the effect of lowering Medicaid drug rebates. Under §447.505(c), manufacturer assistance may only be excluded from best price if the full value of that assistance is passed on to the consumer.

CMS finalizes amendments to §447.505(c) to expressly state that the exclusions for manufacturer assistance from best price apply only to the extent the manufacturer *ensures that the* full value of the assistance or benefit is passed on to the consumer or patient. (instead of only to the extent that the full value of the assistance or benefits is passed on to the consumer or patient.) CMS believes that the proposed amendments would clarify that manufacturers are responsible for ensuring that the benefits of their assistance programs are provided entirely to the consumer in order to be excluded from best price. CMS also makes parallel changes to the definition of AMP since the same exclusions apply to both best price and AMP determinations. Those changes are made to §447.504(c)(25) through (29) and (e)(13) through (17).

In the final rule, CMS extends the effective date of these amendments. They will go into effect January 1, 2023.

Some commenters raised concerns that patients may be negatively impacted by the policy because manufacturers may end their assistance programs rather than obtain the necessary information to continue them. CMS disagrees and believes that the policy could lead to lower

prices for consumers and more use of lower cost alternatives. A commenter cited several studies, one of which showed that for 23 branded drugs, coupons were associated with a 3.4 percent decrease in the rate of generic utilization and estimated excess spending of 1.2 to 4.6 percent higher total drug spending over 5 years.

Some commenters questioned CMS' statutory authority for the changes and others raised concerns over manufacturer's ability to obtain the necessary information in order to ensure the full value of the assistance is passed along to consumers. CMS indicates that the existing electronic prescription claims processing infrastructure currently in place should provide for a way to transmit the needed information to manufacturers to allow their tracking of the assistance. In addition, CMS points out that manufacturers could also work with PBMs to obtain the needed information.

A few commenters raised concerns about the impact of the policy on manufacturers' ability to provide assistance during the COVID-19 pandemic. In response, CMS delays the effective date of the final rule, applying the changes beginning January 1, 2023 to avoid any impact during the public health emergency period.

In response to commenters' concerns that the policy could impact Part B, 340B, and other drug prices, CMS states that it does not believe it will have a significant impact on Medicare drug prices but may impact 340B prices to the extent that such amounts are included in best price calculations.

E. Authorized Generic Drugs (§§ 447.502, 447.504, 447.506)

CMS finalizes changes to implement section 1603 of the Health Extenders Act which prohibits, effective October 1, 2019, manufacturers from including an authorized generic in its calculation of AMP and excludes manufacturers from the definition of a wholesaler.

An authorized generic is a product that a manufacturer (primary manufacturer) allows another manufacturer (secondary manufacturer) to sell under the primary manufacturer's FDA approved new drug application (NDA) using a different National Drug Code (NDC) number. The authorized generic is typically the primary manufacturer's brand product offered at a lower price.

Primary manufacturers sometimes sell the authorized generic product to the secondary manufacturer they are allowing to sell an authorized generic of their brand product (called transfer sales). Under the Health Extenders Act, a primary manufacturer that sells the authorized generic version of the brand drug to a secondary manufacturer can no longer include the price of the transfer sale of the authorized generic to the secondary manufacturer in its calculation of AMP for the brand product.

To conform regulatory text to section 1603 of the Health Extenders Act, CMS proposed the following amendments which are finalized with one clarification.

- The definition of wholesaler is revised to exclude any reference to manufacturers. The definition of AMP is amended to remove a reference to certain sales prices of manufacturers that act as wholesalers (§§447.502 and 447.504(b)). CMS notes that the

AMP for 5i drugs (drugs that are not generally dispensed through retail community pharmacies) does not change because the prohibition only applies to authorized generic sales to wholesalers that distribute to retail community pharmacies.

- The final rule modifies the existing definition of a "secondary manufacturer" at §447.506 to mean a manufacturer that is authorized by the primary manufacturer to sell the drug. In response to comments, the final rule eliminates a phrase at the end of this definition: "but does not hold the NDA" to clarify that that these rules apply even when the manufacturer is the same for both the brand drug and the authorized generic version.
- Requirements specifically related to the treatment of authorized generic drugs in determining AMP and best price are revised to exclude rather than include such drugs in those calculations and to explicitly state that the primary manufacturer must exclude from its calculation of AMP any sales of authorized generic drugs to wholesalers for drugs distributed to retail community pharmacies when reporting the AMP of the brand name drug.

