DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 433, 438, 447 and 456

[CMS–2482–P]

RIN 0938–AT82

Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would advance CMS' efforts to support state flexibility to enter into innovative value-based purchasing arrangements (VBPs) with manufacturers, and to provide manufacturers with regulatory support to enter into VBPs with payers, including Medicaid. To ensure that the regulatory framework is sufficient to support such arrangements and to promote transparency, flexibility, and innovation in drug pricing without undue administrative burden, we are proposing new regulatory policies and clarifying certain already established policies to assist manufacturers and states in participating in VBPs in a manner that is consistent with the law and maintains the integrity of the Medicaid Drug Rebate Program (MDRP). This proposed rule also proposes revisions to regulations regarding: Authorized generic sales when manufacturers calculate average manufacturer price (AMP); pharmacy benefit managers (PBM) accumulator programs and their impact on AMP and best price; state and manufacturer reporting requirements to the MDRP; new Medicaid Drug Utilization Review (DUR) provisions designed to reduce opioid related fraud, misuse and abuse; the definitions of CMS-authorized supplemental rebate agreement, line extension, new formulation, oral solid dosage form, single source drug, multiple source drug, innovator multiple source drug for purposes of the MDRP; payments for prescription drugs under the Medicaid program; and coordination of benefits (COB) and third party liability (TPL) rules related to the special treatment of certain types of care and payment in Medicaid and Children's Health Insurance Program (CHIP).

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on July 20, 2020.

ADDRESSES: In commenting, please refer to file code CMS–2842–P.

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

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

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–2482–P, P.O. Box 8016, Baltimore, MD 21244–8016.

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

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–2482–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

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

FOR FURTHER INFORMATION CONTACT:

Ruth Blatt, (410) 786–1767, for issues related to the definition of line extension, new formulation, oral solid dosage form, single source drug, multiple source drug, and innovator multiple source drug.

Cathy Sturgill, (410) 786–3345, for issues related to Third Party Liability.

Michael Forman, (410) 786–2666 and Whitney Swears (410) 786–6543 for issues related to Drug Utilization Review.

Christine Hinds, (410) 786–4578, for issues related to Value-based Purchasing.

Joanne Meneeley, (410) 786–1361, for issues related to State Drug Utilization Data (SDUD) certification.

Christine Hinds, (410) 786–4578, for issues related to Authorized Generics and Inflation Rebates.

Charlotte Amponsah (410) 786–1092, for issues related to Manufacturer-sponsored Patient Assistance Programs.

SUPPLEMENTARY INFORMATION:

I. Background

Under the Medicaid program, states may provide coverage of prescribed drugs as an optional benefit under section 1905(a)(12) of the Social Security Act (the Act). Section 1903(a) of the Act provides for federal financial participation (FFP) in state expenditures for these drugs. In the case of a state that provides for medical assistance for covered outpatient drugs, as provided under section 1902(a)(54) of the Act, the state must comply with the requirements of section 1927 of the Act. Section 1927 of the Act governs the Medicaid Drug Rebate program (MDRP) and payment for covered outpatient drugs (CODs), which are defined in section 1927(k)(2) of the Act. In general, for payment to be made available for CODs under section 1903(a) of the Act, manufacturers must enter into a National Drug Rebate Agreement (NDRA) as set forth in section 1927(a) of the Act. See also section 1903(i)(10) of the Act. The MDRP is authorized under section 1927 of the Act, and is a program that includes CMS, state Medicaid agencies, and participating drug manufacturers that helps to partially offset the federal and state costs of most outpatient prescription drugs dispensed to Medicaid beneficiaries. The MDRP provides specific requirements for rebate agreements, drug pricing submission and confidentiality requirements, the formulas for calculating rebate payments, drug utilization reviews (DUR), and requirements for states for CODs.

The Covered Outpatient Drugs final rule with comment period (COD final rule) was published in the February 1, 2016 **Federal Register** (81 FR 5170) and became effective on April 1, 2016. The COD final rule implemented provisions of section 1927 of the Act that were added by the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively referred to as the Affordable Care Act) pertaining to Medicaid reimbursement for CODs. It also revised other requirements related to CODs, including key aspects of Medicaid coverage and payment and the MDRP under section 1927 of the Act. The regulations implemented through the COD final rule, and those proposed in this notice of proposed rulemaking are consistent with the Secretary's authority set forth in section 1102 of the Act to publish regulations that are necessary to the efficient administration of the Medicaid program.

A. Changes to Coordination of Benefits/Third Party Liability Regulation Due to Bipartisan Budget Act (BBA) 2018

Medicaid is the payer of last resort, which means that other available

resources—known as third party liability, or TPL—must be used before Medicaid pays for services received by a Medicaid-eligible individual. Title XIX of the Act requires state Medicaid programs to identify and seek payment from liable third parties, before billing Medicaid. Section 53102 of the Bipartisan Budget Act of 2018 (BBA 2018) (Pub. L. 115–123, enacted February 9, 2018) amended the TPL provision at section 1902(a)(25) of the Act. Specifically, section 1902(a)(25)(A) of the Act requires that states take all reasonable measures to ascertain legal liability of third parties to pay for care and services available under the plan. That provision further specifies that a third party is any individual, entity, or program that is or may be liable to pay all or part of the expenditures for medical assistance furnished under a state plan. Section 1902(a)(25)(A)(i) of the Act specifies that the state plan must provide for the collection of sufficient information to enable the state to pursue claims against third parties. Examples of liable third parties include: Private insurance companies through employment-related or privately purchased health insurance; casualty coverage resulting from an accidental injury; payment received directly from an individual who has voluntarily accepted or been assigned legal responsibility for the health care of one or more Medicaid recipients; fraternal groups, unions, or state workers' compensation commissions; and medical support provided by a parent under a court or administrative order.

Effective February 9, 2018, section 53102(a)(1) of the Bipartisan Budget Act of 2018 amended section 1902(a)(25)(E) of the Act to require a state to use standard coordination of benefits cost avoidance when processing claims for prenatal services which now included labor and delivery and postpartum care claims. Additionally, effective October 1, 2019, section 53102(a)(1) of the Bipartisan Budget Act of 2018 amended section 1902(a)(25)(E) of the Act, to require 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 for 90 days.

Section 53102(b)(2) of the Bipartisan Budget Act of 2018 delays the implementation date from October 1, 2017 to October 1, 2019 of the Bipartisan Budget Act of 2013 provision, which allowed for payment up to 90 days after a claim is submitted that is associated with medical support enforcement instead of 30 days under previous law. Medical support is a form of child support that is often provided through an absent parent's employers health insurance plan.

Effective April 18, 2019, section 7 of the Medicaid Services Investment and Accountability Act of 2019 (Pub. L. 116–16) amended section 202(a)(2) of the Bipartisan Budget Act of 2013 to allow 100 days instead of 90 days to pay claims related to medical support enforcement under section 1902(a)(25)(F)(i) of the Act.

B. Changes to the Calculation of Average Manufacturer Price (AMP) Regarding Authorized Generic Drugs Due to the Continuing Appropriations Act, 2020, and Health Extenders Act of 2019

On September 27, 2019, the President signed into law the Continuing Appropriations Act, 2020, and Health Extenders Act of 2019 (Health Extenders Act) (Pub. L. 116–59), which made changes to sections 1927(k)(1) and 1927(k)(11) of the Act, revising how manufacturers calculate the average manufacturer price (AMP) for a covered outpatient drug, for which the manufacturer permits an authorized generic to be sold and redefines the definition of wholesaler. Manufacturers that approve, allow, or otherwise permit any drug to be sold under the manufacturer's own new drug application (NDA) approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act, shall no longer include sales of these authorized generics in the calculation of AMP, regardless of the relationship between the brand name manufacturer and the manufacturer of the authorized generic.

Specifically, section 1603 of the Health Extenders Act, which is titled ''Excluding Authorized Generic Drugs from Calculation of Average Manufacturer Price for Purposes of the Medicaid Drug Rebate Program; Excluding Manufacturers from Definition Of Wholesaler,'' amended the statute as follows:

- Section 1927(k)(1)(C) of the Act to replace the term ''Inclusion'' with ''Exclusion'' in the title and further amended subparagraph (C) to state that, in the case of 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, such term shall be exclusive of the average price paid for such drug by wholesalers for drugs distributed to retail community pharmacies.
- The definition of wholesaler at section 1927(k)(11) of the Act to remove references to manufacturers from the definition of wholesaler.

Typically, 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 NDA but under a different National Drug Code (NDC) number. The authorized generic is typically the primary manufacturer's brand product offered at a lower price point. Primary manufacturers may sell the authorized generic product to the secondary manufacturer they are allowing to sell an authorized generic of their brand product, and such sales are commonly referred to as transfer sales. Under the amendments made to section 1927 of the Act, a primary manufacturer that sells the authorized generic version of the brand drug to the 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. The exclusion of these transfer sales from the primary manufacturer's brand drug AMP will likely result in higher AMPs for the brand drugs and a potential increase to a manufacturer's Medicaid drug rebates to states.

The amendments to section 1927 authorized under section 1603 of the Health Extenders Act are effective October 1, 2019. Therefore, manufacturers must reflect the changes to the calculation of their AMPs for rebate periods beginning October 1, 2019 (reported to CMS no later than 30 days after the end of the rebate period). To assist manufacturers, CMS provided guidance in Manufacturer Release #111 [1] and Manufacturer Release #112.[2] Furthermore, in accordance with 42 CFR 447.510(b), manufacturers have 12 quarters from the quarter in which the data were due to revise AMP, if necessary.

C. Changes as Result of the Bipartisan Budget Act of 2015

Under the Medicaid program, states may provide coverage of prescribed drugs as an optional service under section 1905(a)(12) of the Act. Section 1903(a) of the Act provides for FFP in state expenditures for these drugs. Section 1927 of the Act governs the MDRP and payment for CODs, which are defined in section 1927(k)(2) of the

[1] *https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/mfr-releases/mfr-rel-111.pdf.*

[2] *https://www.medicaid.gov/prescription-drugs/downloads/mfr-rel-112.pdf.*

Act. In general, for payment to be made available under section 1903(a) of the Act for CODs, manufacturers must enter into an NDRA as set forth in section 1927(a) and (b) of the Act. Section 1927 of the Act provides specific requirements for rebate agreements, drug pricing submission and confidentiality requirements, the formulas for calculating rebate payments, and requirements for states for CODs. Section 602 of the Bipartisan Budget Act of 2015 (BBA 2015) (Pub. L. 114–74, enacted November 2, 2015) amended section 1927(c)(3) of the Act to require that manufacturers pay additional rebates on their non-innovator multiple source (N) drugs if the average manufacturer prices of an N drug increase at a rate that exceeds the rate of inflation. This provision of BBA 2015 was effective beginning with the January 1, 2017 quarter, or in other words, beginning with the unit rebate amounts (URAs) that are calculated for the January 1 2017 quarter. This additional inflation adjusted rebate requirement for N drugs was discussed in Manufacturer Release Nos. 97 (Manufacturer Release 97) and 101(Manufacturer Release 101).

D. Current Medicaid Drug Rebate Program and Value-Based Purchasing Arrangements (VBP)

In the preamble of the COD final rule, in response to a comment (81 FR 5253), we recognized the importance of VBPs, especially when such arrangements benefit patients. We acknowledged that, given the uniqueness of each VBP arrangement, we had to consider how to provide more specific guidance on the matter, including how such arrangements affect a manufacturer's calculation of its best price and Medicaid drug rebate obligations. Thereafter, we released a state and manufacturer notice on July 14, 2016 (available at State Release 176 [3] and Manufacturer Release 99 [4]) to inform states and manufacturers on how to seek guidance from us on their specific VBP, as well as to encourage states to consider entering into VBP as a means to address high cost drug treatments.

Since the release, manufacturers and states have shown an increased interest in VBP as a possible option for better managing and predicting drug spending, which helps to assure that manufacturers have some vested interest in assuring positive patient outcomes from the use of their drugs. To this end, CMS has approved several state plan amendments submitted by states that allow states to negotiate supplemental rebates under CMS-authorized rebate agreements with drug manufacturers based on evidence or outcomes-based measures for a patient or beneficiary based on use of the drug. In addition, manufacturers have approached us with their issues and questions regarding the impact of various types of VBP proposals on their MDRP price reporting obligations (that is, AMP and best price), as well as the regulatory challenges they encounter when structuring and implementing VBP. Finally, manufacturers have noted MDRP reporting challenges with VBP programs, whose evidence or outcomes-based measures extend beyond 3 years, particularly given that manufacturers have limited ability to make changes to reporting metrics outside the 12-quarter MDRP reporting period. This proposed regulation would address some of the manufacturer concerns with regards to these MDRP requirements.

E. Definition of Line Extension, New Formulation, and Oral Solid Dosage Form for Alternative Unit Rebate Amount

Section 2501(d) of the Patient Protection and Affordable Care Act (Pub. L. 111–148, enacted March 23, 2010), as amended by section 1206 of the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152, enacted March 30, 2010) (collectively referred to as the Affordable Care Act) added section 1927(c)(2)(C) of the Act effective for drugs paid for by a state on or after January 1, 2010. This provision establishes an alternative formula for calculating the URA for a line extension of a single source drug or innovator multiple source drug that is an oral solid dosage form. We refer to the URA calculated under the alternative formula as the ''alternative URA''. Additionally, the Affordable Care Act defined ''line extension'' to mean, with respect to a drug, a new formulation of the drug, such as an extended release formulation. Section 1927(c)(2)(C) of the Act was further amended by section 705 of the Comprehensive Addiction and Recovery Act of 2016 (CARA) (Pub. L. 114–198, enacted July 22, 2016) to exclude from that definition an abuse-deterrent formulation of the drug (as determined by the Secretary), regardless of whether such abuse-deterrent formulation is an extended release formulation. The determination of whether a drug is excluded because it is an abuse deterrent formulation is explained in at Manufacturer Release 102.[5] The CARA amendment applies to drugs paid for by a state in calendar quarters beginning on or after the July 22, 2016 date of enactment of CARA (that is, beginning with 4Q 2016). Finally, section 1927(c)(2)(C) of the Act was further amended by section 53104 of the BBA of 2018, which provided a technical correction such that the rebate for a line extension of a single source drug or an innovator multiple source drug that is an oral solid dosage form shall be the greater of either (1) the standard rebate (calculated as a base rebate amount plus an additional inflation-based rebate) or (2) the base rebate amount increased by the alternative formula described in section 1927(c)(2)(C)(iii)(I) through (III) of the Act. We refer to the additional inflation-based rebate as the ''additional rebate.'' Additionally, as we have previously used the term ''initial brand name listed drug'' in the ''Medicaid Program; Covered Outpatient Drugs'' proposed rule published in the February 2, 2012 **Federal Register** (77 FR 5318, 5323 through 5324) (hereinafter referred to as the February 2, 2012 proposed rule), the Covered Outpatient Drugs final rule with comment published on February 1, 2016 (81 FR 5197), and 42 CFR 447.509(a)(4)(iii) to refer to the initial single source drug or innovator multiple source drug, we continue to do so in this proposed rule. The BBA of 2018 amendment applies to rebate periods beginning on or after October 1, 2018.

We proposed a definition of ''line extension'' in the February 2, 2012 proposed rule (77 FR 5323 through 5324) and received numerous comments from stakeholders. In the COD final rule, we did not finalize the proposed definition and requested additional comments with a 60-day comment period that closed on April 1, 2016. The additional comments received, although instructive of the public's thoughts at the time, were not informed by the then-current statutory framework. Therefore, we did not finalize a definition of ''line extension'' in the April 1, 2019 final rule (84 FR 12132). We reiterated in the April 1, 2019 final rule that manufacturers are to rely on the statutory definition of ''line extension'' at section 1927(c)(2)(C) of the Act, and where appropriate are permitted to use reasonable assumptions in their determination of whether their drug qualifies as a line extension. We also stated that if we later decide to develop

[3] *https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/state-releases/state-rel-176.pdf.*

[4] *https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/mfr-releases/mfr-rel-099.pdf.*

[5] *https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/mfr-releases/mfr-rel-102.pdf.*

a regulatory definition of ''line extension,'' we would do so through our established Administrative Procedures Act (APA) compliant rulemaking process and issue a proposed rule. For the reasons discussed in section II.C. of this proposed rule, we are proposing definitions of ''line extension'', ''new formulation'', and ''oral solid dosage form''.

The line extension provision has been in effect since January 1, 2010, and the Drug Data Reporting for Medicaid (DDR) system was modified in 2016 to implement the data reporting requirements for line extensions. However, we have found that some manufacturers are unclear about their line extension reporting obligations, for example, whether a particular drug satisfies the statutory definition of line extension and the identification of the initial brand name listed drug. Therefore, in addition to proposing definitions of ''line extension'', ''new formulation'', and ''oral solid dosage form'', we are providing clarification below regarding manufacturers' reporting obligations.

Details regarding how to calculate the additional rebate (calculated as a percentage of AMP) and the alternative URA can be found in the ''Medicaid Program; Covered Outpatient Drug; Line Extension Definition; and Change to the Rebate Calculation for Line Extension Drugs'' final rule and interim final rule with comment period that was published in the April 1, 2019 **Federal Register** (84 FR 12133) (hereinafter referred to as the April 1, 2019 final rule). We note that under § 447.509(a)(4)(iii), manufacturers are required to calculate the alternative URA if the manufacturer of the line extension also manufactures the initial brand name listed drug or has a corporate relationship with the manufacturer of the initial brand name listed drug. As noted later in section II.C. of this proposed rule, although a drug that meets the definition of a line extension should be identified as such in DDR, a manufacturer is not required to calculate the alternative URA unless the manufacturer of the line extension also manufactures, or has a corporate relationship with the manufacturer of, the initial brand name listed drug.

To apply the alternative formula described in section 1927(c)(2)(C)(iii)(I) through (III) of the Act for each line extension and rebate period, the manufacturer must determine which NDC represents the initial brand name listed drug that will be used to calculate the alternative URA. First, the manufacturer must identify all potential initial brand name listed drugs by their respective NDCs by considering all strengths of the initial brand name listed drug in accordance with section 1927(c)(2)(C)(iii)(II) of the Act. Additionally, only those potential initial brand name listed drugs that are manufactured by the manufacturer of the line extension or by a manufacturer with which the line extension manufacturer has a corporate relationship should be considered. Then, the manufacturer must evaluate the additional rebate (calculated as a percentage of AMP) for each potential initial brand name listed drug. The potential initial brand name listed drug that has the highest additional rebate (calculated as a percentage of AMP) is the initial brand name listed drug that must be identified in DDR and used to calculate the alternative URA for the rebate period.

Section 1927(c)(2)(C)(i) of the Act requires the manufacturer to calculate the alternative formula for each quarter in order to determine the initial drug for each quarter that has the highest additional rebate (calculated as a percentage of AMP). Therefore, the manufacturer must re-evaluate the additional rebate (calculated as a percentage of AMP) for each potential initial brand name listed drug each quarter. Because the additional rebate (calculated as a percentage of AMP) for any potential initial brand name listed drug may change from one quarter to the next, the initial brand name listed drug used for the alternative URA calculation may also change from one quarter to the next. Additionally, the NDC for the initial brand name listed drug must be active in MDRP for the quarter, that is, an NDC that is produced or distributed by a manufacturer with an active NDRA and the NDC does not have a termination date that occurred in a rebate period earlier than the rebate period for which the calculation is being performed. Because drugs may come on and off the market, an initial brand name listed drug that was used to calculate the alternative URA for one quarter may not be active in MDRP for the next quarter. However, a different initial brand name listed drug may be active in MDRP and available to use to calculate the alternative URA for the next quarter.

F. Impact of Certain Manufacturer Sponsored Patient Assistance Programs (''PBM Accumulator Programs'') on Best Price and Average Manufacturer Price (AMP)

Manufacturer-sponsored patient assistance programs can be helpful to patients in obtaining necessary medications. However, pharmacy benefit managers (PBMs) contend that manufacturer-sponsored assistance programs steer consumers towards more expensive medications when there may be more cost saving options available to health plans. Therefore, as a cost saving measure, PBMs have encouraged health plans in some cases to not allow the manufacturer assistance provided under such programs to be applied towards a patient's health plan deductible for a brand name drug not on a plan's formulary. This proposed regulation would provide instruction to manufacturers on how to consider the implementation of such programs when determining best price and AMP for purposes of the MDRP.

G. State Drug Utilization Data (SDUD) Reported to Medicaid Drug Rebate Program

Section 1927(b)(2)(A) of the Act requires each State agency to report to each manufacturer not later than 60 days after the end of each rebate period and in a form consistent with a standard reporting format established by the Secretary, information on the total number of units of each dosage form and strength and package size of each covered outpatient drug dispensed after December 31, 1990, for which payment was made under the plan during the period, including such information reported by each Medicaid managed care organization, and shall promptly transmit a copy of such report to the Secretary. In accordance with this requirement, states are required to send state drug utilization data (SDUD) using OMB-approved Rebate Invoice Form, the CMS–R–144 (the data fields and descriptions are included as Exhibit X in this proposed rule) to manufacturers and transmit a copy of this report to CMS.

While many states subject their SDUD on the CMS–R–144 to edits in order to uncover outliers/inaccuracies in the invoices to manufacturers before sending copies to CMS, some states send unedited copies of the SDUD to CMS, resulting in discrepancies that do not conform with the statutory requirement at section 1927(b)(2)(A) of the Act. The statute requires such reporting to be in a form consistent with a standard reporting format established by the Secretary, and we believe that such a copy means that the data submitted on the invoice (CMS–R–144) to the manufacturer must be accurate and identical to the report (copy) states send to CMS. Further, we expect that when states send SDUD updates or changes to manufacturers, they transmit those changes to us concurrently in a copy to CMS. However, in some cases,

states fail to submit these updates causing the data to be mismatched. This results in states not complying with section 1927(b)(2)(A) of the Act and CMS not having an accurate account of rebates billed in the MDRP.