CMS notes that this means that a separate AMP must be provided for the brand drug which must be exclusive of any authorized generic sale, and a separate AMP provided for the authorized generic. Guidance provided to manufacturers (Manufacturer Release #111 and Manufacturer Release #112[8]) implementing section 1603 described this approach. The guidance, however, raised questions about what is meant by "a manufacturer that *approves, allows, or otherwise permits* any drug of the manufacturer to be sold under the manufacturer's new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act…", particularly when a primary manufacturer is itself producing the authorized generic, or if the generic is being produced by an affiliate of the brand manufacturer. CMS responds that the authorized generic cannot be included in the AMP regardless of the relationship of the manufacturer of the brand drug to the manufacturer of the authorized generic even if the manufacturers' NDAs are the same, or if they are affiliated or not affiliated with each other.

In response to comments, CMS makes a modification to the existing definition of a "secondary manufacturer" to be clearer that its interpretation of a manufacturer that approves, allows, or otherwise permits any drug of the manufacturer to be sold under the manufacturer's new drug application includes a circumstance where the manufacturer of both the brand and the authorized generic are one and the same.

CMS also notes that manufacturers are required to reflect the changes to the calculation of their AMPs beginning for rebate periods starting on October 1, 2019 with the data due 30 days after the end of the rebate period; and that manufacturers have 12 quarters from the quarter in which the data were due to revise AMPs, if necessary.

[8] Available at https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx- releases/mfr-releases/mfr-rel-111.pdf and https://www.medicaid.gov/prescription-drugs/downloads/mfr-rel-112.pdf.

F. Medicaid Drug Rebates (§447.509)

CMS implements section 602 of the BBA of 2015 which requires manufacturers to pay additional rebates on non-innovator multiple source (N) drugs when the AMPs of those drugs increase at a rate that exceeds the rate of inflation. The proposals are finalized without change.

Revisions to §447.509 codify the rebate formulas for N drugs. Specifically, CMS makes the following changes.

- Paragraph (a)(6) is amended to distinguish the basic rebate for N drugs from the additional inflation-based rebate.
- New paragraphs (a)(7), (8) and (9):
    - Describe the additional rebate calculation for N drugs. For each dosage form and strength of a N drug, the rebate amount is increased by an amount equal to the product of the total number of units of such dosage form and strength paid for in a rebate period, and the amount, if any, by which the AMP for the dosage form and strength of the drug for the period exceeds the base date AMP for such dosage form and strength, adjusted to the current period by the CPI-U.
    - Describe the total rebate for N drugs as the sum of the basic and the additional inflation-based rebate.
    - Specify that the total rebate amount for such drugs shall not exceed 100 percent of the AMP for those drugs.
- New paragraph (a)(5) specifies that the total rebate amount for other drugs (single source and innovator multiple source drugs) cannot exceed 100 percent of the AMP (a technical change consistent with existing rules).

G. Requirements for Manufacturers (§447.510)

Under existing rules, manufacturers must report product and pricing information, including AMP, best price, prompt pay discounts, and nominal prices for Medicaid covered drugs. Revisions to that information must be made on a timely basis -- generally within 12 quarters from the date when the data were due unless one of several specified exceptions applies. Under prior rules those exceptions included changes resulting from a drug category change, a technical correction, or termination of a manufacturer.

CMS finalizes as proposed but with a delayed effective date, an additional exception to the 12-quarter rule permitting a manufacturer to make changes beyond 12 quarters as a result of a VBP arrangement when the outcome must be evaluated outside of this 12-quarter period. The new exception, effective January 1, 2022, is intended to provide additional flexibility for VBP arrangements where the price of a drug varies based on clinical outcomes. In some of those arrangements, final pricing information could take longer than the permitted 12 quarters if the final health care outcome is not known within 12 months. CMS finalizes the new exception in §447.510 (b)(1)(vi).

In response to comments, CMS declines to adopt a recommendation to add a time limit for manufacturer reporting outside of the 12-quarter period and describes how such exceptions will be processed: CMS will process requests from manufacturers for the exception the same as it

presently does for other exceptions. The manufacturer must submit its request and supporting documentation to CMS and CMS will notify the manufacturer if the change is permitted. The manufacturer would then certify the change.

CMS acknowledges a concern that the proposal could create a misalignment of discounts and sales volumes with respect to AMP calculations but notes that the extent of such misalignment is unclear and it is motivated to provide manufacturers and payers with greater flexibility in establishing VBP arrangements. In response to requests for additional operational detail, CMS will consider issuing operational guidance. CMS does not agree with commenters that the policy will create additional burden for states and fiscal agents as the adjustments will be handled just as prior period adjustments are currently handled.

H. Requirements for States (§447.511)

CMS finalizes as proposed but changes the effective date of a number of amendments to state drug utilization data reporting requirements. CMS states that the changes will improve data integrity and mitigate the impact of inaccurate and untimely data reports. The final rule:

- Specifies that updates or changes to the data on form CMS-R-144 must be included in the state's utilization data submitted to CMS;
- Requires that, on a quarterly basis, the state must submit drug utilization data to CMS, which must be the same information submitted to manufacturers on CMS-R-144;
- Adds regulatory text to conform to the statutory requirement that the state data submission is due no later than 60 days after the end of each rebate period (or if the due date falls on a weekend or federal holiday, on the first business day following that weekend or federal holiday) and to propose that any adjustments to previously submitted data must be transmitted to the manufacturer and CMS in the same reporting period;
- Adds a new requirement that the state data must be certified by the state Medicaid director, the deputy state Medicaid director, or another individual with equivalent or delegated authority to do so; and
- Adds a new requirement that state data certification language be included in the submission.

Because CMS will need to develop a collection instrument to enact these requirements, a delayed effective date of January 1, 2022 is finalized.

I. State Plan Requirements, Findings and Assurances (§447.518)

CMS finalizes proposals to require states that are participating in VBP supplemental rebate arrangements to provide data on those programs to CMS with several changes in response to comments, and extends the effective date of the final requirements. The final rule provides that the reporting requirements will become effective January 1, 2022. CMS states that the information will help it to ensure that Medicaid payments for patients receiving a drug under a VBP arrangement are consistent with efficiency, economy, and quality of care.

In the final rule, CMS clarifies that the reporting requirements apply only to VBP arrangements that are approved under a CMS-authorized supplemental rebate agreement and are exempt from

best price. In addition, CMS clarifies that the reporting data are intended to reflect cumulative costs and savings since many VBP arrangements measure outcomes over months or years. Otherwise, annual reporting that is not cumulative could fail to provide an accurate measure of the impact of the arrangements.

New §447.511(d)(1) and (2) require a state participating in a VBP supplemental rebate arrangement to provide, on an annual basis, and within 60 days of the end of each year:

- State name;
- NDC(s) for the covered drugs;
- Product FDA list name;
- Number of prescriptions;
- Cost to the state to administer the VBP (for example, systems changes, tracking outcomes, etc.); and
- Total savings generated by the supplemental rebate due to VBP.

In response to a commenter's concern that the requirements could affect Medicaid MCOs and their negotiations with states and manufacturers regarding VBP supplemental rebates, CMS agrees that the state and Medicaid MCO will need to establish responsibilities related to the collection and reporting of the required data elements. Other commenters recommended the reporting of additional data elements such as the number of beneficiaries under a VBP arrangement and the net price paid per unit of each drug. CMS declines to require reporting of those additional data elements, however, citing privacy concerns. In response to concerns about consistency of data reporting, CMS responds that it will prepare a collection instrument and will provide additional guidance to ensure consistency.

J. Drug Utilization Review (DUR) Requirements

CMS proposed a series of amendments to implement drug use safety edits and claims reviews, antipsychotic drug monitoring for children, and fraud and abuse process requirements for state DUR programs. It finalizes those amendments with one minor technical change. Most of the amendments implement requirements of the SUPPORT for Patients and Communities Act (the SUPPORT Act). In addition to codifying SUPPORT Act provisions, CMS includes minimum DUR standards for medication assisted treatment (MAT) and for identifying beneficiaries at high risk for opioid overdose a well as provisions to reduce prescription-related fraud, misuse and abuse.