H. Changes Related to the Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act

The epidemic of opioid overdose, misuse, and addiction is a critical public health issue that affects the lives of millions of Americans. Research shows the opioid overdose epidemic has a disproportionate impact on Medicaid beneficiaries and the consequences have been tragic. In 2017, 47,600 people in America died of an opioid overdose per the Centers for Disease Control and Prevention (CDC).[6] Inappropriate opioid prescribing can result in costly medical complications such as abuse, misuse, overdoses, falls and fractures, drug to drug interactions and neonatal conditions. The use of multiple opioids is associated with a higher risk of mortality, with mortality risk increasing in direct relation to the number of opioids prescribed concurrently.[7] [8] Beneficiaries who receive multiple opioids may lack coordinated care and are at higher risk for opioid overdose.[9] These complications are costly, preventable, and result in avoidable healthcare expenditures.[10] Moreover, according to the National Institute on Drug Abuse (NIDA), research suggests that misuse of prescription pain relievers may actually open the door to heroin use, as four in five new heroin users started out misusing prescription painkillers.[11]

Since 1993, section 1927(g) of the Act has required each state to develop a DUR program targeted, in part, at reducing abuse and misuse of outpatient prescription drugs covered under the State's Medicaid Program. The DUR program operates to assure that prescriptions are appropriate, medically necessary, and are not likely to result in adverse medical events. Each state DUR program consists of prospective drug use review, retrospective drug use review, data assessment of drug use against predetermined standards, and ongoing educational outreach activities.

Consistent with section 1927(g)(3)(D) of the Act, we require each state Medicaid Program to submit to us an annual report on the operation of its Medicaid DUR program with respect to the fee-for-service (FFS) delivery system, including information on prescribing patterns, cost savings generated by the state's DUR program, and the state's DUR program's overall operations, including any new or innovative practices. Additionally, § 438.3(s)(4) and (5) require state contracts with any managed care organization (MCO), prepaid inpatient health plan (PIHP) or prepaid ambulatory health plan (PAHP) that covers covered outpatient drugs to require the MCO, PIHP, or PAHP to operate a DUR program that complies with section 1927(g) of the Act and 42 CFR part 456, subpart K, and to submit detailed information about its DUR program activities annually. For the purposes of this proposed rule, managed care program (MCP) references MCOs, managed care entities (MCEs), PAHPs and PIHPs.

The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (Pub. L. 115–271, enacted October 24, 2018) (the SUPPORT for Patients and Communities Act) includes measures to combat the opioid crisis in part by reducing opioid related abuse and misuse by advancing treatment and recovery initiatives, improving prevention, protecting communities, and bolstering efforts to fight deadly illicit synthetic drugs. There are several Medicaid-related DUR provisions for FFS and MCP pharmacy programs contained within section 1004 of the SUPPORT for Patients and Communities Act. These provisions establish drug review and utilization standards in section 1902(a)(85) and (oo) of the Act to supplement existing requirements under section 1927(g) of the Act, in an effort to reduce opioid-related fraud, misuse and abuse. State implementation of these strategies was required by October 1, 2019, and states must include information about their implementation in their annual reports under section 1927(g)(3)(D) of the Act. In turn, the Secretary is required to report to Congress on the information submitted by the states, starting with information from states' FY 2020 reports.

Consistent with section 1927(g) of the Act, the SUPPORT for Patients and Communities Act has the goal of improving the quality of care received by Medicaid recipients by reducing their exposure to hazards resulting from the inappropriate prescribing, gross overuse, or inappropriate or medically unnecessary care. In this context, strategies to assure the appropriate use of opioids are now being implemented in clinical settings, health care systems and public health agencies. Efforts to prevent harms associated with overuse and misuse of opioids must be integrated to ensure patients are receiving appropriate standards of care. We recognize efforts involving multiple stakeholders are needed to address the opioid crisis, to assure the health and well-being of Medicaid beneficiaries, and decrease any related health care expenditures as well as for prevention of future epidemics. We are committed to ensuring there are basic minimum standards implemented through Medicaid DUR programs nationwide to help ensure that prescriptions are appropriate, medically necessary and align with current standards of care, under our authority to implement section 1927(g) of the Act and section 1004 of the SUPPORT for Patients and Communities Act.

I. Single Source Drug, Multiple Source Drug, Innovator Multiple Source Drug

Section 6(c) of the Medicaid Services Investment and Accountability Act of 2019 (Pub. L. 116–16, enacted April 18, 2019) modified the definitions in section 1927(k) of the Act for single source drug, multiple source drug, and innovator multiple source drug. In this proposed rule, we propose to revise the definitions of these terms at § 447.502 to reflect these statutory changes.

II. Provisions of the Proposed Regulations

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

In 1980, under the authority in section 1902(a)(25)(A) of the Act, we issued regulations at 42 CFR part 433, subpart D establishing requirements for state Medicaid agencies to support the coordination of benefits (COB) effort by identifying TPL. Effective February 9, 2018, section 53102(a)(1) of BBA 2018 amended section 1902(a)(25)(E) of the Act to require states to cost avoid claims

[6] *https://www.cdc.gov/drugoverdose/data/statedeaths.html.*

[7] Ray WA, Chung CP, Murray KT, Hall K, Stein CM. Prescription of Long-Acting Opioids and Mortality in Patients with Chronic Noncancer Pain. JAMA. 2016 Jun 14; 315(22):2415–23.

[8] Baumblatt JA, Wiedeman C, Dunn JR, Schaffner W, et al. High-risk use by patients prescribed opioids for pain and its role in overdose deaths. JAMA Intern Med. 2014 May; 174(5):796–801.

[9] Bonnie, Richard J., et al. Pain Management and the Opioid Epidemic: Balancing Societal and Individual Benefits and Risks of Prescription Opioid Use. The National Academies Press, 2017.

[10] Davis, Cory. ''Naloxone for Community Opioid Overdose Reversal.'' Naloxone for Community Opioid Overdose Reversal | Public Health Law Research, Public Health Law Research (PHLR), 22 June 2015, *http://phlr.org/product/naloxone-community-opioid-overdose-reversal.*

[11] ''Opioid Addiction 2016 Facts & Figures—ASAM Home Page.'' American Society of Addition Medicine, *www.asam.org/docs/default-source/advocacy/opioid-addiction-disease-facts-figures.pdf.*

(for example, when the state Medicaid agency has determined there is a legally liable third party responsible for paying the claim, it will reject (''cost avoid'') the claim) for prenatal care for pregnant women including labor and delivery and postpartum care, and to allow the state Medicaid agency 90 days instead of 30 days to pay claims related to medical support enforcement services, as well as requiring states to collect information on TPL before making payments. Effective April 18, 2019, section 7 of the Medicaid Services Investment and Accountability Act of 2019 amended section 1902(a)(25)(E) of the Act to allow 100 days instead of 90 days to pay claims related to medical support enforcement services, as well as requiring states to collect information on TPL before making payments.

Section 433.139(b)(2), (b)(3)(i) and (b)(3)(ii)(B) detail the exception to standard COB cost avoidance by allowing pay and chase for certain types of care, as well as the timeframe allowed prior to Medicaid paying claims for certain types of care. Specifically, we are proposing to delete § 433.139(b)(2). We are also proposing to revise § 433.139(b)(3)(i) by removing ''prenatal care for pregnant women, or'' from pay and chase services, and § 433.139(b)(3)(ii)(B) by removing ''30 days'' and adding ''100 days.''

B. Changes To Address Medicaid Access to Drugs Using Value-Based Purchasing Arrangements (VBP)

In the preamble of the COD final rule, in response to a comment in the COD final rule (81 FR 5253), we recognized the importance of VBP especially when such arrangements benefit Medicaid patients' access to drug treatments. We acknowledged that given the uniqueness of each VBP arrangement, we had to consider how to provide more specific guidance on the matter, including how such arrangements affect a manufacturer's best price and Medicaid drug rebate obligations. Thereafter, we released a state and manufacturer notice on July 14, 2016 (State Release 176 and Manufacturer Release 99) to inform states and manufacturers on how to seek guidance from us on their specific VBPs, as well as encourage states to consider entering into VBPs as a means to address high cost drug treatments.

Since those releases, manufacturers and states have shown an increased interest in VBP as a potential option for better managing and predicting drug spending, which helps to assure that manufacturers have some vested interest in assuring positive patient outcomes from the use of their drugs. However, some manufacturers hesitate to offer VBP arrangements to payers, including Medicaid, because of concerns that the existing Medicaid covered outpatient drug statute and applicable regulations do not specifically address, with respect to price reporting, the purchase or discounting of drugs based on evidence or outcomes-based measures. That is, CMS has not addressed the possible impact of offering VBP arrangements on manufacturer compliance with applicable MDRP price reporting obligations, including best price and AMP reporting.

The Administration supports VBP because it believes it will assist states with providing Medicaid patients access to needed therapies while providing a payment arrangement that allows the state flexibility, including an option to only pay when a therapy actually works. In order for such arrangements to work for Medicaid, we need to consider changes to MDRP regulations to both address manufacturers' concerns with offering Medicaid such innovative payment arrangements, while ensuring the required economies, efficiencies, and quality of care provided under the Medicaid program. If we do not consider such changes, manufacturers may be unwilling to offer VBP to Medicaid, which in turn will mean Medicaid will not have the advantage of accessing these arrangements for some of the drug therapies on the market that could replace other more expensive Medicaid services (such as hospital and physician-based services). In other words, by addressing a number of potential regulatory hurdles in a proposed regulation, states will be able to provide such methods and procedures relating to the utilization of, and payment for care and services as may be necessary to safeguard against unnecessary utilization of such care and services and assure that consistent with section 1902(a)(30)(A) of the Act, Medicaid payments are consistent with efficiency, economy, and quality of care.

One potential regulatory hurdle manufacturers have raised with us is best price reporting. Section 1927(c)(1)(C) of the Act defines best price in relevant part to mean with respect to a single source drug or innovator multiple source drug of a manufacturer *the lowest price available* from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, non-profit entity, or governmental entity within the United States, with certain exclusions enumerated at sections 1927(c)(1)(C)(i)(I) through (VI) of the Act. One of the issues manufacturers face in determining best price with the advent of VBP arrangements is that a manufacturer's best price can be reset based upon the outcome of a drug treatment for one patient or one unit of the drug because of the VBP. When this occurs, the rebate due for that single use of the drug during a quarter that results in a negative outcome will reset the best price to a significantly lower amount, sometimes zero, prompting a significantly higher rebate (sometimes 100 percent of the drug's AMP).

This being the case, manufacturers have questioned how they should calculate best price and account for these units when an outcome of a VBP arrangement results in ''a lowest price available'' of zero or at a significant discount. Manufacturers have expressed concern to CMS that without further guidance from CMS in regulation regarding the determination of best price in this scenario, the manufacturer could be at risk of understating rebates and may potentially be subject to False Claims Act liability, a risk which further diminishes manufacturer interest in offering VBP payment arrangements in either the commercial or Medicaid market. In turn, this may hinder Medicaid access to the care and services provided as part of these VBP arrangements (for example, to gene therapies and potentially curative orphan drug treatments) that are available in the general population and that are consistent with efficiency, economy, and quality of care in accordance with section 1902(a)(30)(A) of the Act.

We believe this proposed rule proposes changes to the MDRP price reporting (in particular best price) to address the regulatory challenges manufacturers encounter when structuring and implementing VBP, and therefore, gives manufacturers the ability to offer these programs to commercial payers or Medicaid without the negative impact on best price or the potential for MDRP regulatory compliance.

Subpart I—Payment for Drugs

1. Definitions (§ 447.502)

a. Value-Based Purchasing Arrangement (VBP)

A VBP arrangement is not expressly defined or addressed in section 1927 of the Act or the MDRP implementing regulations. In order to address the issues noted above, we are proposing a definition of VBP to apply, as appropriate, in implementation of the MDRP.

More specifically, we are proposing to define VBP at § 447.502 to further clarify for manufacturers how discounts,

rebates, pricing etc. as a result of VBP arrangements should be accounted for in a manufacturer's determination of AMP and best price for an applicable covered outpatient drug.

At this time, manufacturers are permitted to make reasonable assumptions in the absence of applicable statute, regulation or guidance regarding how to treat pricing as a result of VBP. However, because of the uncertainty or lack of assurances as to the propriety of those reasonable assurances, we understand manufacturers may be discouraged from offering VBP to payers including Medicaid. Therefore, we propose to define VBP as an arrangement or agreement intended to align pricing and/or payments to an observed or expected therapeutic or clinical value in a population (that is, outcomes relative to costs) and includes (but is not limited to):

- Evidence-based measures, which substantially link the cost of a drug product to existing evidence of effectiveness and potential value for specific uses of that product;
- Outcomes-based measures, which substantially link payment for the drug to that of the drug's actual performance in a patient or a population, or a reduction in other medical expenses.

We have observed that some examples of evidence or outcomes-based measures used by manufacturers in their VBP proposals may be derived by observing and recording the absence of disease over a period of time, reducing a patient's medical spending, or improving a patient's activities of daily living thus resulting in reduced non-medical spending. In response to the proposed definition of VBP, we welcome suggestions for other measures and a rationale for the suggested measures that could be used to reflect value from a drug therapy and considered as we develop a final definition. We also welcome suggestions as to how to interpret ''substantially'' as used in the definition. That is, how much of the drug product's final cost should be associated with the evidence or outcomes based measure in order for the arrangement to be considered a VBP (for example, a drug product cost with less than 90 percent of the discounts/rebates tied to the drug's performance not be considered a VBP arrangement).

b. Bundled Sale

As stated earlier, one of the issues manufacturers contend with in determining best price with the advent of VBP arrangements is that a manufacturer's best price can be reset based upon the outcome of a drug treatment for one patient or one unit of the drug because of the VBP arrangement. When this occurs, the rebate due for that single use of the drug during a quarter that results in a negative outcome will reset the best price to a significantly lower amount, sometimes zero, prompting a significantly higher rebate (sometimes 100 percent of the drug's AMP). We have received stakeholder comments and inquiries regarding how rebates or discounts as part of a VBP arrangement could be considered in a bundled sale when determining best price. Some manufacturers have made reasonable assumptions that such discounts, as a result of a VBP, should be considered part of a bundled sale as defined at § 447.502.

In the COD final rule, we defined bundled sale at § 447.502 as any arrangement regardless of physical packaging under which the rebate, discount, or other price concession is conditioned upon the purchase of the same drug, drugs of different types (that is, at the nine-digit national drug code (NDC) level) 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. Specifically, the discounts in a bundled sale, including those discounts resulting from a contingent arrangement, are allocated proportionally to the total dollar value of the units of all drugs or products sold under the bundled arrangement. Also, for bundled sales where multiple drugs are discounted, the current definition indicates that the aggregate value of all the discounts in the bundled arrangement must be proportionally allocated across all the drugs or products in the bundle. (See § 447.502; 81 FR at 5182.) We understand that based on the bundled sale definition, which provides that 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, some manufacturers have made reasonable assumptions to take into account the discounts from a VBP arrangement that has a performance requirement when a measure (such as a performance-based measure) is not met. When manufacturers recognize the VBP arrangement as a bundled sale, the manufacturer, for example, may assume that the discount that resulted from a performance requirement of a single unit is distributed proportionally to the total dollar value of the units of all the drugs sold in the bundled arrangement. This smooths out the discount over all the units sold under the arrangement in the rebate period and does not reset the manufacturer's best price based upon the ultimate price of one unit of a drug.

For example, a manufacturer could structure a VBP arrangement such that to qualify for a patient outcome rebate, the bundled sale VBP arrangement requires the sale of 1,000 units of the same drug at $200 per unit, and if one patient fails to achieve an outcomes-based performance measure the manufacturer agrees to a $100 price concession on that one unit. In this example, because all of the drugs in the bundle were subject to the performance requirement, the manufacturer's scheme qualified as a bundled sale VBP arrangement, and thus, the manufacturer's rebate of $100 on that one unit would be allocated across all units in that bundled sale as follows:

1,000 units × $200 = $200,000 − $100 price concession = ($199,900/1,000 units) = $199.90

Best price could be set at $199.90 if that $100 rebate available in a qualifying bundled sale resulted in the lowest price available from the manufacturer, and not at $100 ($200/unit − $100).

We agree with the applicability of the bundled sale definition in this context because it will permit manufacturers to have a best price that is not based upon the failure of one patient taking the drug. Therefore, in order to facilitate the appropriate application of a bundled sale offered in the context of a VBP arrangement to the best price determination, we are proposing to revise the definition of bundled sale at § 447.502 to add paragraph (3) that states VBP arrangements may qualify as a bundled sale, if the arrangement contains a performance requirement such as an outcome(s) measurement metric. We expect manufacturers, consistent with the manufacturer recording keeping requirements at § 447.510(f), to maintain documentation of the arrangement to support their calculation of AMP and best price.

2. Definitions—Best Price (§ 447.505(a)) and Reporting of Multiple Best Prices, Adjustments to Best Price (§ 447.505(d)(3))

In the preamble to the Covered Outpatient Drug Final Regulation (81 FR 5253), we indicated that we recognized the value of pharmaceutical value based purchasing arrangements in the marketplace, and that we were

considering how to give specific guidance on this matter, including how such arrangements affect a manufacturer's ''best price.'' In addition to CMS, States, manufacturers, and commercial payers all have an interest in making new innovative therapies available to patients, and we have heard that there are challenges with the current interpretation of statutes and regulations with respect to how ''best price'' can affect the availability of value based purchasing arrangements. Because the statute was drafted more than 30 years ago, when such arrangements were not prevalent in the market, it is understandable that such interpretations by CMS to date regarding ''best price'' have been limited to one ''best price'' per drug.

The Medicaid statute defines best price in relevant part to mean, with respect to a single source drug or innovator multiple source drug of a manufacturer, the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, non-profit entity, or governmental entity within the United States, with certain exclusions enumerated at sections 1927(c)(1)(C)(i)(I) through (VI) of the Act. Historically, we have interpreted this language to result in only one best price per drug. The current Medicaid ''best price'' regulation at § 447.505 generally tracks the statutory language, but reads in relevant part that ''best price'' means, for a single source drug or innovator multiple source drug, the lowest price available from the manufacturer during the rebate period *in any pricing structure* (including capitated payments), in the same quarter for which the AMP is computed (emphasis added).

The current regulation is interpreted further in the preamble language to the COD final rule and MDRP releases where we have indicated that the lowest price available means ''actually realized'' by the manufacturer or the lowest price at which a manufacturer sells a [covered outpatient drug]—that is, one lowest price available per dosage form and strength of a drug. This interpretation results in setting a best price that is either at a greatly reduced price or possibly zero if a single dosage form or strength dispensed to one patient is subject to a full or very large rebate under a VBP arrangement. Thus, we need to reconcile the interpretation of the statute in regulation, which currently contemplates that for any quarter, the ''best price'' is a single price for each dosage form and strength of a drug that represents the actual revenue realized by the manufacturer for that drug—in any pricing structure offered by the manufacturer (such as capitated payments)—with the realities of the current evolving marketplace which contemplate that multiple prices could be made available by the manufacturer for a particular drug based on the drug's performance (such as the case with VBP arrangements that use evidence or outcomes-based measures) in a quarter.

In that regard, because VBP and other innovative payment arrangements sometimes result in various price points for a dosage form and strength of a single drug or therapy being available in a quarter, we are proposing to reflect this possibility in this proposed rule. Specifically, we are proposing that a single drug may be available at multiple price points, each of which may establish a ''best price'' based on the relevant or applicable VBP arrangement and patient evidence-based or outcome-based measures.

We believe we can do this because we previously interpreted the statutory definition of best price at § 447.505(a) to reference the best price ''in any pricing structure,'' contemplating the possibility of various pricing structures, such as capitated payments. With the new VBP pricing structures that are available in the marketplace, we believe it is appropriate and reasonable to propose to further interpret what pricing structures are available, and account for the new VBP pricing structures, which may introduce the offering of a drug at multiple price points. That is, we are proposing to expand our interpretation of ''in any pricing structure'' and also the term ''price available'' by proposing that the price realized in a VBP arrangement by the manufacturer when a measure is not met for a single patient would not reset the best price for the drug in the quarter. Rather, we propose that multiple prices could be realized by the manufacturer and when a price is realized as a result of a VBP pricing structure, multiple price points (price points as a result of a VBP and price points absent a VBP) may be reported for one dosage form and strength.

As an example, under VBP, the manufacturer would report a single best price for the drug for the quarter for sales of the drug in that quarter. In addition, the manufacturer would also 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. As an example, the manufacturer could offer varying rebates based on a patient's response after the drug is administered. The calculated MDRP rebate due to the state using the VBP best price would be a function of whether or not the Medicaid rebate is being paid on a unit of a drug dispensed to a Medicaid patient that participated in a VBP, and the level of rebate associated with that patient's outcome. The rebate paid for that patient would only represent the amount of rebate due to the state from the manufacturer for that patient, not all patients. That is, the rebate would be specific to that patient's outcome, as that price is the lowest price available from the manufacturer based on that patient's outcomes. Otherwise, the best price used in the Medicaid rebate formula would mirror the lowest price available absent a VBP arrangement.

Therefore, we are proposing to further interpret the regulatory language ''in any pricing structure'' to include VBP arrangements. Then, we are proposing to interpret the statutory and regulatory phrase ''lowest price available'' as used in the definition of best price, to permit, in the context of a VBP arrangement, to include a set of prices at which a manufacturer makes a product available based on that pricing structure. This being the case, we are proposing that the definition of best price be expanded at § 447.505(a) to provide that a lowest price available from a manufacturer may include varying best price points for a single dosage form and strength as a result of a VBP (as defined at § 447.502). We understand the operational challenges this may bring to MDRP systems and that it will take us time to make such system changes. We welcome comments on this proposal, its impact on the MDRP, the commercial market, and its operational implications. Specifically, we request comments regarding the potential impact of these changes on supporting payment innovation and health care quality. We also seek comments on steps which would be needed by manufacturers and states to implement these Best Price changes, including how states would track health outcomes for Medicaid beneficiaries to align with the outcomes developed in a private market VBP.

Also, to provide consistency between AMP and best price, as we did under the Medicaid Program; Covered Outpatient Drugs final rule with comment (81 FR 5170), we are proposing to revise § 447.505(d)(3) to make it consistent with § 447.504(f)(3). That is, § 447.504(f)(3) provides that the manufacturer must adjust the AMP for a rebate period if cumulative discounts, rebates, or other arrangements subsequently adjust the prices actually realized to the extent that such cumulative discounts, rebates, or other arrangements are not excluded from the

determination of AMP by statute or regulation. We propose to add a similar qualifying phrase at the end of § 447.505(d)(3) to state that the manufacturer must adjust the best price for a rebate period if cumulative discounts, rebates or other arrangements subsequently adjust the prices available, to the extent that such cumulative discounts, rebates, or other arrangements are not excluded from the determination of best price by statute or regulation. We believe this is consistent with the requirement at section 1927(c)(1)(C)(ii)(I) of the Act, which provides that best price shall be inclusive of cash discounts, free goods that are contingent on any purchase requirement, volume discounts and rebates, and therefore, best price must account for these to the extent they are not excluded by statute or regulation.

C. Changes To Update Definitions To Reflect Recent Statutory Changes Made by Medicaid Services Investment and Accountability Act of 2019 (Pub. L. 116–16, Enacted April 18, 2019), BBA 2018 and the Affordable Care Act

1. Definitions (§ 447.502)

a. Innovator Multiple Source Drug

The Medicaid Services Investment and Accountability Act of 2019 clarified the definition of innovator multiple source drug at section 1927(k) of the Act by removing the phrase ''an original new drug application'' and inserting ''a new drug application,'' removing ''was originally marketed'' and inserting ''is marketed,'' and inserting, '', 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))'' before the period. Section 1927(k)(7)(A)(ii) of the Act now defines innovator multiple source drug to mean a multiple source drug that is marketed under a new drug application approved by the Food and Drug Administration (FDA), unless the Secretary determines that a narrow exception applies (as described in § 447.502 (or any successor regulation)). To align the regulatory definition with the definition in the statute, as clarified by the Medicaid Services Investment and Accountability Act of 2019, we are proposing to define innovator multiple source drug in § 447.502 as a multiple source drug, including an authorized generic drug, that is marketed under a new drug application (NDA) approved by FDA, unless the Secretary determines that a narrow exception applies (as described in this section or any successor regulation). It also includes a drug product marketed by any cross-licensed producers, labelers, or distributors operating under the NDA and a covered outpatient drug approved under a biologics license application (BLA), product license application (PLA), establishment license application (ELA) or antibiotic drug application (ADA).

b. Line Extension and New Formulation

Section 1927(c)(2)(C) of the Act defines line extension to mean, for a drug, a new formulation of the drug, such as an extended release formulation, but does not include an abuse-deterrent formulation of the drug (as determined by the Secretary), regardless of whether such abuse deterrent formulation is an extended release formulation. As discussed earlier in section I.E. of this proposed rule, we proposed to define line extension in the February 2, 2012 proposed rule, but did not finalize a definition in the COD final rule or the April 1, 2019 final rule. We reiterated in the April 1, 2019 final rule that manufacturers are to rely on the statutory definition of line extension at section 1927(c)(2)(C) of the Act, and where appropriate are permitted to use reasonable assumptions in their determination of whether their drug qualifies as a line extension (81 FR 5265).

After several years of experience with manufacturers self-reporting their line extensions, and numerous inquiries from manufacturers regarding the identification of drugs as line extensions, we have noted inconsistency among manufacturers in their identification of drugs as line extensions. In addition, we are concerned that manufacturers may have a financial incentive to be underinclusive in their identification of drugs as line extensions because a drug identified as a line extension may be subject to a higher rebate. We note that if manufacturers underreport their line extensions, rebates may be calculated incorrectly and underpaid.

We believe the line extension provision was codified in statute to assure that manufacturers are not circumventing rebate liability by creating a line extension drug and avoiding inflation-based additional rebates. In order to ensure that section 1927(c)(2)(C) of the Act is fully implemented and the universe of line extensions is identified consistent with our understanding of Congressional intent, we are proposing to provide further interpretation of the statute in this proposed rule.

As an initial matter, we are proposing that only the initial single source drug or innovator multiple source drug (the initial brand name listed drug) must be an oral solid dosage form. In the 2012 proposed rule (77 FR 5338, 5339), we proposed that both the initial brand name drug and the line extension drug had to be an oral solid dosage form. However, as noted above, we did not finalize a regulatory definition of line extension, and instructed manufacturers to make ''reasonable assumptions'' regarding whether a drug is a line extension (81 FR 5265). The statute states that the alternative calculation must be performed in the case of a drug that is a line extension of a single source drug or an innovator multiple source drug that is an oral solid dosage form. Upon further evaluation of this statutory language, we believe that the statutory text can be reasonably construed to provide that only the initial single source drug or innovator multiple source drug must be an oral solid dosage form. We believe this interpretation is appropriate because the alternative construction (requiring both the line extension and the initial single source drug or innovator multiple source drug to be an oral solid dosage form) may inappropriately limit the universe of line extension drugs in a manner which would allow a manufacturer to circumvent rebate liability when creating a line extension and to potentially avoid inflation-based additional rebates, in cases where such rebates should apply. Therefore, we are proposing that when determining whether a drug is a line extension, only the initial single source drug or innovator multiple source drug must be an oral solid dosage form. That is, we are proposing that the line extension of the initial brand name listed drug does not need to be an oral solid dosage form. We believe this is consistent with the statutory language and will assist in appropriately identifying drugs that may be line extension drugs. Therefore, we are proposing to amend § 447.509(a)(4)(i) and (ii) 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,'' and §§ 447.509(a)(4)(i)(A) and (a)(4)(ii)(A) to refer to ''a single source drug or an innovator multiple source drug'' in the regulatory text that describes the alternative rebate calculation.

In response to requests to provide more specific guidance on how to identify a line extension drug, we are proposing to define ''line extension'' and ''new formulation'' at § 447.502. Specifically, we are proposing that as provided in section 1927(c)(2)(C) of the

Act, the term ''line extension'' means, for a drug, a new formulation of the drug, but does not include an abuse-deterrent formulation of the drug (as determined by the Secretary).

Additionally, we are proposing to define ''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. New formulations, (for the purpose of determining if a drug is a line extension) would not include abuse deterrent formulations but would include, but would not be 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. We are requesting comments about whether a drug approved with a new indication that is not separately identifiable should be considered a new formulation and, if so, how such a drug could be identified in DDR for purposes of calculating the alternative URA.

We note that under § 447.509(a)(4)(iii), manufacturers are required to calculate the alternative URA if the manufacturer of the line extension also manufactures the initial brand name listed drug or has a corporate relationship with the manufacturer of the initial brand name listed drug. Although a drug may satisfy the definition of line extension, and should therefore be identified in DDR as a line extension, a manufacturer is not required to calculate the alternative URA unless the manufacturer of the line extension also manufactures, or has a corporate relationship with the manufacturer of the initial brand name listed drug.

Based on the definition of line extension that was included in the Affordable Care Act, we believe that the statute gives us discretion and authority to interpret the term ''line extension'' broadly. We are expressly soliciting comments on our proposed definitions of ''line extension'' and ''new formulation,'' specifically on whether these terms should be interpreted more narrowly. Moreover, if stakeholders believe that a narrower interpretation is appropriate, we are soliciting comments on how to identify those drugs that constitute a line extension and a new formulation to apply the alternative URA calculation when required by statute.

i. Combination Drugs

The statutory definition of line extension does not expressly exclude 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, and, as noted previously in this rule, our proposed definition of new formulation includes combination drugs provided that the new formulation contains at least one active ingredient in common with the initial brand name listed drug.

As noted in the COD final rule (81 FR 5197, 5265 through 5267), we received numerous comments regarding our proposal in the February 2, 2012 proposed rule to include combination drugs in the definition of line extension. In particular, commenters were concerned that our proposal required sharing of proprietary pricing information with competitors. We believe that the commenters' concerns have been mitigated by § 447.509(a)(4)(iii), which requires the additional rebate to be calculated only if the manufacturer of the line extension also manufactures the initial brand name listed drug or has a corporate relationship with the manufacturer of the initial brand name listed drug. Therefore, we are clarifying that while our proposed definition of new formulation includes combination drugs, the alternative URA calculation is only required under § 447.509(a)(4)(iii) for a rebate period if the manufacturer of the line extension also manufactures the initial brand name listed drug or has a corporate relationship with the manufacturer of the initial brand name listed drug.

Furthermore, we note that in the event that the initial brand name listed drug is a combination drug, neither the statutory definition of line extension nor our proposed definitions of line extension or new formulation exclude new formulations of combination drugs. For example, if an initial brand name listed drug is a combination drug consisting of a previously approved drug plus a new molecular entity, and FDA subsequently approves a new drug consisting only of the new molecular entity, then we would consider the new drug to be a new formulation of the initial brand name listed drug because it would constitute a change to the initial brand name listed drug and contains at least one active ingredient in common with the initial brand name listed drug.

As stated previously, we believe we have the discretion and authority to include a broad range of drugs as a line extension, including combination drugs. However, we are also aware that some combination drugs appear to be slightly different than an existing drug while other combination drugs are very different drugs than the initial brand name listed drug. For example, if a new combination drug contains a new molecular entity in combination with a previously approved drug, the resultant new combination may appear to be very different from the initial brand name listed drug, however, we believe that it is a new formulation of an initial brand name listed drug. Conversely, we believe that a new combination of two previously approved drugs, or a combination of a previously approved drug and a non-drug product (for example, a dietary supplement or a device), may not be a significant alteration even though it also is a new formulation of an initial brand name listed drug. Given that different stakeholders have differing thoughts on what constitutes a new formulation of an initial brand name listed drug, and CMS is attempting to provide a reasonable interpretation of the statute to define or describe what constitutes a change that should be considered a new formulation, we are soliciting comments that may provide a way to define and identify those combination drugs that should be identified as line extensions while excluding those combination drugs that should not be so identified.

ii. New Strengths

In the COD final rule (81 FR 5267), we indicated that we do not consider new strengths of the same formulation of the initial brand name listed drug to be a line extension because section 1927(c)(2)(C) of the Act does not expressly contemplate that a new strength is a line extension. As noted previously in this proposed rule though, we did not finalize a regulatory definition of line extension, and instructed manufacturers to make ''reasonable assumptions'' regarding whether a drug is a line extension. As noted in section I.E. of this proposed rule, we are proposing to interpret the definition of line extension more broadly, which includes proposing a much broader definition of new formulation. The statutory definition of line extension does not expressly exclude a new strength of a drug, and we believe a change in strength is a relatively simple modification to a currently marketed product. Furthermore, changing the strength of an initial brand name listed drug allows a manufacturer to establish a new base date AMP, thereby avoiding inflation

based rebate liability, which may incentivize a manufacturer to change the strength of a drug that is losing its exclusivity or patent protection to prolong the lifecycle of the drug, preventing money saving generic substitution. Therefore, consistent with the intent of the statute, we believe that a new strength of a drug, produced or distributed at a later time than the initial strength(s), should be identified as a line extension and made subject to the line extension alternative URA calculation. Therefore, as noted in section I.E. of this proposed rule, our proposed definition of new formulation includes changes in strength.

iii. New Indication

In the February 2, 2012 proposed rule, we proposed that a drug approved with a new indication for an already approved drug would be a line extension (77 FR 5323). We received several comments stating that the proposal was not feasible because the approval of a new indication for an already approved drug may not result in a different drug product and it would not be logical that a drug is a line extension of itself. Additional comments noted 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 the newly approved indication. We agree 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 URA 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, we are proposing that the alternative URA calculation would apply. Thus, as discussed previously in this proposed rule, our proposed definition of new formulation includes changes in indication accompanied by marketing as a separately identifiable drug (for example, a different NDC).[12] We are requesting comments about whether a drug approved with a new indication that is not separately identifiable should be considered a new formulation and, if so, how such a drug could be identified in DDR for purposes of calculating the alternative URA.

We believe that Congress included the alternative URA calculation for a line extension in order to address changes to a drug that allow a manufacturer to avoid inflation-based additional rebates by establishing a new market date and base date AMP for the drug. We agree with the comments suggesting that if there is a change to a drug but that drug is not separately identifiable, then it is not feasible for the manufacturer to identify the drug as a line extension and perform an alternative URA calculation.

c. Oral Solid Dosage Form

Oral solid dosage form is defined at § 447.502 to mean capsules, tablets, or similar drugs products intended for oral use as defined in accordance with FDA regulation at 21 CFR 206.3 that defines solid oral dosage form. As we now have more experience reviewing and dealing with the line extension provisions from the Affordable Care Act, we believe that manufacturers may not be interpreting the term oral solid dosage form consistently. To mitigate any potential confusion, we believe that manufacturers and other stakeholders would benefit from a more detailed definition. In this proposed rule, we are proposing to modify the definition of oral solid dosage form.

In the COD final rule (81 FR 5198), CMS interpreted an oral route of administration as any drug that is intended to be taken by mouth. Because there is potential confusion about whether a dosage form must be swallowed, or otherwise enter the gastrointestinal tract in order to be considered an orally administered dosage form, we are proposing to interpret that an oral form of a drug is one that enters the oral cavity. This includes, but is not limited to, a tablet or film administered sublingually and a drug that is orally inhaled. We believe that this interpretation provides greater clarity to stakeholders regarding what constitutes an oral form of a drug.

Additionally, we believe that manufacturers may not be interpreting the term solid dosage form consistently. To mitigate any potential confusion, we are proposing to interpret that a solid dosage form is a dosage form that is neither a gas nor a liquid.

The FDA regulation at 21 CFR 206.3 defines the term ''solid oral dosage form'' for the purpose of identifying drugs for which a code imprint is required to permit identification of the product. The phrase ''capsules, tablets or similar drugs products'' may not encompass the range of dosage forms that we believe should be considered for the application of the line extension provision in the Affordable Care Act. For example, a sublingual film is an oral solid dosage form; however, because of the physical attributes of the dosage form, there may not be a requirement to imprint an identifying code on the dosage form. Another example of an oral solid dosage form is a powdered drug administered by oral inhalation. Therefore, we are proposing to modify the definition of oral solid dosage form at § 447.502 to read that it is an orally administered dosage form that is not a liquid or gas at the time the drug enters the oral cavity. Additionally, an oral solid dosage form that incorporates a medical device would not be exempt from this definition solely due to the addition of a device to the oral solid dosage form. For example, if a manufacturer adds a device to a tablet, the new drug would not be exempt from being a line extension solely due to the addition of a device to the tablet.

d. Multiple Source Drug

The Medicaid Services Investment and Accountability Act of 2019 clarified the definition of multiple source drug in section 1927(k) of the Act by removing ''(not including any drug described in paragraph (5))'' and inserting '', including a drug product approved for marketing as a non-prescription drug that is regarded as a covered outpatient drug under paragraph (4),''. Section 1927(k)(7)(A)(i) of the Act now provides that the term multiple source drug means, with respect to 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 Act for which there is at least 1 other drug product which: Is rated as therapeutically equivalent (under FDA's most recent publication of ''Approved Drug Products with Therapeutic Equivalence Evaluations''), except as provided in section 1927(k)(7)(B) of the Act, is pharmaceutically equivalent and bioequivalent, as defined in section 1927(k)(7)(C) of the Act and as determined by FDA, and is sold or marketed in the United States during the period.

We are proposing to revise the definition of multiple source drug at § 447.502 to align with the statutory definition. Specifically, we are proposing to revise the definition of multiple source drug to mean, 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

[12] An NDC comprises three segments. The first segment is a labeler code, associated with the labeler, the second segment is a product code, which in association with a specific labeler code identifies the product, and the third segment is a package code, which, in association with the preceding segments, identifies the package size and type. For purposes of reporting to the MDRP, FDA's 10-digit NDC must be converted to an 11-digit NDC. The 9-digit NDC cited here is a combination of the labeler code plus the product code. FDA requirements for an NDC are at 21 CFR 207.33.

drug under section 1927(k)(4) of the Act, for which there is at least 1 other drug product which meets all the following criteria:

- 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/*).
- 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 the FDA.
- Is sold or marketed in the United States during the period.

e. Single Source Drug

The Medicaid Services Investment and Accountability Act of 2019 clarified the definition of single source drug in section 1927(k) of the Act by removing the phrase ''an original new drug application'' and inserting ''a new drug application'', inserting '', including a drug product approved for marketing as a non-prescription drug that is regarded as a covered outpatient drug under paragraph (4),'' after ''covered outpatient drug'', inserting ''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'' and adding language to specify that such term also includes a covered outpatient drug that is a biological product licensed, produced, or distributed under a biologics license application approved by the FDA. Section 1927(k)(7)(A)(iv) of the Act now defines a single source drug to mean 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 (as described in § 447.502 or any successor regulation) and the term includes a covered outpatient drug that is a biological product licensed, produced, or distributed under a biologics license application approved by the FDA. To align the regulatory definition with the definition in the statute at section 1927(k)(7)(A)(iv) of the Act, as clarified by the Medicaid Services Investment and Accountability Act of 2019, we are proposing to revise the regulatory definition of single source drug at § 447.502. We are proposing to define single source drug in § 447.502 to mean 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 (as described in § 447.502 or any successor regulation) and includes a covered outpatient drug that is a biological product licensed, produced, or distributed under a biologics license application approved by the FDA.

e. CMS-Authorized Supplemental Rebate Agreements

States may enter into separate or supplemental drug rebate agreements as long as such agreements achieve drug rebates equal to or greater than the drug rebates set forth under the national drug rebate agreement. See section 1927(a)(1) of the Act. CMS approval to enter directly into such agreements with manufacturers is required under section 1927(a)(1) of the Act, and thus, states are required to use the state plan amendments process as a means to seek CMS authorization. Supplemental rebates must be considered a reduction in the amount expended under the State plan in the quarter for medical assistance as provided at section 1927(b)(1)(B) of the Act. See program guidance at *https://www.medicaid.gov/federal-policy-guidance/downloads/smd091802.pdf*.

The Affordable Care Act revised section 1927(b)(1)(A) of the Act to require that manufacturers provide rebates for covered outpatient drugs dispensed to individuals enrolled with a Medicaid MCO when the organization is responsible for coverage of such drugs. At that time, states had to re-assess whether or not to directly collect supplemental rebates related to covered outpatient drugs dispensed to Medicaid managed care enrollees if the MCO was responsible for such drug coverage. Some states required their MCOs to collect and share supplemental rebates under the CMS-authorized supplemental rebate agreement, while other states permitted their MCOs to negotiate their own rebates with manufacturers outside of the CMS-authorized supplemental rebate agreement, allowing the MCO to keep the savings generated by the supplemental rebates.

The Affordable Care Act amendment to section 1927(b)(1)(A) of the Act also prompted some manufacturers to make assumptions with regard to AMP and best price calculations. Specifically, manufacturers made assumptions that all supplemental rebates paid by manufacturers for prescriptions dispensed to Medicaid managed care enrollees should be excluded from the manufacturer's determination of AMP and best price. That included those rebates paid directly to Medicaid MCOs, even if those rebates were not a result of a CMS-authorized supplemental rebate agreement, and therefore, not shared with the state or eventually used to offset state drug expenditures prior to claiming Federal financial participation (FFP) from the federal government. Since CMS-authorized supplemental rebate agreement is not defined as it is used at §§ 447.504(c)(19) and (e)(9) and 447.505(c)(7), manufacturers assumed that any supplemental rebates paid based on dispensing to Medicaid managed care enrollees are always a part of a CMS-authorized supplemental rebate agreement with the states. However, rebates paid to Medicaid MCOs may be paid by manufacturers that are not part of a CMS-authorized rebate agreement and are not shared with the state to offset drug expenditures prior to claiming FFP. Therefore, in order to clarify that such rebates paid by manufacturers are not part of a state's CMS-authorized supplemental rebate agreement, we propose to define CMS-authorized supplemental rebate agreement to mean an agreement 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 that are at least as large as the rebates set forth in the Secretary's national rebate agreement with drug manufacturers.

Furthermore, and consistent with section 1927(b)(1)(B) of the Act which provides that the amounts received by a State under subsection (a)(1) (Federal rebates) or an agreement under (a)(4) (the existing state rebates) in any quarter shall be considered to be a reduction in the amount expended under the State plan in the quarter for medical assistance for purposes of section 1903(a)(1) of the Act. The proposed definition further states that the revenue from these rebates must be paid directly to the state and be used by the state to offset a state's drug expenditures resulting in shared savings with the Federal government.

D. Exclusion of Certain Manufacturer Sponsored Patient Assistance Programs (''PBM Accumulator Programs'') From Determination of Best Price (§ 447.505) and Average Manufacturer Price (AMP) (§ 447.504)

Manufacturers participating in the MDRP are required to report certain pricing information to the Secretary, including a covered outpatient drug's best price and AMP. Best price is defined at section 1927(c)(1)(C) of the Act to mean, with respect to a single source or innovator multiple source drug of a manufacturer (including the lowest price available to any entity for any such drug of a manufacturer that is sold under a new drug application approved under section 505(c) of the Federal, Food, Drug and Cosmetic Act), the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or government entity within the United States, subject to certain exclusions. Section 1927(c)(1)(C)(ii) of the Act further defines the term best price to be inclusive of cash discounts, free goods that are contingent on any purchase requirement, volume discounts, and rebates (other than rebates under this section). The definition of best price is further defined at § 447.505(a) and includes the lowest price available from the manufacturer during the rebate period to any provider, which is defined to mean a hospital, HMO, MCO, or entity that provides coverage or services to individuals for illnesses or injuries or providers services or items in the provision of healthcare. Paragraph (b) further indicates that best price includes all prices, including applicable discounts, rebates, or other transactions that adjust prices either directly or indirectly to the best price eligible entities in paragraph (a).