CMS describes existing Medicaid drug utilization review requirements, approaches, and the purposes of those programs. It states that while it recognizes that the SUPPORT Act permits states to use the processes or programs in place before October 1, 2019 for new required safety edits and claims review, CMS believes that a set of minimum national standards are necessary. Comments were sought on potential additional standards for future rulemaking for DUR programs to ensure that drugs are appropriate, medically necessary and not likely to result in adverse impacts. CMS notes that it is also considering establishing "best practices" or guidance for states in advance of and in anticipation of future rulemaking.

(i) Minimum Standards for DUR Programs (§456.703)

CMS finalizes a series of minimum drug utilization standards for opioid use including those codifying SUPPORT Act requirements, and sought feedback on additional standards to ensure that prescribed drugs are appropriate, medically necessary, and not likely to result in adverse medical results. Section 1004 of the SUPPORT Act requires states to implement safety edits and claims review automated processes for opioids as DUR requirements. CMS interprets those requirements as including both prospective DUR review and retrospective DUR review. CMS acknowledges that many states already have effective DUR processes, but to ensure a consistent baseline of minimum standards, makes the proposals, which are finalized with one technical change, as described below.

CMS reviews prior Centers for Disease Control (CDC) guidance on treatment for chronic pain and recommended prescribing practices for opioids,[9] an HHS report on best practices for pain management,[10] as well as data on the human and financial toll of chronic daily pain. It also describes unintended consequences and misinterpretation of CDC Guidelines which have resulted in forced taper and patient abandonment and identifies an HHS report on proper tapering and discontinuation of opioids.[11]

CMS finalizes, largely as proposed, safety edits to implement state-defined limits on initial prescription fill days' supply for patients not currently receiving opioid therapy, quantity, duplicate fills, and early refills. CMS notes that detailed design and implementation decisions are left to states' discretion.

Under the final rule, state DUR programs must include the following minimum standards:

- Prospective safety edits for opioid prescriptions relating to (i) days' supply for patients not currently receiving opioid therapy for initial prescription fills; (ii) quantity of prescription dispensed for initial and subsequent prescriptions; (iii) therapeutically-duplicative initial and subsequent opioid prescriptions to alert a dispenser of potential duplication before a prescription is filled; and (iv) early refills for subsequent prescriptions. The term "days' supply" is meant to reflect the number of days that the supply of the dispensed medication is meant to last. CMS describes CDC recommendations for days' supply of new prescriptions and results of surveys of the many states that already have fill limitations in place. CMS states that quantity limits should take into account both dosage and frequency and expects states to consider current

[9] "CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016." Centers for Disease Control and Prevention, Aug. 2017, https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6501e1er.pdf and "CDC Guideline for Prescribing Opioids for Chronic Pain - United States, 2016." Centers for Disease Control and Prevention, Mar. 2016, https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm?CDC_AA_refVal=https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1er.html.

[10] The HHS Pain Management Best Practices Inter-Agency Task Force Report is available at https://www.hhs.gov/ash/advisory-committees/pain/index.html.

[11] HHS Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics. Oct. 2019, www.hhs.gov/opioids/sites/default/files/2019-10/Dosage_Reduction_Discontinuation.pdf.

opioid guidelines, clinical indications, and dosing schedules of opioids to ensure prescriptions are appropriate, medically necessary, and not likely to result in adverse events. Clinicians should also be evaluating benefits and harms of continuing ongoing opioid therapy every three months or more frequently.

- Prospective safety edit limits for opioid prescriptions on the maximum daily morphine milligram equivalent dosage for treatment of pain, for both initial and subsequent prescription fills. States would designate those limitations. In the final rule, CMS eliminates the word "chronic" from this requirement so that this standard applies with respect to opioids prescribed for all pain and not only "chronic pain." CMS reviews CDC recommendations for maximum daily dosages and refers readers to HHS guidance on discontinuing opioid use as well as an April 2019 FDA safety announcement regarding decreasing or discontinuing opioid use.
- A retrospective, automated claims review process that identifies prescription fills of opioids in excess of the safety edit limits specified by the state to identify fraud, abuse, excessive use, inappropriate or medically unnecessary care, or prescribing or billing practices that indicate abuse, inappropriate or medically unnecessary care among prescribers, pharmacists and individuals receiving Medicaid benefits. CMS states that it expects states to consider, in addition to opioid claims data, incorporating other available data or records such as prescription histories, diagnoses, medical records, and prescription drug monitoring program files, to identify fraud, misuse, abuse, excessive utilization, or inappropriate or medically unnecessary care.
- A retrospective claims review automated process and, at the option of the state, prospective safety edits that monitor when an individual is concurrently prescribed opioids and benzodiazepines or antipsychotics.
- A program to monitor and manage the appropriate use of antipsychotic medications by children enrolled in Medicaid, including Medicaid expansion groups for the Children's Health Insurance Program (CHIP).
- A process to identify potential fraud or abuse of controlled substances by Medicaid enrollees, providers, and pharmacies.
- Prospective safety edits, retrospective claims review automated processes, or a combination of these approaches as determined by the state, to identify when:
    - A beneficiary is prescribed an opioid after the beneficiary has been prescribed one or more drugs used for MAT of an opioid use disorder or has been diagnosed with an opioid use disorder, within a timeframe specified by the state, in the absence of a new indication to support utilization of opioids (such as a new cancer diagnosis or entry into hospice care); and
    - A beneficiary could be at high risk of opioid overdose and should be considered for co-prescription or co-dispensing of naloxone.

CMS notes that none of the provisions prohibit the exercise of clinical judgement by a provider regarding the best treatment for a patient and that prior authorization may be necessary for patients who need clinical care to minimize withdrawal when tapering off of high doses of opioids. CMS also encourages states to offer education and training to all health care providers.

Response to Comments. Commenters made a number of suggestions for including additional standards or for including more specific standards. Recommendations included that CMS establish uniform limits across Medicare and Medicaid programs; codify non-pharmacological pain management strategies; establish specific quantity, days' supply or early refill limits; require programs based on particular state models; or provide for education and training to providers on DUR programs. CMS declines making changes in response to those recommendations. In response to concerns that utilization management could result in discriminating against enrollees on the basis of disabilities, CMS states that nothing in the rule is intended to interfere with providers' clinical decision-making or with the provider-patient relationship and reviews non-discrimination statutes including those in the ACA, the Civil Rights Act, the Americans with Disabilities Act, the Rehabilitation Act, among others that continue to apply.

Other commenters recommended CMS eliminate requirements for a safety edits on days' supply for opioid-naïve beneficiaries or prohibit days' supply limits of fewer than 7 days for fear that those limitations could be harmful to certain patient groups or incorporate exceptions from those limits for emergencies. A commenter questioned the need for a safety edit for duplicative therapies pointing out that some patients may take duplicative opioid-based medications for chronic pain. CMS reiterates that the purpose of the safety edit is to flag for the pharmacist to assess the patient's need including potentially by discussing it with the prescriber and the beneficiary. It is not intended to replace the patient-provider relationship or the provider's exercise of clinical judgement. In addition, CMS expects that states would not establish limits that could not be overridden and would provide for exceptions based on specific patient factors, and that state DUR Boards which include both physicians and pharmacists will review state safety edit parameters.

In response to a concern that the use of an MME limit does not correspond to current CDC guidelines, CMS notes that the current CDC Opioids Workgroup is updating those guidelines and is planning to release their recommendations in 2021.

In response to commenters who recommended additional safety edits, CMS points out that states have the flexibility to implement additional edits or monitoring. CMS also provides clarification regarding its interpretation that medications used for MAT are covered outpatient drugs (even through they are prescribed as part of a bundled service), and the application of DUR to MAT services.

(ii) Exclusions

CMS finalizes as proposed, permitting states to exempt individuals from the above requirements who are receiving hospice or palliative care or treatment for cancer; who are residents of long-term care facilities, intermediate care facilities for the intellectually disabled, or facilities that dispense frequently abused drugs through a contract with a single pharmacy; or others whom the state elects to exempt. States would have the ability to elect to apply those requirements to those populations.

Commenters recommended additional exclusions including, for example, residents in assisted living facilities, or those with sickle cell disease. Others recommended making the exclusions mandatory for states. CMS declines to make those changes.