We have learned that some health plans (which meet the definition of provider when determining best price) are being instructed or encouraged by their pharmacy benefit managers (PBMs) to apply manufacturer sponsored patient assistance programs, such as patient copay assistance programs, to the benefit of the plan, instead of entirely to the patient. (Note that Medicaid patients are not eligible for these manufacturer patient assistance programs, but the administration of these programs by commercial health plans and PBMs can affect the rebates that the Medicaid program receives from the manufacturer-sponsor of these programs.)

For example, certain PBMs have instructed health plans to not allow the manufacturer copay assistance to be applied towards a patient's plan deductible for a brand name drug not on a plan's formulary. PBMs contend that such programs steer consumers towards more expensive medications when there may be more cost saving options, such as generic substitution. Therefore, PBMs offer health plans that are commonly referred to as PBM accumulator programs and tout them as cost saving measures. For instance, using a copayment assistance card program as an example, instead of applying the manufacturer sponsored patient assistance program in a manner that bestows the entire benefit of the program to the patient or consumer, and ensures no contingency on a purchase requirement, as applicable, the PBM (on behalf of the plan) identifies when a copayment card is used by a patient and adjusts the beneficiary's deductible only in instances when the out-of-pocket contribution is made by the beneficiary. As a result, the manufacturer assistance does not accrue towards a patient's deductible and the patient sometimes does not realize this until the manufacturer copayment assistance runs out and the patient receives a significantly larger bill for the drug. This results in the health plan delaying the application of its plan benefit to the patient to the detriment of the patient or consumer, thus generating savings for the plan. We provide an illustration below:

Example:

Assume:

$2500—Drug cost
$2500—Patient Deductible
$10,000—Copayment Assistance Program Maximum

Copay Assistance Program With No PBM Accumulator Program

In this scenario, the manufacturer's copayment assistance accrues to the benefit of the patient because the patient has a high deductible, which is what we believe the manufacturer intended. In such cases, it is clear that the manufacturer's program is directly assisting the patient's copayment/deductible costs.

TABLE 1—COPAY ASSISTANCE PROGRAM WITH NO PBM ACCUMULATOR PROGRAM

	Jan	Feb	Mar	Apr	May	June
Plan Pays	$0	$2000	$2000	$2000	$2000	$2000
Patient Pays	25	25	25	25	25	25
Manufacturer Pays	2475	475 deductible reached. Manufacturer only pays $475.	475	475	475	475

Copay Assistance Program With PBM Accumulator Program

In the PBM accumulator scenario, the PBM does not apply the manufacturer's copayment assistance to the deductible of the patient thus delaying the patient satisfying his/her deductible, which benefits the health plan. The patient usually is not aware of the change until he/she is subject to a larger cost share of the drug when the manufacturer's support copay benefit maximum is reached (see May column). At that time, the patient receives a significantly a larger bill.

TABLE 2—COPAY ASSISTANCE PROGRAM WITH PBM ACCUMULATOR PROGRAM

	Jan	Feb	Mar	Apr	May	June
Plan Pays	$0	$0	$0	$0	$0	$2000
Patient Pays	25	25	25	25	2400	500
Manufacturer Pays	2475	2475	2475	2475	100 manufacturer copay benefit max. reached.	0

As demonstrated by the example above, the health plan is benefiting from the manufacturer sponsored copay assistance program instead of the patient (consumer). However, manufacturers, in these instances, claim they are not aware of when these practices by the health plans take place, and therefore, make reasonable assumptions that their discount programs meet the criteria at § 447.505(c) that exclude such programs from best price.

Specifically, manufacturers make reasonable assumptions that their programs meet the best price exclusions listed in § 447.505(c)(8) through (12) which provide:

- Manufacturer-sponsored drug discount card programs, *but only to the extent that the full value of the discount is passed on to the consumer and the pharmacy, agent, or other entity does not receive any price concession.* § 447.505(c)(8).
- Manufacturer coupons to a customer redeemed by a consumer, agent, pharmacy, or another entity acting on behalf of the manufacturer; *but only to the extent that the full value of the coupon is passed on to the consumer, and the pharmacy, agent, or other entity does not receive any price concession.* § 447.505(c)(9).
- Manufacturer copayment assistance programs, *to the extent that the program benefits are provided entirely to the patient and the pharmacy, agent, or other entity does not receive any price concession.* § 447.505(c)(10).
- Manufacturer-sponsored patient refund or rebate programs, *to the extent that the manufacturer provides a full or partial refund or rebate to the patient for out-of-pocket costs and the pharmacy, agent or other entity does not receive any price concession.* § 447.505(c)(11).
- Manufacturer-sponsored programs that provide free goods, including but not limited to vouchers and patient assistance programs, but only to the extent that the voucher or benefit of such program is not contingent on any other purchase requirement; *the full value of the voucher or benefit of such program is passed on to the consumer; and the pharmacy, agent or other entity does not receive any price concession.* § 447.505(c)(12).

However, we understand from some manufacturers that they do not monitor or place parameters around how the benefits of their manufacturer sponsored assistance programs are applied when an individual has health plan coverage. Therefore, we are proposing to revise these paragraphs to provide expressly that the exclusions discussed above apply only to the extent the manufacturer ensures the full value of the assistance or benefit is passed on to the consumer or patient. We believe manufacturers have the ability to establish coverage criteria around their manufacturer assistance programs to ensure the benefit goes exclusively to the consumer or patient. We note that nothing in this proposed change should be construed to contradict any OIG guidance. We welcome comments on this proposal.

The current list of prices excluded from best price as noted above also apply to AMP as specified in § 447.504(c) and (e). As stated in the COD final rule, in order to provide consistency between the AMP and best price sections, where applicable, and to help with streamlining and clarifying a manufacturer's price reporting responsibilities, the same methodology is applied to AMP (81 FR 5253), and for the same reasons already discussed above, we are making a corresponding proposal with respect to these exclusions in the context of AMP.

Accordingly, we are proposing to revise the determination of best price § 447.505 to add a requirement that manufacturers ensure that the benefits of their assistance programs as provided at § 447.505(c)(8) through (12) are provided entirely to the consumer and are proposing corresponding changes to the AMP regulations at § 447.504(c)(25) through (29) and (e)(13) through (17).

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

The Continuing Appropriations Act of 2020, and Health Extenders Act of 2019 (Health Extenders Act) made changes to section 1927(k) of the Act, revising how manufacturers calculate the AMP for a covered outpatient drug for which the manufacturer permits an authorized generic to be sold. Manufacturers that approve, allow, or otherwise permit any drug to be sold under the manufacturer's own new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act shall no longer include those sales of these authorized generics in the calculation of AMP.

Specifically, section 1603 of Health Extenders Act, which is titled—*Excluding Authorized Generic Drugs from Calculation of Average Manufacturer Price for Purposes of the Medicaid Drug Rebate Program; Excluding Manufacturers from Definition of Wholesaler,* amended:

- Section 1927(k)(1)(C) of the Act to replace the term ''inclusion'' with ''exclusion'' in the title and further amended subparagraph (C) to read (emphasis added)—In the case of 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, such term shall be *exclusive* of the average price paid for such drug by wholesalers for drugs distributed to retail community pharmacies.
- The definition of wholesaler at section 1927(k)(11) of the Act to remove references to manufacturers from the definition of wholesaler.

The amendments to section 1927 of the Act authorized under section 1603 of the Health Extenders Act are effective October 1, 2019. Therefore, manufacturers must reflect the changes to the calculation of their AMPs for rebate periods beginning October 1, 2019 (reported to CMS no later than 30 days after the end of the rebate period). Furthermore, in accordance with 42 CFR 447.510(b), manufacturers have 12 quarters from the quarter in which the data were due to revise AMP, if necessary.

Therefore, in accordance with the statutory amendments to section 1927(k)(1)(C) and (k)(11) of the Act described above, we are proposing to revise §§ 447.502, 447.504, and 447.506 as they apply to AMP and authorized generic sales as follows:

- We are proposing to revise § 447.502 to change the definition of wholesaler to reflect the revised statutory definition of wholesaler at section 1927(k)(11) of the Act. Wholesaler has been revised to remove any reference to ''manufacturer(s)'' consistent with the changes to the definition of wholesaler made by section 1603(b) of the Health Extenders Act. We are proposing the term ''Wholesaler'' to mean a drug wholesaler that is engaged in wholesale distribution of prescription drugs to retail community pharmacies, including but not limited to repackers, distributors, own-label distributors, private-label distributors, jobbers, brokers, warehouses (including distributor's warehouses, chain drug warehouses, and wholesale drug warehouses), independent wholesale drug traders, and retail community pharmacies that conduct wholesale distributions.
- Since the definition of wholesaler at section 1927(k)(11) of the Act no longer includes manufacturers, we further propose to remove from the list of sales, nominal price sales, and associated discounts, rebates, payments or other financial transactions included in AMP, sales to other manufacturers who act as wholesalers for drugs distributed to

retail community pharmacies at § 447.504(b)(2). The nominal price sales, and associated discounts, rebates, payments or other financial transactions included in AMP in accordance with § 447.504(d) (AMP for 5i drugs that are not generally dispensed through retail community pharmacies) do not change because the statute at 1927(k)(1)(C) only speaks to authorized generic sales from the manufacturer to wholesalers that distribute to retail community pharmacies.

• We propose to revise § 447.506, which provides specific requirements to manufacturers regarding the treatment of authorized generic drug sales when determining AMP and best price. For purposes of those calculations, the current regulation defines primary manufacturer as the manufacturer that holds the NDA of the authorized generic drug and the secondary manufacturer as the manufacturer that is authorized by the primary manufacturer to sell the drug, but does not hold the NDA. The regulation further requires that the primary manufacturer must include in its calculation of AMP its sales of authorized generic drugs that have been sold or licensed to a secondary manufacturer, acting as a wholesaler for drugs distributed to retail community pharmacies, or when the primary manufacturer holding the NDA sells directly to a wholesaler. The Health Extenders Act revised the definition of wholesaler at 1927(k)(11) of the Act by removing ''manufacturer'' and revised the determination of AMP at section 1927(k)(1)(C) of the Act by replacing the term ''inclusion'' with ''exclusion'' in the title and further amended paragraph (C) to state, in the case of 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, such term shall be *exclusive* of the average price paid for such drug by wholesalers for drugs distributed to retail community pharmacies. Therefore, we are proposing to revise § 447.506(b) to replace the word ''Inclusion'' with ''Exclusion'' in the first sentence and replace the second sentence in its entirety to state that the primary manufacturer (as defined at § 447.506(a)) 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.

More specifically, we are proposing that a separate AMP is determined for the brand drug, which shall be exclusive of any authorized generic sale, and a separate AMP shall be generated for the authorized generic. As discussed previously in this proposed rule, typically, 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) but under a different National Drug Code (NDC) number. The authorized generic is typically the primary manufacturer's brand product offered at a lower price point. Primary manufacturers may sell the authorized generic product to the secondary manufacturer they are allowing to sell an authorized generic of their brand product, and such sales are commonly referred to as transfer sales. Primary manufacturers have included those transfer sales in the determination of the brand product's AMP. Under the amendments made to section 1927 of the Act, a primary manufacturer that sells the authorized generic version of the brand drug to the 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. The exclusion of these transfer sales from the primary manufacturer's brand drug AMP will likely result in higher AMPs for the brand drugs and a potential increase to a manufacturer's Medicaid drug rebates to states. To assist manufacturers, we provided guidance in *Manufacturer Release #111* and Manufacturer Release #112. In turn, we received inquiries as to what is meant by ''In the case of 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, such term shall be *exclusive* of the average price paid for such drug by wholesalers for drugs distributed to retail community pharmacies.'' Specifically, we received questions regarding when a primary manufacturer itself, or an affiliate of the manufacturer is also producing the authorized generic, and whether, such a case, constitutes ''a case of a manufacturer that approves, allows, or otherwise permits'' the drug to be sold under the manufacturer's NDA, such that the exclusion applies. And if not, whether the primary manufacturer may include the average price paid for the authorized generic when calculating AMP for the brand drug. We believe that irrespective of the relationship between the manufacturer of the brand drug, and the manufacturer of the authorized generic, if the primary manufacturer ''approves, allows, or otherwise permits'' is the drug to be sold under the primary manufacturer's NDA, then the AMP for the brand should be calculated separately from (not include) the sales of the authorized generic. That is, it would not matter whether the manufacturer being approved, allowed, or otherwise permitted to sell the drug under the primary manufacturer's NDA was the same, affiliated or non-affiliated.

Therefore, we are interpreting section 1927(k)(1)(C) of the Act, which provides that in the case of a manufacturer approves, allows, or otherwise permits any of its drugs to be sold under the same NDA, the AMP for that brand drug shall be exclusive of the average price paid for such drug by wholesalers for drugs distributed to retail community pharmacies, to mean a separate AMP should be calculated for each drug product—that is, one AMP for the brand drug, and one AMP for the authorized generic product, and the AMP for the brand drug should always exclude sales of the authorized generic product. This includes a situation when it is the same manufacturer making both the brand name drug and authorized generic, or if the drugs are being manufactured by different, but affiliated manufacturers or even non-affiliated manufacturers. We are proposing a policy that applies irrespsective of a specific brand manufacturer's sales arrangement.

The amendments made by section 1603 of the Health Extenders Act are effective October 1, 2019. Therefore, manufacturers are required to reflect the changes to the calculation of their AMPs for rebate periods beginning October 1, 2019 (reported to CMS no later than 30 days after the end of the rebate period). Furthermore, in accordance with § 447.510(b), manufacturers have 12 quarters from the quarter in which the data were due to revise AMP, if necessary.

F. Medicaid Drug Rebates (MDR) (§ 447.509)

Manufacturers that participate in the MDRP are required to pay rebates for covered outpatient drugs that are dispensed to Medicaid patients. The rebates are calculated based on formulas described in section 1927(c) of the Act. As described in section I. of this proposed rule, the BBA 2015 made revisions to the statutory rebate formula for covered outpatient drugs other than single source or innovator multiple source drugs. That is, section 602 of BBA 2015, amended section 1927(c)(3)

of the Act to require that manufacturers pay additional rebates on their covered outpatient drugs other than single source or innovator multiple source drugs (non-innovator multiple source (N) drugs) when the AMP of the N drug increases at a rate that exceeds the rate of inflation. The amendments made by section 602 of BBA 2015, were effective beginning with the January 1, 2017 quarter (that is, first quarter of 2017). The implementation of these amendments was discussed in Manufacturer Release 97 and Manufacturer Release 101.

Prior to the enactment of BBA 2015, the basic quarterly URA calculation for N drugs was equal to 13 percent of a drug's quarterly AMP. However, section 602(a) of BBA 2015 amended section 1927(c)(3) of the Act by adding an inflation-based additional rebate requirement to the URA for N drugs, which is similar to the additional rebate applied to single source (S) and innovator multiple source (I) drugs.

To calculate the additional rebate portion of the URA calculation for N drugs, section 602(a) of BBA 2015 amended section 1927 of the Act to establish a base AMP or base date AMP value for N drugs based, in part, upon each N drug's market date. In general, for N drugs marketed on or before April 1, 2013, the base date AMP is equal to the third quarter of 2014 and the Base CPI–U is the CPI–U for September 2014. For N drugs marketed after April 1, 2013, the base date AMP is equal to the AMP for the fifth full calendar quarter after which the drug is marketed as a drug other than a single source or innovator multiple source drug and the base CPI–U is equal to the CPI–U for the last month of the base AMP quarter.

We are proposing to revise § 447.509 to codify the rebate formulas in regulation. Specifically, we are proposing to revise paragraph (a)(6) to distinguish the basic rebate for N drugs from this additional rebate. In addition, we are proposing to add paragraph (a)(7) to expressly include the additional rebate calculation for N drugs. We are proposing that in addition to the basic rebate under paragraph (a)(6), for each dosage form and strength of a N drug, the rebate amount will increase by an amount equal to the product of the following: The total number of units of such dosage form and strength paid for under the State plan in the 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, increased by the percentage by which the consumer price index for all urban consumers (United States city average) for the month before the month in which the rebate period begins exceeds such index associated with the base date AMP of the drug. We also are proposing to add paragraph (a)(8) to capture the that the total rebate amount for noninnovator multiple source drugs is equal to the basic rebate amount plus the additional rebate amount, if any.

In addition to the proposed regulatory changes related to section 602 of BBA 2015 amendments noted above, we also propose to amend § 447.509 at:

- Paragraph (a)(5) to specify that in no case will the total rebate amount exceed 100 percent of the AMP of the single source or innovator multiple source drug; and
- By adding paragraph (a)(9) to specify that in no case will the total rebate amount exceed 100 percent of the AMP of the noninnovator multiple source drug.
- We also added to paragraph (a)(7)(B) to state that the base date AMP has the meaning of AMP set forth in sections 1927(c)(2)(A)(ii)(II), 1927(c)(2)(B) and 1927(c)(3)(C) of the Act as the regulation did not provide a specific definition of base date AMP for calculating the additional rebate. We believe it is reasonable to include this in regulation in order to provide further clarity for manufacturers and states with regard to the calculation of the additional rebate, and to ensure the appropriate product data and pricing information is submitted to CMS.

G. Requirements for Manufacturers (§ 447.510)

In accordance with section 1927(b)(3) of the Act and the terms of the NDRA, manufacturers are required to report pricing information to CMS on a timely basis or face a penalty. Current regulations at § 447.510 implement the manufacturer price reporting requirements including the timing of revisions to pricing data. The current regulation at 42 CFR 447.510(b)(1) requires that the revision to pricing data be made within the 12 quarters from which the data were due, unless it meets one of the exceptions in paragraphs (i) through (v).

As previously discussed in section II.B. of this proposed rule, VBP has evolved into a possible option for states and manufacturers to help manage drug expenditures. Many VBP arrangements or pay-over-time models may be better suited for periods longer than 12 quarters, and manufacturers entering into such arrangements may need to adjust AMPs and best prices beyond the 12 quarters because the evidence-based or outcomes-based measures are being measured beyond a period of 12 quarters or a final installment payment is being made outside of the 12 quarters. With this evolution it has become apparent that certain manufacturer reporting requirements could be viewed as an impediment to adopting VBP arrangements. For instance, under current regulations, a manufacturer would not be able to account for any adjustments to prices that may occur outside of the 12 quarters because of VBP arrangements (or even pay-over-time models), as required.

The definition of AMP at section 1927(k)(1)(B)(ii) of the Act, indicates that any other discounts, rebates, payments or other financial transactions that are received by, paid by, or passed through to retail community pharmacies shall be included in AMP for a covered outpatient drug. The special rules in section 1927(c)(1)(C)(ii) of the Act define best price to be inclusive of cash discounts, free goods that are contingent on any purchase requirement, volume discounts and rebates. Since manufacturers are required to report AMP and best price that capture these statutory required financial transactions, including such financial transactions (for example, rebates, incremental payments) that are a result of VBP arrangements or pay-over-time models, and such pricing structures may be designed to result in transactions taking place outside of the 3-year window, we are proposing to add § 447.510(b)(1)(vi) to specify an additional exception to the 12-quarter rule to account for the unique nature of VBP arrangements and pay-over-time models. Specifically, we are proposing that the manufacturer may make changes outside of the 12-quarter rule as a result of a VBP arrangement when the outcome must be evaluated outside of this 12-quarter period.

G. Requirements for States (§ 447.511)

Section 1927(b)(2)(A) of the Act requires that states be held responsible to report to each manufacturer not later than 60 days after the end of each rebate period and in a form consistent with a standard reporting format established by the Secretary, information on the total number of units of each dosage form and strength and package size of each covered outpatient drug dispensed after December 31, 1990, for which payment was made under the plan during the period, including such information reported by each Medicaid managed care organization, and shall promptly transmit a copy of such report to the Secretary. The accuracy and timeliness of this SDUD report is important for the MDRP, other programs, and legislative efforts including, but not limited to:

- Actuarial and cost impact projections of legislative or regulatory changes to the MDRP;
- The calculation of Medicaid's portion of the branded prescription drug fee specified at section 9008 of the ACA); and
- Ongoing audits that demonstrate that some states still fail to bill rebates for physician-administered drugs (PADs), although it has been 13 years since the requirement began.

States are required to send invoices (CMS–R–144 Medicaid Drug Rebate Invoice) to each manufacturer in the MDRP for which payment was made on behalf of the state and federal government for the manufacturers' drugs, or in the case of MCOs, drugs dispensed to a beneficiary in a rebate period. States are required to send a copy of their SDUD (a summary report of their invoice utilization data) to CMS each quarter. If a state makes an adjustment to a rebate invoice, the state is required to send an updated SDUD to us in the same reporting period in which the manufacturer received the adjustment.

We have found that some states do not have sufficient edits in place to detect, reject and investigate SDUD outliers, which may distort the rebate amounts due by manufacturers. This results in states overbilling manufacturers and generating disputes on rebate invoices; imposing resource burdens on manufacturers, states, CMS, and other MDRP partners, as well as interrupting the payment of rebates to states and CMS. Many states seemingly fail to implement needed system edits to identify such disputes prior to billing manufacturers. Although both overbilling and underbilling must be disputed, manufacturers often neglect to dispute instances of rebate underbilling.

We have also found that many states do not send the same SDUD to CMS as they transmit to manufacturers. In fact, some states send us ''pre-edited'' SDUD, while the manufacturer's rebate invoice contains edited data. These practices do not comply with § 447.511(b), which requires that states submit the same SDUD to us on a quarterly basis that they transmit to the manufacturers. As we move to implement new systems, we expect to put in place data error screening to better reject or alert identified potential inaccuracies to SDUD. States should also be improving current systems and planning updates to future systems to better identify and correct inaccurate SDUD before reporting to manufacturers and CMS.

To better hold states accountable for their data integrity and to mitigate the effects of inaccurate and untimely SDUD, we are proposing to revise § 447.511. Specifically, we are proposing to revise paragraph (a) to specify that any subsequent updates or changes in the data on the CMS–R–144 must be included in the state's utilization data submitted to CMS. We are also proposing to revise paragraph (b) to state that, on a quarterly basis, the state must submit drug utilization data to CMS, which will be the same information as submitted to the manufacturers on the CMS–R–144, as specified in § 447.511(a). In addition, to conform to the statutory requirement at section 1927(b)(2)(A) of the Act, we are proposing to add in regulatory text that the state data submission will be due no later than 60 days after the end of each rebate period. In the event that a due date falls on a weekend or federal holiday, the submission will be due on the first business day following that weekend or federal holiday. We also propose that any adjustments to previously submitted data would be transmitted to the manufacturer and CMS in the same reporting period.