(iii) Managed Care Requirements

Medicaid programs with managed care contracts are required to include the SUPPORT Act DUR provisions in those contracts by October 1, 2019. CMS finalizes its proposal to extend the requirements to other types of managed care contracts as well: to prepaid ambulatory health plans (PAHPs) and prepaid inpatient health plans (PIHPs). In addition, the SUPPORT Act requires that Medicaid managed care organizations and managed care entities within a state must operate a DUR program. In the final rule, CMS also specifies that primary care case management organizations (PCCMs) are subject to the requirements.

CMS had proposed to define a managed care entity in §438.2 as a Medicaid managed care organization that provides or arranges for services for enrollees under a contract under section 1903(m) of the Act (which describes Medicaid managed care organizations), or a primary care case manager. It does not finalize this technical change as the approach described in the paragraph above (adding PCCMs) is determined to be simpler. No substantive change is intended.

(iv) State Plan Amendment (SPA) Requirements

The SUPPORT Act requires states to implement the DUR requirements by October 1, 2019 and to submit an amendment to their state plan implementing the requirements no later than December 31, 2019. CMS provided guidance in August of 2019 about this in an information bulletin.[12] It indicates that all states have already done so and those SPAs have been approved and that state plans must be amended as necessary to describe how the state complies with section 1004 of the SUPPORT Act.

(v) DUR Reporting Requirements (§456.712)

CMS finalizes its proposal to modify existing annual DUR reporting requirements to add new paragraph (c) providing that all FFS and managed care DUR reports received by CMS will be publicly posted on a website maintained by CMS for the sharing of reports and other information concerning Medicaid DUR programs. The public disclosure will, according to CMS, encourage innovative and collaborative practices.

II. Information Collection Requirements

CMS identifies several provisions for which it estimates potential burden and that would require an information collection review and approval under the Paperwork Reduction Act of 1995.

[12] https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/cib080519-1004.pdf.

- VBP program reporting requirements. Under the final rule, states are required to report data annually and no later than 60 days after the end of each year. Required data would include: state name, NDC (for drugs covered under the VBP), product FDA list name, number of prescriptions, cost to the state to administer VBP, and the total savings generated by the supplemental rebate due to the VBP. CMS states that in the aggregate, the ongoing annual burden would be 306 hours at a total cost of $36,200.
- Requirements for states. States are required to certify quarterly rebate invoices to manufacturers as well as state drug utilization reports to CMS. CMS estimates that it will take 5 hours for the certifying authority to obtain CMS systems access at a one-time cost aggregate cost of $52,192. In addition, an additional 2 hours for a chief executive to certify the data would, in the aggregate, cost $20,877.
- Third-party liability provisions. States are required to avoid claims for prenatal care for pregnant women including for labor, delivery, and postpartum care; and state agencies are permitted 100 days instead of 90 days to pay claims related to medical support enforcement services. CMS estimates minor data entry/information processing would be required at an aggregate cost of $8,550.

Table 5 in the final rule detail on the estimated burden and is summarized below.

Summary of Annual Requirement and Burden

Section under Title 42 of the CFR	# of Respondents	Total Responses (per year)	Time per Response (hours)	Total Time (hours)	Labor Rate ($/hr)	Total cost ($)	OMB Control Number (CMS ID Number)
§447.518(d) (1) and (2)	51	51	6	306	118.30	36,200	0938-1385 (CMS-10722)
§447.511	56	56	5	280	186.40	52,192	0938-0582 (CMS-R-144)
§447.511	56	224	0.5	112	186.40	20,877	0938-0582 (CMS-R-144)
§433.139(b)(2), (b)(3)(i) and (b)(3)(ii)(B)	56	224	1	224	35.04	7,849	0938-1265 (CMS-10529)
TOTAL	56	555	Varies	922	Varies	117,118	n/a

Source: HPA excerpt of Table 5: Summary of Annual Requirement and Burden.

III. Regulatory Impact Analysis

OMB has determined that this proposed rule would not be "economically significant" within the meaning of Executive Order 12866, because it is unlikely to have an annual effect of $100 million or more in any one year, nor would it have a significant impact on a substantial number of small entities or small rural hospitals. The rule is not estimated to have a consequential effect on state, local, or tribal governments nor need offsetting regulations as its costs are unlikely to be greater than minimal.