We are also proposing to add § 447.511(d) to specify that the state data must be certified by the state Medicaid director (SMD), the deputy state Medicaid director (DSMD), or an individual other than the SMD or DSMD, who has authority equivalent to an SMD or DSMD or an individual with the directly delegated authority to perform the certification on behalf of the individuals noted above.

We are also proposing to add § 447.511(e) to specify the state data certification language that must be included in the submission. That is, each data submission by a state must include the following certification language: I hereby certify, to the best of my knowledge, that the state's data submission is complete and accurate at the time of this submission, and was prepared in accordance with the state's good faith, reasonable efforts based on existing guidance from CMS, section 1927 of the Act and applicable federal regulations. I further certify that the state has transmitted data to CMS, including any adjustments to previous rebate periods, in the same reporting period as provided to the manufacturer. Further, the state certifies that it has applied any necessary edits to the data for both CMS and the labeler to avoid inaccuracies at both the NDC/line item and file/aggregate level. Such edits are to be applied in the same manner and in the same reporting period to both CMS and the manufacturer.

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

Traditionally, states have utilized the supplemental rebate agreement (SRA) pathway to secure additional rebates over and above the federal rebate required of manufacturers participating in the MDRP. In order to do so, the Secretary must authorize a state to enter directly into these agreements with a manufacturer in accordance with section 1927(a)(1) of the Act. In accordance with section 1927(a)(1) of the Act, we require states to submit a state plan amendment for a SRA which includes a template of the SRA providing the framework for the agreement the state has with the manufacturer. A CMS-authorized SRA provides the parameters the state and manufacturer agree upon regarding the supplemental rebates, most importantly, that such rebates are at least as large as the rebates required by the federal government in accordance with 1927(a)(4) of the Act.

To make new and expensive innovative drugs more available to Medicaid patients, states are permitted to use a SRA pathway to negotiate VBP agreements with manufacturers that are intended to be financially beneficial for Medicaid. As with a traditional SRAs, these VBP SRAs must be financially advantageous for states, but must also include an evidence or outcomes-based measure. As with any other SRA, states are required to seek a SPA approval for a VBP SRA in accordance with section 1927(a)(1) of the Act. Through the SRA SPA process, a state, when approved by CMS, can enter into VBP SRAs directly with manufacturer(s) for both FFS and MCO covered outpatient drug claims. Under the SRA VBP arrangement, the state may need set up processes to report the results of the evidence or outcomes-based measures of the patient back to the manufacturer. This could require the state to take on additional responsibilities and expense in order to eventually collect a rebate, such as tracking the patient, collecting data on the patient (such as the results of evidence or outcomes-based measures) or providing services to the patient.

We understand that more states want to develop their own VBP arrangements, but states want to better understand the challenges, resources and costs to structure these programs and make them successful. In addition, given that we have a significant interest in the success of these innovative VBP programs, as well as the nature of the drugs that are subject to these agreements, we have an interest in helping evaluate these programs' effectiveness. To accomplish

this, we want to create a mechanism to exchange information about state VBP programs. This approach is consistent with section 1902(a)(30)(A) of the Act which requires that methods and procedures be established relating to the utilization of, and the payment for, care and services available under the plan (including but not limited to utilization review plans) as may be necessary to safeguard against unnecessary utilization of such care and services and to assure that payments are consistent with efficiency, economy, and quality of care.

Therefore, in accordance with section 1902(a) of the Act, we propose that states provide to us specific data elements associated with these VBP SRAs to ensure that payments associated with Medicaid patients receiving a drug under a VBP structure are consistent with efficiency, economy, and quality of care. To that end, we propose adding § 447.511(d)(1) and (2) to specify that a state participating in a VBP arrangement report data as specified on a yearly basis, and within 60 days of the end of each year, including the following data elements:

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

We invite comments on this approach and are particularly interested in understanding from states the burden with such a proposal and from all commenters whether the data elements are appropriate and useful with the goals of the proposal that we have laid out above.

I. Drug Utilization Review (DUR) Program and Electronic Claims Management System for Outpatient Drug Claims (§§ 456.700 Through 456.725), Managed Care Standard Contract Requirements and Requirements for MCOs, PIHPs, or PAHPs That Provide Covered Outpatient Drugs (§ 438.3(s))

Section 1004 of the SUPPORT for Patients and Communities Act requires states to implement certain opioid-specific drug use review (DUR) standards within their fee-for-service (FFS) and managed care programs. These requirements supplement prior DUR standards under section 1927(g) of the Act. In Medicaid, DUR involves the structured, ongoing review of healthcare provider prescribing, pharmacist dispensing, and patient use of medication. DUR involves a comprehensive review of patients' prescription and medication data and dispensing to help ensure appropriate medication decision making and positive patient outcomes. Potentially inappropriate prescriptions, unexpected and potentially troublesome patterns, data outliers, and other issues can be identified when reviewing prescriptions through prospective DUR or retrospective DUR activities. In Prospective DUR, the screening of prescription drug claims occurs to identify problems such as therapeutic duplication, drug-disease contraindications, incorrect dosage or duration of treatment, drug allergy and clinical misuse or abuse prior to dispensing of the prescription to the patient. Retrospective DUR involves ongoing and periodic examination and reviews of claims data to identify patterns of inappropriate use, fraud, abuse, or medically unnecessary care and facilitates corrective action when needed. Often times, these activities are synergistic; information gleaned through retrospective DUR claim reviews can be used to shape effective safety edits that can be implemented through prospective DUR, better enabling prescribers and dispensers to investigate prescription concerns prior to dispensing the medication to the patient. From prospective alerts (which can incorporate information from the beneficiary's claims data), potential issues can be identified to help promote the appropriate prescription and dispensing of outpatient drugs to beneficiaries. DUR programs play a key role in helping health care systems understand, interpret, and improve the prescribing, administration, and use of medications.

Section 1902 of the Act, as amended by section 1004 of the SUPPORT for Patients and Communities Act, requires states to implement safety edits and claims review automated processes for opioids as DUR requirements. We interpret ''safety edits'' to refer to the prospective DUR review specified in section 1927(g)(2)(A) of the Act. These prospective safety edits provide for identifying potential problems at point of sale (POS) to engage both patients and prescribers about identifying and mitigating possible opioid misuse, abuse, and overdose risk at the time of dispensing. The POS safety edits provide real-time information to the pharmacist prior to the prescription being dispensed to a patient, but do not necessarily prevent the prescription from being dispensed. When a safety edit is prompted, the pharmacist receives an alert and may be required, as dictated by good clinical practice and predetermined standards determined by the state, to take further action to resolve the alert before the prescription can be dispensed.[13] A claims review automated process, which we interpret to refer to as a retrospective DUR review) as defined in section 1927(g)(2)(B) of the Act, provides for additional examination of claims data to identify patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care. Retrospective reviews often involve reviews of patient drug and disease history generated from claims data after prescriptions have been dispensed to the beneficiary. For many retrospective reviews, in an effort to promote appropriate prescribing and utilization of medications, claims data is evaluated against state determined criteria on a regular basis to identify recipients with drug therapy issues, enabling appropriate action to be taken based on any issues identified. After these reviews, prescribers often have the opportunity to review prescriptions and diagnosis history and make changes to therapies based on the retrospective review intervention. Retrospective claims reviews provide access to more comprehensive information relevant to the prescriptions and services that are being furnished to beneficiaries and better enable and encourage prescribers and dispensers to minimize opioid risk in their patients, and assure appropriate pain care.

Many of the proposed safety edits and reviews described in this proposed rule are designed to implement requirements outlined in the SUPPORT for Patients and Communities Act. The purpose of these safety edits and claims reviews is to prompt prescribers and pharmacists to conduct additional safety reviews to determine if the patient's opioid use is appropriate and medically necessary. Provisions to address antipsychotic utilization in children and fraud and abuse requirements are also included in the SUPPORT for Patient and Communities Act and are measures designed to enhance appropriate utilization of medication. We recognize that the SUPPORT for Patients and Communities Act provides considerable flexibility for states to specify particular parameters of the safety edits, claims review automated processes, program for monitoring use of antipsychotic

[13] Prada, Sergio. (2019). Comparing the Medicaid Prospective Drug Utilization Review Program Cost-Savings Methods Used by State Agencies in 2015 and 2016. American Health and Drug Benefits. 12. 7–12.

medications in children, and process for identifying fraud and abuse. Additionally, we acknowledge that many states already have effective DUR processes and other controls in place, and that section 1902(oo)(1)(E) of the Act (as added by section 1004 of the SUPPORT for Patients and Communities Act) clarifies that states may meet new opioid-related requirements with such safety edits, claims review automated processes, programs, or processes as were in place before October 1, 2019. However, to ensure a consistent baseline of minimum national standards for these DUR activities, while preserving appropriate flexibility for the states to determine their particular parameters and implementation, we believe it is necessary under our authority to implement section 1927(g) of the Act, to assure that prescriptions are appropriate, medically necessary, and not likely to result in adverse medical results, to codify in regulation the proposed safety edits, claims review automated processes, program for monitoring antipsychotic medications in children, and fraud and abuse process requirements as described in this proposed rule. Accordingly, the provisions of this proposed rule would implement opioid-related requirements established in the SUPPORT for Patients and Communities Act and further implement requirements under section 1927(g) of the Act, in an effort to reduce prescription-related fraud, misuse and abuse.

In addition to codifying the SUPPORT for Patients and Communities Act requirements, we are proposing additional minimum DUR standards in this proposed rule that states would be required to implement as part of their DUR programs. Specifically, section 1927 of the Act provides for drug use review programs for covered outpatient drugs to assure that prescriptions (1) are appropriate, (2) are medically necessary, and (3) are not likely to result in adverse medical results. Accordingly, under our authority to implement section 1927(g) of the Act and consistent with the goals of the SUPPORT for Patients and Communities Act to assure the appropriate use of prescription opioids, we are proposing minimum standards for DUR reviews related to medication assisted treatment (MAT) and identification of beneficiaries who could be at high risk of opioid overdose for consideration of naloxone prescribing or dispensing.

We also are seeking comments on potential additional standards that we might implement through future rulemaking, to ensure minimally adequate DUR programs that help ensure prescribed drugs are: Appropriate, medically necessary, and not likely to result in adverse medical results. We are interpreting adverse medical results to include medication errors or medical adverse events, reactions and side effects. We anticipate that any such additional standards would be clinically based and scientifically valid and developed with state collaboration, standards development organizations, and entities that support Medicaid DUR programs, and would help ensure all states have established a reasonable and appropriate DUR program. Such proposed standards would align with current clinical guidelines and could address the following: Maintaining policies and systems to assist in preventing over-utilization and under-utilization of prescribed medications, establishing quality assurance measures and systems to reduce medication errors and adverse drug interactions, and improving medication compliance and overall well-being of beneficiaries. We are considering other mechanisms to encourage states to adopt additional DUR standards in a timely manner to respond to new and emerging issues in drug use, as the rulemaking process can be a lengthy process. For example, we are considering issuing possible future suggested ''best practices'' or guidance for states in advance of and in anticipation of rulemaking. We are seeking comments on the best processes for collaboratively developing future minimum DUR standards and are seeking comments from states and other stakeholders on potential approaches.

The early signs of the opioid crisis emerged years ago, with groundwork for the crisis being laid in the late 1990s, when providers began to prescribe opioid analgesics at greater rates, which led to widespread misuse and abuse of both prescription and illegal opioids. After what the CDC characterizes as a ''first wave'' of opioid deaths, a second wave followed in 2010, involving heroin, with a third wave beginning in 2013 involving overdoses from synthetic opioids.[14] CDC data indicate that from 1999 through 2017, almost 400,000 people died from an overdose involving any opioid, including prescription and illicit opioids.[15] In 2018, there was an additional 67,367 drug overdose deaths occurred in the United States. The age-adjusted rate of overdose deaths decreased by 4.6 percent from 2017 (21.7 per 100,000) to 2018 (20.7 per 100,000). Opioids—mainly synthetic opioids (other than methadone)—are currently the main driver of drug overdose deaths. Opioids were involved in 46,802 overdose deaths in 2018 (69.5 percent of all drug overdose deaths)[16] and two out of three (67.0 percent) opioid-involved overdose deaths involved synthetic opioids.[17]

In a 2016 informational bulletin titled, ''Best Practices for Addressing Prescription Opioid Overdoses, Misuse and Addiction'' CMS issued guidance to states to outline both how to help curb the opioid crisis,[18] and in 2019 guidance was issued on how states can use statutory authority to expand the treatment of pain through complementary and integrative approaches.[19] Another section of the SUPPORT for Patients and Communities Act, section 6032, has directed HHS to collaborate with the Pain Management Best Practices Inter-Agency Task Force (PMTF), to develop an Action Plan on payment and coverage in Medicare and Medicaid for acute and chronic pain, and substance use disorders, informed by a Request for Information and a public meeting held at CMS in September, 2019.[20] The Action Plan is related to CMS's Fighting the Opioid Crisis Roadmap, which describes our three-pronged approach to managing pain using a safe and effective range of treatment options that rely less on prescription opioids, expanding treatment for OUD, and using data to target prevention efforts and identify fraud and abuse.[21]

In 2018, the SUPPORT for Patients and Communities Act was passed as

[14] ''Understanding the Epidemic.'' Centers for Disease Control and Prevention, Centers for Disease Control and Prevention, 19 Dec. 2018, *https://www.cdc.gov/drugoverdose/epidemic/index.html.*

[15] ''Understanding the Epidemic.'' Centers for Disease Control and Prevention, Centers for Disease Control and Prevention, 19 Dec. 2018, *www.cdc.gov/drugoverdose/epidemic/index.html.*

[16] Hedegaard H, Miniño AM, Warner M. Drug Overdose Deaths in the United States, 1999–2018.pdf icon NCHS Data Brief, No 356. Hyattsville, MD: National Center for Health Statistics. 2020.

[17] Wilson N, Kariisa M, Seth P, et al. Drug and Opioid-Involved Overdose Deaths—United States, 2017–2018. MMWR Morb Mortal Wkly Rep 2020;69:290–297.

[18] ''Best Practices for Addressing Prescription Opioid Overdoses, Misuse and Addiction.'' CMCS Informational Bulletin available at *www.medicaid.gov/federal-policy-guidance/downloads/CIB-02-02-16.pdf.*

[19] ''Medicaid Strategies for Non-Opioid Pharmacologic and Non-Pharmacologic Chronic Pain Management.'' CMCS Informational Bulletin at *https://www.medicaid.gov/sites/default/files/federal-policy-guidance/downloads/cib022219.pdf.*

[20] ''Request for Information for the Development of a CMS Action Plan to Prevent Opioid Addiction and Enhance Access to Medication-Assisted Treatment.'' CMCS request for information available at *https://www.cms.gov/About-CMS/Story-Page/Opioid-SUPPORT-Act-RFI.pdf.*

[21] ''CMS Roadmap: Fighting the Opioid Crisis.'' Available at *https://www.cms.gov/About-CMS/Agency-Information/Emergency/Downloads/Opioid-epidemic-roadmap.pdf.*

part of a bipartisan effort to address the opioid crisis, as well as the treatment of pain. The practice of chronic pain management and the opioid crisis have influenced one another as each has evolved in response to different influences and pressures. At the same time CMS seeks to implement these requirements, we want to ensure Medicaid beneficiaries with chronic pain can work with their health care providers to optimize function, quality of life, and productivity while minimizing risks for opioid misuse and harm such as addiction and overdose.[22] Therefore, we are considering appropriate approaches through which we could collaboratively develop future minimum DUR standards with involvement from states and other stakeholders, taking into account the need for administrative flexibility and adequate time for operational implementation, which could be implemented more quickly to respond to public health crises that may arise in the future on a more rapid timeframe. We are also considering posting DUR recommendations on our website or through guidance to States to allow quick dissemination of the information.

1. Minimum Standards for DUR Programs Under the SUPPORT for Patients and Communities Act and Section 1927 of the Act

In § 456.703, we are proposing to redesignate paragraph (h) as paragraph (i) and to add a new paragraph (h), specifying minimum standards for DUR programs. The proposed minimum standards in § 456.703(h)(1), discussed in greater detail below, would implement the amendments made by section 1004 of the SUPPORT for Patients and Communities Act and section 1927(g) of the Act and are intended to help ensure DUR programs continue to adapt and improve the quality of pharmaceutical care provided to beneficiaries in the face of evolving healthcare guidelines and technology practices.

We are proposing the provisions below for implementation of requirements in the SUPPORT for Patients and Communities Act [23] consistent with section 1927(g) of the Act. The proposed safety edits and claim reviews are intended to help protect beneficiaries from serious potential consequences of overutilization, including misuse, abuse, overdose, and increased side effects. In addition to the risk of abuse, misuse, and diversion, opioids can have side effects including respiratory depression, confusion, tolerance, and physical dependence.[24]

The Centers for Disease Control and Prevention has recommended, in 2016 guidance,[25] that primary care providers prescribing to adults in outpatient settings consider non-pharmacologic therapy and non-opioid pharmacologic therapy as the first-line treatment for chronic pain.[26] The CDC guideline defines chronic pain as ''pain continuing or expected to continue for greater than 3 months or past the time of normal tissue healing.'' Regarding chronic pain, CDC states clinicians should use caution when initiating prescribing opioids at any dosage, and should carefully reassess evidence of individual benefits and risks when considering increasing dosage to ≥50 morphine milligram equivalents (MME)/day, and should avoid increasing dosage to ≥90 MME/day or carefully justify a decision to titrate dosage to ≥90 MME/day.[27] Caution is also recommended in prescribing opioids for acute pain, noting that long-term opioid use often begins with treatment of acute pain; when opioids are prescribed for non-traumatic, non-surgical acute pain, primary care clinicians should prescribe the lowest effective dose for the shortest duration possible—usually 3 days or less is sufficient and more than 7 days will rarely be needed.[28] Non-pharmacologic therapies pose minimal risks, and many of these treatments, when available and accessible—such as exercise therapy, physical therapy, and cognitive behavioral therapy (CBT) have been shown to effectively treat chronic pain associated with some conditions.[29] For example, exercise therapy can be effective in treating moderate pain associated with lower back pain, osteoarthritis, and fibromyalgia in some patients.[30]

In 2019 the Department of Health and Human Services' PMTF issued its report to HHS and Congress, *the Pain Management Best Practices Inter-Agency Task Force Report,* on best practices for the treatment of acute and chronic pain. The CDC has identified 50 million adults in the United States with chronic daily pain,[31] and the NIH states that chronic daily pain cost the nation between $560 billion and $635 billion annually.[32] [33] The PMTF final report emphasizes a person-centered approach to pain care that includes the use of individualized, multimodal treatment based on an effective pain treatment plan, and the PMTF identified and described five broad treatment categories: Medications, restorative therapies, interventional approaches, behavioral approaches, and complementary and integrative health that can be used through multidisciplinary care. In its report, the PMTF recognized that there have been ''unintended consequences that have resulted following the release of the CDC Guideline in 2016, which are due in part to misapplication or misinterpretation of the Guideline, including forced tapers and patient abandonment'' [34] and noted the ''CDC has also published a pivotal article in the New England Journal of Medicine on April 24, 2019, specifically reiterating that the CDC Guideline has

[22] Pain Management Best Practices Inter-Agency Task Force. ''Pain Management Best Practices.'' Available at *https://www.hhs.gov/sites/default/files/pmtf-final-report-2019-05-23.pdf.*

[23] *https://www.congress.gov/115/bills/hr6/BILLS-115hr6enr.pdf.*

[24] ''CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016.'' Centers for Disease Control and Prevention, Centers for Disease Control and Prevention, 29 Aug. 2017, *https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6501e1er.pdf.*

[25] ''CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016.'' *Centers for Disease Control and Prevention,* Centers for Disease Control and Prevention, 18 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.*

[26] Dowell, D., Haegerich, T.M., Chou, R. CDC Guideline for Prescribing Opioids for Chronic Pain—United States 2016, *Morbidity and Mortality Weekly Report* March 18, 2016: 65)1 [Accessed February 11, 2019 at *https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm.*

[27] ''CDC Guidelines for Prescribing Opioids for Chronic pain. '' Available at *https://www.cdc.gov/drugoverdose/pdf/guidelines_at-a-glance-a.pdf.*

[28] Dowell, D., Haegerich, T.M., Chou, R. CDC Guideline for Prescribing Opioids for Chronic Pain—United States 2016, *Morbidity and Mortality Weekly Report* March 18, 2016: 65)1 [Accessed February 11, 2019 at *https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm*].

[29] For a review of the evidence base for CBT, see Ehde D.M., Dillworth, T.M. and Turner, J.A. Cognitive-Behavioral Therapy for Individuals with Chronic Pain: Efficacy, Innovations, and Directions for Research. *American Psychologist,* 69(2); 153–166.

[30] Additional information on non-opioid treatments for chronic pain are available at *https://www.cdc.gov/drugoverdose/pdf/nonopioid_treatments-a.pdf.*

[31] ''Managing Chronic Pain.'' *Centers for Disease Control and Prevention,* Centers for Disease Control and Prevention, 18 Dec. 2019, *www.cdc.gov/learnmorefeelbetter/programs/chronic-pain.htm.*

[32] Gaskin, Darrell J. ''The Economic Costs of Pain in the United States.'' *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research.,* U.S. National Library of Medicine, 1 Jan. 1970, *www.ncbi.nlm.nih.gov/books/NBK92521/.*

[33] ''Prevalence of Chronic Pain and High-Impact Chronic Pain Among Adults—United States, 2016.'' Centers for Disease Control and Prevention, Centers for Disease Control and Prevention, 16 Sept. 2019, *www.cdc.gov/mmwr/volumes/67/wr/mm6736a2.htm.*

[34] Additional information on non-opioid treatments for chronic pain are available at *https://www.cdc.gov/drugoverdose/pdf/nonopioid_treatments-a.pdf.*

been, in some instances, misinterpreted or misapplied.'' [35] HHS recently issued the *Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics,* to assure proper tapering and discontinuation of long-term opioids, in part to avoid harms and encourage person-centered care that is tailored to the specific needs and unique circumstances of each pain patient,[36] in addition to the CMS-issued guidance to states in 2016 and 2019 to both outline how to help curb the opioid crisis and provide guidance to states that want to expand care for the treatment of pain.[37] [38]

Accordingly, we are proposing to add § 456.703(h)(1)(i) to include minimum standard requirements as described in this proposed rule, with the detailed design and implementation specifications left to the state's discretion to meet state-specific needs. The purpose of these proposed safety edits (specifically, 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) and reviews is to further implement section 1927(g) of the Act to prevent and reduce the inappropriate use of opioids and potentially associated adverse medical events to sufficiently address the nation's opioid overdose epidemic, consistent with the provisions under section 1004 of the SUPPORT for Patients and Communities Act.

When implementing the SUPPORT for Patients and Communities Act, we propose the following safety edits in § 456.703(h)(1)(i) in addition to a comprehensive opioid claims review automated retrospective review process where trends witnessed in safety edits can be reviewed and investigated. These reviews will allow subsequent appropriate actions to be taken as designed by the states.

[35] Dowell D., Haegerich T.M., Chou R. No shortcuts to safer opioid prescribing. N Engl J Med 2019; 380: 2285–2287.

[36] 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.*

[37] ''Best Practices for Addressing Prescription Opioid Overdoses, Misuse and Addiction.'' CMCS Informational Bulletin available at *www.medicaid.gov/federal-policy-guidance/downloads/CIB-02-02-16.pdf.*

[38] ''Medicaid Strategies for Non-Opioid Pharmacologic and Non-Pharmacologic Chronic Pain Management.'' CMCS Informational Bulletin at *https://www.medicaid.gov/federal-policy-guidance/downloads/cib022219.pdf*).

a. Opioid Safety Edits Including Initial Fill Days' Supply for Opioid-Naïve Beneficiaries, Quantity, Therapeutically Duplicative Fills, and Early Refill Limits

The SUPPORT for Patients and Communities Act requires states to have in place prospective safety edits (as specified by the state) for subsequent fills for opioids and a claims review automated process (as designed and implemented by the state) that indicates when an individual enrolled under the state plan (or under a waiver of the state plan) is prescribed a subsequent fill of opioids in excess of any limitation that may be identified by the state.[39] As discussed in detail below, consistent with the SUPPORT for Patients and Communities Act and DUR requirements under section 1927(g)(2)(A) of the Act, we are proposing that state-identified limitations must include state-specified restrictions on initial prescription fill days' supply for patients not currently receiving opioid therapy; quantity limits for initial and subsequent fills, therapeutically duplicative fills, and early fills on opioids prescriptions; and a claims review automated process that indicates prescription fills of opioids in excess of these limitations to provide for the ongoing periodic reviews of opioids claim data and other records in order to identify patterns of fraud, abuse, excessive utilization, or inappropriate or medically unnecessary care, or prescribing or billing practices that indicate abuse or excessive utilization among physicians, pharmacists and individuals receiving Medicaid benefits. To further implement section 1927(g)(1) of the Act, and consistent with section 1004 of the SUPPORT for Patients and Communities Act, we are proposing to require these safety edits to reinforce efforts to combat the nation's opioid crisis and ensure DUR opioid reviews are consistent with current clinical practice. These proposed safety edits are intended to protect Medicaid patients from serious consequences of overutilization, including overdose, dangerous interactions, increased side effects and additive toxicity (additive side effects). In addition, overutilization of opioids may serve as an indication of uncontrolled disease and the need of increased monitoring and coordination of care.

(i) Limit on Days' Supply for Opioid Naïve Beneficiaries

To further implement section 1927(g)(1) of the Act, and consistent with section 1004 of the SUPPORT for Patients and Communities Act, we are proposing to require states to establish safety edit limitations on the days' supply for an initial prescription opioid fill for beneficiaries who have not filled an opioid prescription within a defined time period to be specified by the state. In most cases, ''Days Supply'' is calculated by dividing the dispensed quantity of medication by the amount of the medication taken by the patient in one day per the prescriber's instructions. ''Days' Supply'' means how many days the supply of dispensed medication will last. This limit would not apply to patients currently receiving opioids and is meant for beneficiaries who have not received opioids within this specified time period (as defined and implemented by the state). The patients who have not received opioids within a specified timeframe are referred to as opioid naïve and would be subjected to the days' supply limit on the opioid prescription. While the SUPPORT for Patients and Communities Act mentions limits on subsequent fills of opioids, consistent with section 1927(g) of the Act, we are proposing this edit on initial fills of opioids to help avoid excessive utilization by opioid naïve beneficiaries, with its attendant risk of adverse effects.

The CDC Guideline recommends that opioids prescribed for acute pain in outpatient primary care settings to adults generally should be limited to 3 days or fewer, and more than a 7 days' supply is rarely necessary.[40] Nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred [for chronic pain] and should be considered by practitioners and patients prior to treatment with opioids.[41] Clinical evidence cited by the CDC review found that opioid use for acute pain is associated with long-term opioid use, and that a greater amount of early opioid exposure is associated with greater risk for long-term use. An expected physiologic response in patients exposed to opioids for more than a few days is physical dependence and the chances of long-term opioid use begin to increase after just 3 days of use and rise rapidly thereafter.[42] The CDC

[39] Section 1902(oo)(1)(A)(i)(I) of the Act, as added by section 1004 of the SUPPORT for Patients and Communities Act.

[40] ''CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016.'' Centers for Disease Control and Prevention, Centers for Disease Control and Prevention, 29 Aug. 2017, *https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6501e1er.pdf.*

[41] Ibid.

[42] Shah A., Hayes C.J., Martin B.C. Characteristics of Initial Prescription Episodes and Likelihood of Long-Term Opioid Use—United States, 2006–2015. Morbidity and Mortality Weekly Report 2017; 66:265–269 [Accessed February 11, 2019 at *http://dx.doi.org/10.15585/mmwr.mm6610a1*].

Guideline mentions that more than a few days of exposure to opioids significantly increases hazards, that each day of unnecessary opioid use increases likelihood of physical dependence without adding benefit, and that prescriptions with fewer days' supply would minimize the number of pills available for unintentional or intentional diversion.[43]

Long-term opioid use often begins with treatment of acute pain. When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids.[44] Limiting days for which opioids are prescribed for opioid naïve patients could minimize the need to taper opioids to prevent distressing or unpleasant withdrawal symptoms and help prevent opioid dependence, the risk of which is associated with the amount of opioid initially prescribed.[45]

On state DUR surveys many states indicated they already have initial fill limitations in place describing the limitations of 100 dosage units or a 34 days supply. Initial opioid analgesic prescriptions of less than or equal to 7 days' duration appear sufficient for many pain patients seen in primary care settings.[46] We note that in its 2019 clarification of the Guideline, the CDC noted that it was ''intended for primary care clinicians treating chronic pain for patients 18 and older, and examples of misapplication include applying the Guideline to patients in active cancer treatment, patients experiencing acute sickle cell crises, or patients experiencing post-surgical pain.'' States can consider the current CDC Guideline and other clinical guidelines when implementing initial fill limitations, being mindful of the context in which such guidelines are written (for example, acute pain, chronic pain, treatment setting, population, etc.).

The CDC Guideline states primary care clinicians should assess benefits and harms of opioids with patients early on when starting opioid therapy for chronic pain and regularly when escalating doses and continue to evaluate therapy with patients on an ongoing basis. If benefits do not outweigh harms of continued opioid therapy, clinicians should optimize other therapies and work with patients to taper opioids to lower dosages or to taper and discontinue opioid therapy. Consistent with the foregoing clinical recommendations, we are proposing to require states to implement safety edits aligned with clinical guidelines alerting the dispenser at the POS when an opioid prescription is dispensed to an opioid naïve patient that exceeds a state-specified days' supply limitation. In consideration of clinical recommendations to limit opioid use to the shortest possible duration and to assess the clinical benefits and harms of opioid treatment on an ongoing basis, we believe this safety edit is necessary to assure that opioid prescriptions are appropriate, medically necessary, and not likely to result in adverse events, and to accomplish other purposes of the DUR program under section 1927(g) of the Act and of the SUPPORT for Patients and Communities Act. Accordingly, we are proposing in § 456.703(h)(1)(i)(A) to require states to implement a days' supply limit when an initial opioid prescription is dispensed to a patient not currently receiving ongoing therapy with opioids.

(ii) Opioid Quantity Limits

To further implement section 1927(g)(1) of the Act and section 1004 of the SUPPORT for Patients and Communities Act, we are proposing to require states establish safety edits to implement quantity limits on the number of opioid units to be used per day, as identified by the state. We propose that states take clinical indications and dosing schedules into account when establishing quantity limits to restrict the quantity of opioids per day to ensure dose optimization and to minimize potential for waste and diversion. While the SUPPORT for Patients and Communities Act mentions quantity limits on subsequent fills of opioids, consistent with section 1927(g) of the Act, we are proposing this edit to apply with respect to initial and subsequent fills of opioids to avoid excessive utilization, with its attendant risk of adverse effects.

We propose that the quantity limits would be required to take into account both dosage and frequency, to allow for dose optimization of pills, capsules, tablets, etc. (pills) and limit the supply of opioids being dispensed. Dose optimization is a method to consolidate the quantity of medication dispensed to the smallest amount required to achieve the desired daily dose and/regimen. Dosage optimization seeks to prospectively identify patients who have been prescribed multiple pills, capsules and/or tablets (''pills'') per day of a lower strength medication meant to be taken together to achieve higher dose, when a higher strength of medication already is available, and provides clinicians a tool to switch these patients to a regimen that is an equivalent daily dose given as a single pill (or a smaller quantity of pills). Performing this intervention with medications that are available in multiple strengths, with comparable pricing among these strengths, can yield significant drug cost savings. In addition, dose-optimization yields simplifies dosing schedules, decreases pill burdens, improves treatment compliance and limits the number of excess units available for diversion.[47] This proposed safety edit would allow most patients to achieve pain relief while minimizing patient pill burdens and unnecessary unused opioids.[48] When implementing this edit we expect states to also consider current opioid guidelines, clinical indications, and dosing schedules of opioids to ensure prescriptions are appropriate, medically necessary, and not likely to result in adverse events.

Decreasing the initial amount prescribed will lower the risk that patients develop an addiction to these drugs and transition to chronic use or misuse.[49] A survey of adults in Utah estimated that in the previous 12 months, 1 in 5 state residents were prescribed an opioid medication and 72 percent had leftover pills and nearly three-quarters of those with leftover pills kept them.[50] Leftover medications are an important source of opioids that are misused or diverted.[51] We believe that decreasing the initial amount prescribed will lower the risk that patients develop opioid use disorder.[52]

[43] Ibid.

[44] ''CDC Guideline for Prescribing Opioids for Chronic Pain.'' Centers for Disease Control and Prevention, Centers for Disease Control and Prevention, *https://www.cdc.gov/drugoverdose/pdf/guidelines_at-a-glance-a.pdf.*

[45] Shah A, Hayes CJ, Martin BC. Characteristics of initial prescription episodes and likelihood of long-term opioid use—United States, 2006–2015. *MMWR Morb Mortal Wkly Rep.* 2017;66(10):265–269. doi:10.15585/mmwr.mm6610a1.

[46] ''Days' Supply of Initial Opioid Analgesic Prescriptions and Additional Fills for Acute Pain Conditions Treated in the Primary Care Setting—United States, 2014 | MMWR.'' Centers for Disease Control and Prevention, Centers for Disease Control and Prevention, *https://www.cdc.gov/mmwr/volumes/68/wr/mm6806a3.htm.*

[47] Calabrese D., Baldinger S., Dose Optimization Intervention Yields Significant Drug Cost Savings. *https://www.jmcp.org/doi/pdf/10.18553/jmcp.2002.8.2.146.*

[48] Daoust R. Limiting Opioid Prescribing. *JAMA.* 2019; 322(2):170–171. doi:10.1001/jama.2019.5844.

[49] Ibid.

[50] Ibid.

[51] ''FDA Patient Education Campaign Targets Opioid Diversion, Disposal.'' Available at *https://patientengagementhit.com/news/fda-patient-education-campaign-targets-opioid-diversion-disposal.*

[52] Opioid Use During the Six Months After an Emergency Department Visit for Acute Pain: A Prospective Cohort Study. Friedman, Benjamin W. et al. Annals of Emergency Medicine, Volume 0, Issue 0.

Prescribing opioids using lowest dosage at fewest possible units dispensed based on product labeling, and matching duration to scheduled reassessment, helps reduce the quantity of unused, leftover opioid pills. Additionally, clinicians should continue to evaluate benefits and harms of continued ongoing therapy with opioid patients every 3 months or more frequently.[53] If benefits do not outweigh harms of continued opioid therapy, clinicians should optimize other therapies and work with patients to taper opioids to lower dosages or to taper and discontinue opioids.[54] In consideration of clinical recommendations to limit opioid units to the fewest number possible and to assess the clinical benefits and harms of opioid treatment on an ongoing basis, we believe this safety edit is necessary to assure that opioid prescriptions are appropriate, medically necessary, and not likely to result in adverse events, and to accomplish other purposes of the DUR program under section 1927(g) of the Act and of the SUPPORT for Patients and Communities Act. Accordingly, we are proposing at § 456.703(h)(1)(i)(B) that states be required to implement quantity limits on opioids prescriptions (both initial and subsequent fills) to help identify abuse, misuse, excessive utilization, or inappropriate or medically unnecessary care.

iii. Therapeutic Duplication Limitations

To further implement section 1927(g)(1) of the Act and section 1004 of the SUPPORT for Patients and Communities Act, we are proposing to require states to establish safety edits to alert the dispenser to potential therapeutic duplication before a prescription is filled for an opioid product that is in the same therapeutic class as an opioid product currently being prescribed for the beneficiary. Prescriptions for multiple opioids and multiple strengths of opioids increase the supply of opioids available for diversion and abuse, as well as the opportunity for self-medication and dose escalation.[55] Some patients, especially those living with multiple chronic conditions, may consult multiple physicians, which can put them at risk of receiving multiple medications in the same therapeutic class for the same diagnosis.[56] In some instances, the side-effects produced by overmedication, due to the duplication of prescriptions within the same therapeutic class, are more serious than the original condition.[57] We propose to require this opioid safety edit to help avoid inappropriate or unnecessary therapeutic duplication when simultaneous use of multiple opioids is detected.

In consideration of clinical recommendations to use caution in combining opioids and to limit opioid use to only when necessary while assessing clinical benefits and harms of opioid treatment on an ongoing basis, we believe this safety edit is necessary to assure that opioid prescriptions are appropriate, medically necessary, and not likely to result in adverse medical results, and to accomplish other purposes of the DUR program under section 1927(g) of the Act and of the SUPPORT for Patients and Communities Act. Accordingly, we are proposing at § 456.703(h)(1)(i)(C) that states must implement safety edits for therapeutically duplicative fills for initial and subsequent prescription fills on opioids prescriptions and identify suspected abuse, misuse, excessive utilization, or inappropriate, or medically unnecessary care.

iv. Early Fill Limitations

To further implement section 1927(g)(1) of the Act and section 1004 of the SUPPORT for Patients and Communities Act, we are proposing to require that states establish safety edits to alert the dispenser before a prescription is filled early for an opioid product, based on the days' supply provided at the most recent fill or as specified by the state. These early fill edits on opioids are intended to protect beneficiaries from adverse events associated with using an opioid medication beyond the prescribed dose schedule and to help minimize the opioid supply available for diversion.

In consideration of clinical recommendations to limit opioid use to only when necessary and as prescribed, we believe this safety edit is necessary to assure that opioid prescriptions are appropriate, medically necessary, and not likely to result in adverse medical results, and to accomplish other purposes of the DUR program under section 1927(g) of the Act and of the SUPPORT for Patients and Communities Act. Accordingly, we are proposing at § 456.703(h)(1)(i)(D) that states must implement early fill safety alerts on opioids prescriptions to identify abuse, misuse, excessive utilization, or inappropriate, or medically unnecessary care.

b. Maximum Daily Morphine Milligram Equivalent (MME) Limits

Section 1004 of the SUPPORT for Patients and Communities Act requires state DUR programs to include safety edit limits (as specified by the state) on the maximum daily morphine equivalent that can be prescribed to an individual enrolled under the state plan (or under a waiver of the state plan) for treatment of chronic pain (as designed and implemented by the state) that indicates when an individual enrolled under the plan (or waiver) is prescribed the morphine equivalent for such treatment in excess of any threshold identified by the state.[58] Accordingly, to further implement section 1927(g)(1) of the Act and section 1004 of the SUPPORT for Patients and Communities Act, we are proposing that states must include in their DUR programs safety edit limitations identified by the State on the maximum daily morphine milligram equivalent (MME) for treatment of pain and a claims review automated process, discussed below in connection with paragraph (h)(1)(iii), that indicates when an individual is prescribed a morphine milligram equivalent in excess of these limitations.

Section 1004 of the SUPPORT for Patients and Communities Act specifically addresses MME limitations in the context of chronic pain. According to the CDC, acute pain (as distinct from chronic pain) usually occurs suddenly and usually has a known cause, like an injury, surgery, or infection. For example, acute pain can be caused from a wisdom tooth extraction, a surgery, or a broken bone after an automobile accident. Acute pain normally resolves as your body heals. Chronic pain, on the other hand, can last weeks, months or years—past the normal time of healing.[59] Regarding chronic pain, CDC states clinicians should use caution when prescribing opioids at any dosage, and should carefully reassess evidence of individual

[53] Dowell, Deborah, et al. ''CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016.'' JAMA, U.S. National Library of Medicine, 19 Apr. 2016, *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6390846/.*

[54] Frieden TR, Houry D. Reducing the Risks of Relief—The CDC Opioid-Prescribing Guideline. *N Engl J Med.* 2016; 374(16):1501–1504. doi:10.1056/NEJMp1515917.

[55] Manchikanti, Laxmaiah, et al. ''Opioid Epidemic in the United States.'' Pain Physician, U.S. National Library of Medicine, July 2012, *www.ncbi.nlm.nih.gov/pubmed/22786464.*

[56] Ibid.

[57] ''Therapeutic Duplication.'' Journal of the American Medical Association, vol. 160, no. 9, 1956, p. 780, doi:10.1001/jama.1956.02960440052016.

[58] Section 1902(oo)(1)(A)(i)(II) of the Act, as added by section 1004 of the SUPPORT for Patients and Communities Act.

[59] ''Opioids for Acute Pain.'' Centers for Disease Control and Prevention, available at *https://www.cdc.gov/drugoverdose/pdf/patients/Opioids-for-Acute-Pain-a.pdf.*

benefits and risks when considering increasing dosage to ≥50 morphine milligram equivalents (MME)/day, and should avoid increasing dosage to ≥90 MME/day or carefully justify a decision to titrate dosage to ≥90 MME/day.[60] With this proposal to require maximum daily MME limits, we do not mean to suggest rapid discontinuation of opioids already prescribed at higher dosages. The MME/day metric is often used as a gauge of the overdose potential of the amount of opioid that is being given at a particular time.[61]

Calculating the total daily dosage of opioids helps identify patients who may benefit from closer monitoring, reduction or tapering of opioids, prescribing of naloxone, or other measures to reduce risk of overdose. The opioid MME levels mentioned previously in this proposed rule typically would not be clinically appropriate for acute, short term pain; moreover, if the prescription were for acute pain, given the risks associated with high acute doses (in particular, respiratory risks), we believe that this limitation also would be appropriate to ensure appropriateness, medical necessity, and avoidance of adverse events. Accordingly, we are proposing to require states to establish MME threshold amounts for implementation regardless of whether the prescription is for treatment of chronic or acute pain.

The proposed prospective safety edit must include a MME threshold amount to meet statutory requirements, to assist in identifying patients at potentially high clinical risk who may benefit from closer monitoring and care coordination. Calculation of MMEs is used to assess the total daily dose of opioids, taking into account the comparative potency of different opioids and frequency of use. The calculation to determine MMEs includes drug strength, quantity, days' supply and a defined conversion factor unique to each drug.[62] Patients prescribed higher opioid dosages are at higher risk of overdose death.[63] Calculating the total MME daily dose of opioids can help identify patients who may benefit from closer monitoring, reduction or tapering of opioids, prescribing of naloxone, or other measures to reduce risk of overdose.[64] HHS's *Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics,*[65] is also a valuable resource for considering how best to taper and/or discontinue usage in a thoughtful manner consistent with best clinical practices. We note that HHS does not recommend opioids be tapered rapidly or discontinued suddenly due to the significant risks of opioid withdrawal, unless there is a life-threatening issue confronting the individual patient. The FDA issued a safety announcement on tapering in April 2019 noting concerns about safely decreasing or discontinuing doses of opioids in patients who are physically dependent after hearing reports about serious harm.[66]

When determining MME threshold amounts, states are reminded that clinical resources, including, for example, the CDC Guideline,[67] recommend caution when prescribing opioids for chronic pain in certain circumstances, and recommend that primary care practitioners reassess evidence of individual benefits and risks when increasing doses and subsequently, justifying decisions by thoroughly documenting the clinical basis for prescribing in the patient's medical record.[68] It is important to be cognizant that the CDC Guideline states the dosage thresholds referenced therein pertain solely to opioids used to treat chronic pain in primary care settings and that these thresholds, as recommended by the CDC, do not represent hard limits for opioid prescriptions.[69]

In consideration of clinical recommendations and to assess the clinical benefits and harms of opioid treatment on an ongoing basis, we believe this proposed safety edit is necessary to assure at risk individuals are receiving appropriate treatment that is not likely to result in adverse medical results, and to accomplish other purposes of the DUR program under section 1927(g) of the Act and of the SUPPORT for Patients and Communities Act. Accordingly, we are proposing at § 456.703(h)(1)(ii) that states be required to implement safety edits that indicates when an individual enrolled under the plan (or waiver) is prescribed the morphine equivalent for such treatment in excess of the MME dose limitation identified by the state.

c. Automated Claims Reviews for Opioids

To further implement section 1927(g) of the Act and section 1004 of the SUPPORT for Patients and Communities Act, we propose that states must have in place a claims automated review process (as designed and implemented by the state) that indicates when an individual enrolled under the state plan (or under a waiver of the state plan) is prescribed opioids in excess of above-proposed limitations identified by the state. In these ongoing, comprehensive reviews of opioid claim data, states should continuously monitor opioid prescriptions, including overrides of safety edits by the prescriber or dispenser on initial fill days' supply for opioid naïve patients, quantity limits, therapeutically duplicative fills, early refills and maximum daily MME limitations on opioids prescriptions.

These opioid claim reviews are necessary to allow states to continually monitor opioid prescriptions beneficiaries are receiving and determine and refine future potential prospective DUR safety edits, based on the findings of the claims reviews. Information obtained through retrospective DUR claim reviews can be used to shape effective safety edits that can be implemented through prospective DUR, better enabling prescribers and dispensers to investigate prescription concerns prior to dispensing the medication to the patient. Through ongoing monitoring and observation of trends over time, these reviews will allow for regular updates to safety edits in an evolving pain treatment landscape.

Accordingly, we are proposing at § 456.703(h)(1)(iii) that states must conduct retrospective claims review automated processes that indicate prescription fills in excess of the

[60] ''CDC Guidelines for Prescribing Opioids for Chronic pain.'' Available at *https://www.cdc.gov/drugoverdose/pdf/guidelines_at-a-glance-a.pdf.*

[61] Ibid.

[62] Calculating Total Daily Dose of Opioids For Safer Dosage. Centers for Disease Control and Prevention, available at *https://www.cdc.gov/drugoverdose/pdf/calculating_total_daily_dose-a.pdf.*

[63] Guideline for Prescribing Opioids for Chronic Pain. *www.cdc.gov/drugoverdose/pdf/guidelines_at-a-glance-a.pdf.*

[64] Ibid.

[65] *https://www.hhs.gov/opioids/sites/default/files/2019-10/Dosage_Reduction_Discontinuation.pdf*).

[66] ''FDA identifies harm reported from sudden discontinuation of opioid pain medicines and requires label changes to guide prescribers on gradual, individualized tapering.'' Food and Drug Administration. Available at *https://www.fda.gov/drugs/drug-safety-and-availability/fda-identifies-harm-reported-sudden-discontinuation-opioid-pain-medicines-and-requires-label-changes.*

[67] Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016. MMWR Recomm Rep 2016;65(No. RR–1):1–49. DOI: *http://dx.doi.org/10.15585/mmwr.rr6501el. https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fmmwr%2Fvolumes%2F65%2Frr%2Frr6501e1er.htm.*

[68] Dowell, Deborah, et al. ''CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016.'' JAMA, U.S. National Library of Medicine, 19 Apr. 2016, *https://www.ncbi.nlm.nih.gov/pubmed/26977696.*

[69] Staff, News. ''CDC Clarifies Opioid Guideline Dosage Thresholds.'' AAFP Home, 12 Jan. 2018, *www.aafp.org/news/health-of-the-public/20180112cdcopioidclarify.html.*

prospective safety edit limitations specified by the state under paragraphs § 456.703(h)(1)(i) or (h)(1)(ii) to provide for the ongoing review of opioid claims data to identify patterns of fraud, misuse, abuse, excessive utilization, inappropriate or medically unnecessary care, or prescribing or billing practices that indicate abuse or provision of inappropriate or medically unnecessary care among prescribers, pharmacists and individuals receiving Medicaid benefits above-proposed limitations. In addition to opioid claims data, we also intend for states to consider incorporating other available records to provide for the ongoing periodic reviews of opioids claim data and other records (including but not limited to prescription histories, diagnoses, medical records, and prescription drug monitoring program (PDMP) files, when available), in their retrospective claims review automated processes order to identify patterns of fraud, misuse, abuse, excessive utilization, or inappropriate or medically unnecessary care, or prescribing or billing practices that indicate abuse or excessive utilization among physicians, pharmacists and individuals receiving Medicaid benefits.

d. Concurrent Utilization Reviews

Section 1902 of the Act, as amended by the SUPPORT for Patients and Communities Act, requires states to have an automated process for claims review (as designed and implemented by the state) that monitors when an individual enrolled under the state plan (or under a waiver of the state plan) is concurrently prescribed opioids and benzodiazepines or opioids and antipsychotics.[70] This requirement is consistent with the requirement in section 1927(g)(1)(A) of the Act that state DUR programs must assure that prescriptions are appropriate, medically necessary, and not likely to result in adverse medical results.

Clinically, through the use of retrospective automated claim reviews, concurrent use of opioids and benzodiazepines and opioids and antipsychotics, as well as potential complications resulting from other medications concurrently being prescribed with opioids, can be reduced. States are reminded that the requirement for a retrospective automated claims review added by section 1004 of the SUPPORT for Patients and Communities Act does not preclude the state from also establishing a prospective safety edit system to provide additional information to patients and providers at the POS about concurrent utilization alerts.[71] In addition, the state could use the authorities under section 1927 to subject these patients to appropriate utilization management techniques. We also would like to remind states that section 1927(g)(1) of the Act also currently supports including other potentially harmful opioid interactions as additional prospective or retrospective reviews in state DUR programs, such as opioids and central nervous system (CNS) depressants, including alcohol or sedatives. We fully support states including such additional opioid interactions or contraindications in prospective or retrospective reviews as part of a comprehensive DUR program.

In consideration of clinical recommendations to limit opioids interactions with certain other drugs, including benzodiazepines and antipsychotics, and to assess the clinical benefits and harms of opioid treatment on an ongoing basis, we believe the retrospective reviews we are proposing to require are necessary to assure at-risk individuals are receiving appropriate treatment that is not likely to result in adverse medical results, and to accomplish purposes of the DUR program under section 1927(g) of the Act and of the SUPPORT for Patients and Communities Act. Accordingly, we are proposing in § 456.703(h)(1)(iv)(A) and (B) that states be required to implement a claims review automated process that monitors when an individual is concurrently prescribed opioids and benzodiazepines; or opioids and antipsychotics.

i. Opioid and Benzodiazepines Concurrent Fill Reviews

In 2016, FDA added a boxed warning to prescription opioid analgesics, opioid-containing cough products, and benzodiazepines with information about the serious risks associated with using these medications concurrently.[72] The CDC Guideline recommends that clinicians avoid prescribing benzodiazepines concurrently with opioids whenever possible. Benzodiazepines may be abused for recreational purposes by some individuals, with some opioid overdoses also involving opioids and benzodiazepines or other substances, such as alcohol.[73]

Studies show that people concurrently using both drugs are at higher risk of visiting the emergency department or being admitted to a hospital for a drug-related emergency.[74] Due to the heightened risk of adverse events associated with the concurrent use of opioids and benzodiazepines, physicians should avoid the initial combination of opioids and benzodiazepines by offering alternative approaches.[75] This review would alert providers when these drugs have been prescribed concurrently to assist in avoiding and mitigating associated risks.

ii. Opioid and Antipsychotic Concurrent Fill Reviews

This alert is supported by FDA's boxed warning of increased risk of respiratory and central nervous system (CNS) depression with concurrent use of opioid and CNS depressants such as antipsychotics or sedatives, including extreme sleepiness, slowed or difficult breathing, unresponsiveness or the possibility that death can occur.[76] Patients concurrently prescribed opioid and antipsychotic drugs can benefit from increased coordination of care. Additionally, improving treatment of comorbid mental disorders is an important consideration when trying to reduce the overall negative impacts of pain. As the PMTF report noted, ''the occurrence of pain and behavioral health comorbidities, including depression, post-traumatic stress disorder, and substance use disorders, is well documented, and it is established that psychosocial distress can contribute to pain intensity, pain-related disability, and poor response to chronic pain treatment.'' [77] Evidence indicates that

[70] Section 1902(oo)(1)(A)(i)(III) of the Act, as added by section 1004 of the SUPPORT for Patients and Communities Act.

[71] *See* section 1902(oo)(1)(A)(iii) of the Act, as added by section 1004 of the SUPPORT for Patients and Communities Act.

[72] Office of the Commissioner. ''Drug Safety Communications—FDA warns about serious risks and death when combining opioid pain or cough medicines with benzodiazepines; requires its strongest warning.'' *U.S. Food and Drug Administration Home Page,* Office of the Commissioner, *https://www.fda.gov/media/99761/download.*

[73] Jones, Jermaine D, et al. ''Polydrug Abuse: a Review of Opioid and Benzodiazepine Combination Use.'' Drug and Alcohol Dependence, U.S. National Library of Medicine, 1 Sept. 2012, *www.ncbi.nlm.nih.gov/pmc/articles/PMC3454351/.*

[74] Forum, Addiction Policy. ''Sedative Use Disorder.'' Addiction Policy Forum, *https://www.addictionpolicy.org/sedative-use-disorder.*

[75] ''Reduce Risk of Opioid Overdose Deaths by Avoiding and Reducing Co-Prescribing Benzodiazepines.'' MLN Matters Number: SE19011. Available at *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/SE19011.pdf.*

[76] Office of the Commissioner. ''Drug Safety Communications—FDA warns about serious risks and death when combining opioid pain or cough medicines with benzodiazepines; requires its strongest warning.'' *U.S. Food and Drug Administration Home Page,* Office of the Commissioner, *https://www.fda.gov/media/99761/download.*

[77] Pain Management Best Practices Inter-Agency Task Force. ''Pain Management Best Practices.'' Available at *https://www.hhs.gov/sites/default/files/pmtf-final-report-2019-05-23.pdf.*

optimizing mental health and pain treatment can improve outcomes in both areas for patients seen in primary and specialty care settings. Untreated psychiatric conditions may increase the risk of both unintentional and intentional medication mismanagement, OUD, and overdose.[78] Given the intersection between psychiatric/psychological symptoms and chronic pain, it is important that the behavioral health needs of patients with pain are appropriately and carefully evaluated and treated with the concurrent physical pain problem.[79] As such, beneficiaries who are concurrently prescribed both opioids and antipsychotics should be considered from a health system or policy perspective when addressing their treatment.[80] A patient's unique presentation and circumstances should be considered when prescribing opioids and antipsychotics. This review would encourage coordination of care for patients taking antipsychotic and opioid medications concurrently.

e. Other Considerations

Consistent with section 1902(oo)(1)(A)(iii) of the Act, as added by section 1004 of the SUPPORT for Patients and Communities Act, the provisions proposed to be implemented in § 456.703(h)(1) would not prohibit states from designing and implementing an automated claims review process that provides for other processes for the prospective or retrospective review of claims. Furthermore, none of these proposed provisions would prohibit the exercise of clinical judgment by a provider regarding the best or most appropriate care and treatment for any patient.

We encourage states to develop prospective and retrospective drug reviews that are consistent with medical practice patterns in the state to help meet the health care needs of the Medicaid patient population. In doing so, we encourage states to utilize, for example, the 2016 CDC Guideline [81] for primary care practitioners on prescribing opioids in outpatient settings for chronic pain.

In order to avoid abrupt opioid withdrawal, prior authorization may be necessary for patients who will need clinical intervention to taper off high doses of opioids to minimize potential symptoms of withdrawal and manage their treatment regimen, while encouraging pain treatment using non-pharmacologic therapies and non-opioid medications, where available, and appropriate.

When implementing these requirements, we encourage states to offer education and training and to provide consistent messaging across all healthcare providers. Education and training of all providers on new opioid-related provisions and on the treatment of acute and chronic pain, and on behavioral health issues related to pain, would help minimize workflow disruption and ensure beneficiaries have access to their medications in a timely manner.

f. Program To Monitor Antipsychotic Medications in Children

Under section 1004 of the SUPPORT for Patients and Communities Act, states must have a program (as designed and implemented by the state) to monitor and manage the appropriate use of antipsychotic medications by children enrolled under the state plan (or under a waiver of the state plan), including any Medicaid expansion group for Children's Health Insurance Program (CHIP).[82] Additionally, states must annually submit information on activities carried out under this program for individuals not more than the age of 18 years old generally, and children in foster care specifically, as part of the annual report submitted to the Secretary under section 1927(g)(3)(D) of the Act, as provided in section 1902(oo)(1)(D) of the Act.

Antipsychotic medications are increasingly used for a wide range of clinical indications in diverse populations, including privately and publicly insured youth.[83] Antipsychotics' adverse metabolic effects have heightened concern over growth in prescribing to youth, including off-label prescribing and polytherapy of multiple antipsychotics.[84] Studies have raised concerns regarding the long-term safety and effectiveness of antipsychotics in this broadened population. Studies in adults have found that antipsychotics can cause serious side effects and long-term safety and efficacy for off-label utilization is a particular concern in children.[85] Some of the most concerning effects include uncontrollable movements and tremors, an increased risk of diabetes, substantial weight gain, elevated cholesterol, triglycerides and prolactin, changes in sexual function, and abnormal lactation.[86] Children appear to be at higher risk than adults for a number of adverse effects, such as extrapyramidal symptoms and metabolic and endocrine abnormalities. Some studies suggests that antipsychotic treatment may be associated with increased mortality among children and youths and the distal benefit/risk ratio for long-term off-label treatment remains to be determined.[87] [88]

In consideration of clinical recommendations to monitor and manage the appropriate use of antipsychotic medications by children and to assess the clinical benefits and harms of treatment on an ongoing basis, we believe this program is necessary to assure children are receiving appropriate treatment that is not likely to result in adverse medical results, and to accomplish other purposes of the DUR program under section 1927(g) of the Act and of the SUPPORT for Patients and Communities Act. Accordingly, we are proposing at § 456.703(h)(1)(v) that states be required to implement programs to monitor and manage the appropriate use of antipsychotic medications by children enrolled under the State plan, including any Medicaid expansion groups for the Children's Health Insurance Program (CHIP). We understand states need considerable flexibility when implementing this program. These proposed provisions are not meant to prohibit the exercise of clinical judgment by a provider regarding the best or most appropriate care and treatment for any patient. States are expected to consult national guidelines and are encouraged to work with their pharmacy and therapeutics (P&T) and DUR committees to identify clinically appropriate safety edits and reviews. We recommend states consider expanding DUR programs to include reviews on children for polytherapy (therapy that

[78] Ibid.

[79] Ibid.

[80] Davis, Matthew A., et al. ''Prescription Opioid Use among Adults with Mental Health Disorders in the United States.'' The Journal of the American Board of Family Medicine, vol. 30, no. 4, 2017, pp. 407–417, doi:10.3122/jabfm.2017.04.170112.

[81] ''CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016.'' Centers for Disease Control and Prevention, Centers for Disease Control and Prevention, 29 Aug. 2017, *https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6501e1er.pdf.*

[82] Section 1902(oo)(1)(B) of the Act, as added by section 1004 of the SUPPORT for Patients and Communities Act.

[83] Crystal, Stephen et al. ''Broadened use of atypical antipsychotics: safety, effectiveness, and policy challenges.'' *Health affairs (Project Hope)* vol. 28,5 (2009): w770–81. doi:10.1377/hlthaff.28.5.w770.

[84] Ibid.

[85] Ibid.

[86] Marder SR, et al. Physical health monitoring of patients with schizophrenia. Am J Psychiatry. 2004;161(8):1334.

[87] *https://jamanetwork.com/journals/jamapsychiatry/article-abstract/2717966.*

[88] *https://www.healthline.com/health/consumer-reports-antipsychotics-children#1.*

uses more than one medication), inappropriate utilization or off label utilization.

g. Fraud and Abuse Identification

Section 1902(oo)(1)(C) of the Act, as added by section 1004 of the SUPPORT for Patients and Communities Act, provides that States must have a process (as designed and implemented by the state) that identifies potential fraud or abuse of controlled substances by individuals enrolled under the state plan (or under a waiver of the state plan), health care providers prescribing drugs to individuals so enrolled, and pharmacies dispensing drugs to individuals so enrolled. We propose to implement this requirement at § 456.703(h)(1)(vi); specifically, we propose that the state's DUR program must include a process to identify potential fraud or abuse of controlled substances by individuals enrolled under the State plan, health care providers prescribing drugs to individuals so enrolled, and pharmacies dispensing drugs to individuals so enrolled.

We intend that this proposed process would operate in a coordinated fashion with other state program integrity efforts. States would have flexibility to define specific parameters for reviews for fraud and abuse, as well as protocols for recommendation, referral, or escalation of reviews to the relevant Program Integrity/Surveillance Utilization Review (SURS) unit, law enforcement, or state professional board, based on patterns discovered through the proposed DUR process. Additionally, state policy should specify the documentation required when suspected fraud and/or abuse results in a recommendation, referral, or escalation for further review, including the findings of any subsequent investigation into the potential deviation from the standard of care. States would be expected to ensure that DUR reviews conducted pursuant to this proposed requirement are aligned with all applicable federal requirements, including those specified in 42 CFR 455.12, 455.13 through 455.21 and 455.23 and section 1902(a)(64) of the Act.

We acknowledge that other initiatives, which many states are already undertaking, could work synergistically with the proposed requirement to help reduce fraud, misuse, and abuse related to opioids. For example, patient review and restriction programs (lock-in programs)[89] and prescription drug monitoring programs[90] also play an important role in detecting and preventing opioid-related fraud, misuse and abuse. Lock-in programs, also called patient review and restriction or drug management programs, are meant to cut down on ''doctor shopping''—the practice of going to several doctors or pharmacies to fill multiple prescriptions for opioids or other controlled substances for illicit sale or misuse or to support an addiction. Such programs are used primarily to restrict overutilization of medications. Additionally, programs may require beneficiaries to receive all prescriptions through one pharmacy, have all prescriptions written by one prescriber, receive health care services from one clinical professional, or all three depending on how the program is designed.[91]

Section 5042 of the SUPPORT for Patients and Communities Act requires covered providers who are permitted to prescribe controlled substances and who participate in Medicaid to query qualified Prescription Drug Monitoring Programs (PDMPs) before prescribing controlled substances to most Medicaid beneficiaries, beginning October 1, 2021. PDMPs are database tools sometimes utilized by government officials and law enforcement for reducing prescription drug fraud, abuse and diversion, but which more frequently can be used to monitor controlled substance use by healthcare providers including prescribers and pharmacists. PDMPs collect electronically transmitted prescribing and some dispensing data submitted by pharmacies and dispensing practitioners. The data are monitored and analyzed to support states' efforts in education, research, enforcement and abuse prevention.[92] Data analytics can help to determine the extent to which beneficiaries are prescribed high amounts of opioids, identify beneficiaries who may be at serious risk of opioid misuse or overdose, and identify prescribers with questionable opioid prescribing patterns for these beneficiaries.[93] [94] The process required under the SUPPORT for Patients and Communities Act and this proposed rule to identify potential fraud or abuse, can help ensure that state officials and staff implementing the state's program integrity, PDMP, and DUR functions work collaboratively to identify opportunities for DUR activities to assist in the identification of potential fraud and abuse.

2. Other CMS Proposed Standards

In addition to codifying the SUPPORT for Patients and Communities Act requirements, we are proposing additional minimum DUR standards in this proposed rule that states would be required to implement as part of their DUR programs at § 456.703(h)(1)(vii). Specifically, under our authority to implement section 1927(g) of the Act and consistent with the goals of the SUPPORT for Patients and Communities Act to help combat the nation's opioid overdose epidemic, we are proposing minimum standards related to MAT and identification of beneficiaries who could be at high risk of opioid overdose and should be considered for co-prescription or co-dispensing of naloxone. These additional standards are being included to ensure prescribed drugs are: (1) Appropriate; (2) medically necessary; and (3) not likely to result in adverse medical results.

State DUR programs would be required to include prospective safety edit alerts, automatic retrospective claims review, or a combination of these approaches as determined by the state, to identify cases where a beneficiary is prescribed an opioid after the beneficiary has been prescribed one or more drugs used for MAT, and prospective safety edit alerts, automatic retrospective claims review, or a combination of these approaches as determined by the state to expand appropriate utilization of naloxone for dispensing to individuals at risk of overdose. As further discussed below, we are proposing these minimum requirements to further implement section 1927(g) of the Act to prevent and reduce the inappropriate use of opioids and potentially associated adverse medical results, consistent with the

[89] ''Pharmacy Lock-In Programs Slated For Expanded Use.'' OPEN MINDS, *www.openminds.com/market-intelligence/executive-briefings/pharmacy-lock-programs-slated-expanded-use/.*

[90] Office of National Drug Control Policy. Prescription Drug Monitoring Program. Prescription Drug Monitoring Program, April 2011. *https://www.ncjrs.gov/pdffiles1/ondcp/pdmp.pdf.*

[91] ''Pharmacy Lock-In Programs Slated For Expanded Use.'' OPEN MINDS, *www.openminds.com/market-intelligence/executive-briefings/pharmacy-lock-programs-slated-expanded-use/.*

[92] ''Prescription Drug Monitoring Frequently Asked Questions (FAQ)| The PDMP Training and Technical Assistance Center.'' *Prescription Drug Monitoring Frequently Asked Questions (FAQ)| The PDMP Training and Technical Assistance Center, www.pdmpassist.org/content/prescription-drug-monitoring-frequently-asked-questions-faq.*

[93] Beaton, Thomas. ''Preventing Provider Fraud through Health IT, Data Analytics.'' *HealthPayerIntelligence,* 5 Oct. 2018, *https://healthpayerintelligence.com/news/preventing-provider-fraud-through-health-it-data-analytics.*

[94] OIG, *Opioids in Medicare Part D: Concerns about Extreme Use and Questionable Prescribing,* OEI–02–17–00250, July 2017. *https://oig.hhs.gov/oei/reports/oei-02-17-00250.pdf.*

provisions under section 1004 of the SUPPORT for Patients and Communities Act.

a. Medication Assisted Treatment (MAT)

To further implement section 1927(g)(1) of the Act and consistent with section 1004 of the SUPPORT for Patients and Communities Act, we are proposing to require states to establish prospective safety edit alerts, automatic retrospective claims review, or a combination of these approaches as determined by the state, to identify cases where a beneficiary is prescribed an opioid after the beneficiary has been prescribed one or more drugs used for MAT or had an OUD diagnosis within a specified number of days (as determined by the state), without having a new indication to support utilization of opioids (such as a new cancer diagnosis, new palliative care treatment or entry into hospice).

MAT is treatment for opioid use disorder (OUD) that includes addiction treatment and services plus a medication approved by FDA for opioid addiction, detoxification, or maintenance treatment or relapse prevention for opioid use disorder.[95] The SUPPORT for Patient and Communities Act defines MAT to include all FDA approved drugs and licensed biological products to treat opioid disorders, as well as counseling services and behavioral therapies with respect to the provision of such drugs and biological products.[96] MAT has proven to be clinically effective in treating opioid use disorder and significantly reduces the need for inpatient detoxification services.[97] Medications such as buprenorphine and methadone, in combination with counseling and behavioral therapies, provide a whole-patient approach to the treatment of opioid use disorders.

Using opioid medications during the course of MAT is dangerous from a clinical perspective. A safety edit designed to notify healthcare providers about the co-administration of MAT drugs and opioids would be useful to alert the providers regarding a possible need for increased coordination of care. We believe states could take effective action to help prevent adverse medical results, possible OUD relapse, and increase coordination of care in patients with a history of OUD. We understand states need considerable flexibility when implementing these reviews to address complicated patient populations. The proposed prospective safety edits, automatic retrospective claims reviews, or a combination of these approaches, would help identify cases where a beneficiary is prescribed an opioid after the beneficiary has been prescribed one or more drugs used for MAT or has received an OUD diagnosis. Accordingly, we are proposing that states would have flexibility to determine which of these DUR approaches the state would implement, including the flexibility to incorporate both into an effective DUR program. State flexibility also would extend to specifying the time period between the prior episode of MAT or OUD diagnosis (or most recent prior episode of MAT or OUD diagnosis) and the subject opioid prescription that, if not met, would trigger the alert (for example, an opioid prescription within 24 months of the end of the most recent episode of MAT would trigger a prospective safety edit). Flexibility could also extend to diagnoses where opioid use after MAT is appropriate without compromising OUD treatment (for example in end of life care or in cancer patients with severe pain resulting from their disease or that does not respond to alternative pain management options).

In consideration of clinical recommendations to ensure appropriate MAT treatment, and to prevent opioid related abuse and misuse, we believe the proposed prospective safety edits and/or retrospective claim reviews are necessary to assure that prescriptions are appropriate, medically necessary, and not likely to result in adverse medical results, and to accomplish other purposes of the DUR program under section 1927(g) of the Act and of the SUPPORT for Patients and Communities Act. This proposed requirement is authorized by and expected to advance the purposes of section 1927(g) of the Act and is consistent with the purposes of section 1004 of the SUPPORT for Patients and Communities Act. Accordingly, we are proposing at § 456.703(h)(1)(vii)(A) that states be required to implement reviews to alert when the beneficiary is prescribed an opioid after the beneficiary has been prescribed one or more drugs used for Medication Assisted Treatment (MAT) for 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 new cancer related pain diagnosis or entry into hospice care). In addition to helping ensure appropriate utilization of medications, these edits would assist in coordination of care, and potentially in improved treatment of pain.

b. Naloxone

To further implement section 1927(g)(1) of the Act, and consistent with section 1004 of the SUPPORT for Patients and Communities Act, we are proposing and seeking comment on requiring states to establish prospective safety edit alerts, automatic retrospective claims review, or a combination of these approaches as determined by the state, to identify beneficiaries who could be at high risk of opioid overdose and should be considered for co-prescription or co-dispensing of naloxone with the goal of expanding appropriate utilization of naloxone to individuals at risk of opioid overdose. Naloxone is a medication designed to rapidly reverse opioid overdose by binding to opioid receptors and reversing the effects of opioids. Naloxone works quickly to restore normal respiration to a person whose breathing has slowed or stopped as a result of an opioid overdose, including both illicit and prescription opioids. However, naloxone only works if a person has opioids in their system; the medication has no effect if opioids are absent.[98]

The prescribing or coprescribing of naloxone in patients at elevated risk for opioid overdose or for those who have overdosed on opioids can save lives.[99] We recommend states consider ways for expanded use, distribution and access to naloxone when clinically appropriate.

When implementing this review, states should determine standards for identifying individuals at high risk for opioid overdose, such as individuals who have been discharged from emergency medical care following opioid overdose, individuals who use heroin or misuse prescription pain relievers as well as those who use high dose opioids for long-term management of chronic pain.[100] Before starting and

[95] There are four drugs or drug combinations currently used in MAT: Buprenorphine; naltrexone; buprenorphine in combination with naloxone; and methadone.

[96] Support for Patients and Communities Act, Section 1006(b). Requirement For State Medicaid Plans To Provide Coverage For Medication-Assisted Treatment.

[97] ''Medication and Counseling Treatment''. September 28, 2015. Available at *https://www.samhsa.gov/medication-assisted-treatment/treatment.*

[98] ''Understanding Naloxone.'' Harm Reduction Coalition. Available at *https://harmreduction.org/issues/overdose-prevention/overview/overdose-basics/understanding-naloxone/.*

[99] NEJM Journal Watch: Summaries of and Commentary on Original Medical and Scientific Articles from Key Medical Journals, HHS-recommends-coprescribing-naloxone-with-opioids-high. *https://www.jwatch.org/fw114907/2018/12/20/hhs-recommends-coprescribing-naloxone-with-opioids-high.*

[100] Ibid.

periodically during continuation of opioid therapy, clinicians should evaluate risk factors for opioid-related harms. When prescribing opioids, the CDC Guideline recommends clinicians should incorporate strategies to mitigate opioid risks, including considering offering naloxone when factors that increase risk for opioid overdose, such as history of overdose, history of substance use disorder, higher opioid dosages (≥50 MME/day), or concurrent benzodiazepine use, are present.[101] We understand states need considerable flexibility when implementing this review to address a complex problem and are proposing that states would have flexibility to determine which DUR approach the state would implement into an effective DUR program: Either or both of prospective safety edits and/or retrospective claims reviews. Further, we propose that states would have flexibility to determine the particular criteria they would use to identify which beneficiaries may be at high risk of opioid overdose such that they should be considered for co-prescription or co-dispensing of naloxone.

In consideration of clinical recommendations to expand naloxone use to prevent adverse medical events among those who are prescribed opioids or those who may be at high risk of opioid overdose or have previously overdosed, we believe this review is necessary to assure at risk individuals are receiving appropriate treatment that is not likely to result in adverse medical results, and to accomplish other purposes of the DUR program under section 1927(g) of the Act and of the SUPPORT for Patients and Communities Act. Accordingly, we are proposing at § 456.703(h)(1)(vii)(B) that states be required to implement prospective safety edit alerts, automatic retrospective claims review, or a combination of these approaches as determined by the state to identify when a beneficiary could be at high risk of opioid overdose and should be considered for co-prescription or co-dispensing of naloxone. We anticipate that this proposal may help expand appropriate utilization of naloxone, including by facilitating dispensing to individuals at risk of overdose.

3. Exclusions

The above described DUR requirements added to section 1902(oo) of the Act by section 1004 of the SUPPORT for Patients and Communities Act, which we propose to implement along with additional related proposals under section 1927(g) of the Act at § 456.703(h)(1)(i) through (vii)(B), do not and would not apply for individuals who are receiving hospice or palliative care or those in treatment for cancer; residents of a long-term care facility, a facility described in section 1905(d) of the Act (that is, an intermediate care facility for the intellectually disabled), or of another facility for which frequently abused drugs are dispensed for residents through a contact with a single pharmacy; or other individuals the state elects to treat as exempted from such requirements.

States are expected to consult national guidelines and are encouraged to work with their pharmacy and therapeutics (P&T) and DUR committees to identify other clinically appropriate patient populations for possible exclusion from the safety reviews specified in § 456.703(h)(1)(i) through (vii) to avoid impeding critical access to needed medication when managing specific complex disease states.

We understand states need considerable flexibility when implementing these reviews to address complicated patient populations. We propose to implement this statutory exclusion at § 456.703(h)(2), such that states would not be required to implement the specified DUR requirements with respect to these populations. However, while states are not required to comply with these requirements with respect to these individuals, we clarify, and propose to codify in the regulation, that states voluntarily may apply to them the prospective safety edits and claims review automated processes otherwise required under the SUPPORT for Patients and Communities Act and this proposed rule.[102] We also recognize that it is important for patients who are taking opioid-based MAT drugs to continue their therapy without disruption. In this regard, states may at their discretion include these drugs in their DUR reviews under section 1927(g) of the Act.

4. Managed Care Requirements

Consistent with section 1902(oo)(1)(A)(ii) of the Act, as added by the SUPPORT for Patients and Communities Act, states also must ensure that their contracts with MCOs under section 1903(m) of the Act and managed care entities (MCEs) under section 1905(t)(3) of the Act require that the MCOs or MCEs have safety edits, an automated review processes, a program to monitor antipsychotic medications in children, and fraud and abuse identification requirements as described in this proposed rule for individuals eligible for medical assistance under the state plan (or waiver of the state plan) who are enrolled with the entity, subject to the exclusions of individuals as proposed in section 1902(oo)(1)(C) of the Act.[103] States must include these DUR provisions in managed care contracts by October 1, 2019. Although the foregoing provisions added by the SUPPORT for Patients and Communities Act address only MCOs and MCEs in the managed care context, we propose also to extend these requirements to contracts with prepaid ambulatory health plans (PAHPs) and prepaid inpatient health plans (PIHPs) under our authority in section 1902(a)(4) under which existing PIHP and PAHP requirements are based. Thus, under this proposed rule, states would be required to include prepaid ambulatory health plans (PAHPs) and prepaid inpatient health plans (PIHPs) when uniformly implementing the updates and requirements specified in the SUPPORT for Patients and Communities Act for all Medicaid managed care plans. Furthermore, as required by section 1004 of the SUPPORT for Patients and Communities Act, each Medicaid MCO and MCE within a state must also operate a DUR program that complies with the above specified requirements. We are proposing to define MCEs in § 438.2 to have the meaning given to the term under section 1932(a)(1)(B) of the Act, which defines the term to mean a Medicaid managed care organization, as defined in section 1903(m)(1)(A), that provides or arranges for services for enrollees under a contract pursuant to section 1903(m) of the Act, or a primary care case manager, as defined in section 1905(t)(2) of the Act. Managed care regulations at § 438.3(s)(4) require Medicaid managed care DUR programs in which an MCO, PIHP, or PAHP contracts to provide coverage for covered outpatient drugs to operate consistently with section 1927(g) of the Act and part 456, subpart K, and that state contracts must be updated to include these requirements. We are proposing to amend the regulation at § 438.3(s) and (s)(4) and (5) to require that MCEs comply with the requirements in section 1902(oo)(1)(A) of the Act as implemented in these proposed regulations, similar to MCOs, PIHPs, and PAHPs.

[101] ''CDC Guidelines for Prescribing Opioids for Chronic pain.'' Available at *https://www.cdc.gov/drugoverdose/pdf/guidelines_at-a-glance-a.pdf.*

[102] Section 1902(oo)(3) of the Act, as added by section 1004 of the SUPPORT for Patients and Communities Act.

[103] *H.R. 6. 24 Oct. 2018, www.congress.gov/115/bills/hr6/BILLS-115hr6enr.pdf. Page 17.*

5. Reporting Requirements

Consistent with section 1927(g)(3)(D) of the Act, we require each State Medicaid agency to submit to us an annual report on the operation of its Medicaid DUR program. Under § 456.712(a), the state must require the DUR Board to prepare and submit, on an annual basis, a report to the State Medicaid agency. Under § 456.712(b), each State Medicaid agency must in turn submit this report to us, as well as specified additional information, including but not limited to descriptions of the nature and scope of the state's prospective and retrospective DUR programs, detailed information on the specific DUR criteria and standards in use, a description of the actions taken to ensure compliance with predetermined standards requirements in § 465.703, a summary of the educational interventions used and an assessment of their effect on quality of care, and an estimate of the cost savings generated as a result of the DUR program. We have compiled state FFS Medicaid DUR annual reports since 1995 and has published them on *Medicaid.gov* since 2010. Since 2016, § 438.3(s)(4) requires any MCO, PIHP or PAHP that covers covered outpatient drugs to operate a DUR program that complies with section 1927(g) of the Act and 42 CFR part 456, subpart K, as though these requirements applied to the MCO, PIHP, or PAHP instead of the state, including requirements related to annual DUR reporting. Given the commercial nature of many managed care entities, incorporation of information posted to *Medicaid.gov* provides new considerations with regards to public disclosure of information received by CMS.

In an effort to share and encourage innovative and collaborative practices, we also are proposing to publish all information received in annual DUR reports from managed care programs and FFS programs on a CMS website. Accordingly, we are proposing to add new paragraph (c) to § 456.712 to provide that all FFS and managed care DUR reports received by CMS under § 456.712(b) and, as applicable, pursuant to § 438.3(s), will be publicly posted on a website maintained by CMS for the sharing of reports and other information concerning Medicaid DUR programs.

6. State Plan Amendment (SPA) Requirements

The SUPPORT for Patients and Communities Act amended the state plan requirements in section 1902(a) of the Act to include a new paragraph (85), which requires the state plan to provide that the state is in compliance with the new drug review and utilization requirements set forth in section 1902(oo) of the Act, as also added by the SUPPORT for Patients and Communities Act. The SUPPORT for Patients and Communities Act also requires all states to implement these requirements by October 1, 2019, and to submit an amendment to their state plan no later than December 31, 2019, consistent with the state plan amendment requirements in 42 CFR part 430, subpart B, to describe how the state addresses these provisions in the state plan. States are also expected to give appropriate tribal notification, as required, if applicable. Guidance regarding requirements was issued to states in a CMS informational bulletin *https://www.medicaid.gov/federal-policy-guidance/downloads/cib080519-1004.pdf.* If provisions in this proposed rule that would implement the amendments made by section 1004 of the SUPPORT for Patients and Communities Act are finalized, an additional state plan amendment potentially could be needed to ensure that state plans are in compliance with applicable final regulations. We would expect to provide related guidance in connection with any final rule.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a ''collection of information'' requirement is submitted to the Office of Management and Budget (OMB) for review and approval. For the purposes of the PRA and this section of the preamble, collection of information is defined under 5 CFR 1320.3(c) of the PRA's implementing regulations.

To fairly evaluate whether an information collection must be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this proposed rule that contain information collection requirements.

A. Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2018 National Occupational Employment and Wage Estimates (*http://www.bls.gov/oes/current/oes_nat.htm*). Table 3 presents the mean hourly wage, the cost of fringe benefits and overhead (calculated at 100 percent of salary), and the adjusted hourly wage.

TABLE 3—NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation title	Occupation code	Mean hourly wage ($/hr)	Fringe benefits and overhead ($/hr)	Adjusted hourly wage ($/hr)
Chief Executives	11–1011	96.22	96.22	192.44
Data Entry and Information Processing Workers	43–9020	17.05	17.05	34.10
General Operations Mgr	11–1021	59.56	59.56	119.12

As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

B. Proposed Information Collection Requirements (ICRs)

1. ICRs Regarding State Plan Requirements, Findings, and Assurances (§ 447.518(d)(1) and (2))

The following proposed changes will be submitted to OMB for approval under control number 0938–TBD (CMS–10722). The control number is currently to be determined (TBD) but will be issued by OMB upon their clearance of this proposed rule's information collection request (a.k.a., ''PRA package''). The subsequent final rule will set out the assigned control number.

Under section 1902(a)(30)(A) the Act, we are granted the authority to require that methods and procedures be established by states relating to the utilization of, and the payment for, care and services available under the state plan process (including but not limited to utilization review plans) as may be necessary to safeguard against unnecessary utilization of such care and services and to assure that state payments to providers of Medicaid services are consistent with efficiency, economy, and quality of care.

To that end, as part of the state plan approval process relative to the VBP program, this rule proposes new reporting requirements that would affect the 51 state Medicaid programs (the 50 states and the District of Columbia). Specifically, a State participating in value-based purchasing arrangements must report data described in § 447.518(d)(1) and (2) on an annual basis and no later than 60 days after the end of each year. The reported data would include: The State name, National drug code(s) (for drugs covered under the VBP), product FDA list name, number of prescriptions, cost to the State to administer VBP (for example: Systems changes, tracking evidence or outcomes-based measures, etc.), and the total savings generated by the supplemental rebate due to the VBP. The reporting requirements would be applicable to both FFS and MCO COD claims. Following our evaluation of the response to this proposed rule, we may decide to issue a form to help ensure that the proper information is reported at the proper address.

We estimate it would take an additional 4 hours at $119.12/hr for a general operations manager to collect the supplemental rebate agreement VBP drug utilization information, add this data to the state's quarterly report when due annually (we will choose the quarter in which the annual data will be due), and submit the report to CMS. In aggregate we estimate an ongoing annual burden of 306 hours (6 hr/report × 1/year × 51 respondents) at a cost of $36,444.60 (816 hr × $119.12/hr).

2. ICRs Regarding Requirements for States (§ 447.511(b), (d) and (e))

The following proposed changes will be submitted to OMB for approval under control number 0938–0582 (CMS–R–144). Subject to renewal, the control number is currently set to expire on July 31, 2020. It was last approved on March 14, 2019, and remains active.

Under proposed § 447.511(b) states, territories, and the District of Columbia would be required to ensure by certification that the quarterly rebate invoices sent to manufacturers that participate in the MDRP no later than 60 days after the end of each rebate period via CMS–R–144 (Quarterly Medicaid Drug Rebate Invoice), mirrors the data sent to us. This rule would not impose any changes to the CMS–R–144 form.

Under proposed § 447.511(d) states would now be required to certify that their SDUD meets the requirements specified under proposed § 447.511(e) via a certification statement. We believe the certification would not impose a significant burden as we will provide systems access to state certifiers to log in once per quarter to certify their SDUD report. Certifiers would have to apply for a CMS user ID and password, and keep current with required annual computer-based training, as current state staff with access to our systems must do. To comply with the proposed certification requirements, States must already have system edits in place to find and correct SDUD outliers prior to reporting to manufacturers and CMS.

We estimate it would take 5 hours at $192.44/hr for the State Medicaid Director, Deputy State Medicaid Director, another individual with equivalent authority, or an individual with directly delegated authority from one of the above to obtain current CMS systems access. In aggregate we estimate a one-time system ID/password access burden of 280 hours (5 hr × 56 respondents) at a cost of $53,883 (280 hr × $192.44/hr).

We also estimate an additional annual burden of 2 hours (or 30 minutes/quarter) at $192.44/hr for a chief executive to certify such data and to add the state data certification language in their submission. In aggregate we estimate a burden of 112 hours (2 hr × 56 respondents) at a cost of $21,553 (112 hr × $192.44/hr).

3. ICRs Regarding the Payment of Claims 18 (§ 433.139(b)(2), (b)(3)(i) and (b)(3)(ii)(B))

The following proposed changes will be submitted to OMB for approval under control number 0938–1265 (CMS–10529). Subject to renewal, the control number is currently set to expire on April 30, 2021. It was last approved on June 10, 2019, and remains active.

This proposed rule would implement provisions of Bipartisan Budget Act of 2018 (BBA 2018) (Pub. L. 115–123, enacted February 9, 2018), which includes several provisions that modify COB and TPL in both statute and regulation related to special treatment of certain types of care and payment in Medicaid and Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA) (Pub. L. 111–3, enacted February 4, 2009). Section 53102 of BBA 2018 amended the TPL provision at section 1902(a)(25) of the Act. Effective February 9, 2018, section 53102(a)(1) of the BBA 2018 amended section 1902(a)(25)(E) of the Act to require states to cost avoid claims for prenatal care for pregnant women including labor and delivery and postpartum care, and to allow the state Medicaid agency 90 days instead of 30 days to pay claims related to medical support enforcement services, as well as requiring states to collect information on TPL before making payments. Effective April 18, 2019, section 7 of the Medicaid Services Investment and Accountability Act of 2019 (the MSIAA) amended section 1902(a)(25)(E) of the Act to allow 100 days instead of 90 days to pay claims related to medical support enforcement services, as well as requiring states to collect information on TPL before making payments.

On April 18, 2019, section 7 of the MSIAA amended section 1902(a)(25)(E) of the Act to allow 100 days instead of 90 days to pay claims related to medical support enforcement and preventive pediatric services, as well as requiring all states, the District of Columbia, and the territories (56 respondents) to collect information on third party TPL before making payments (§ 433.139(b)(2), (b)(3)(i) and (b)(3)(ii)(B)). Under the authority in section 1902(a)(25)(A) of the Act, our regulations at 42 CFR part 433, subpart D establishes

requirements for state Medicaid agencies to support the coordination of benefits (COB) effort by identifying TPL. Sections 433.139(b)(2), (b)(3)(i) and (b)(3)(ii)(B) detail the exception to standard COB cost avoidance by allowing pay and chase for certain types of care, as well as the timeframe allowed prior to Medicaid paying claims for certain types of care. Title XIX of the Act requires state Medicaid programs to identify and seek payment from liable third parties, before billing Medicaid.

We estimate it would take 1 hour at $34.10/hr for a data entry/information processing worker to collect information on TPL and report that information to CMS on CMS–64 (approved by OMB under the aforementioned OMB control number and CMS ID number) on a quarterly basis. In aggregate we estimate an annual burden of 224 hours (1 hr/response × 4 responses/year × 56 respondents) at a cost of $7,638 (224 hr × $34.10/hr).

C. Summary of Proposed Requirements and Annual Burden Estimates

Table 4 sets out our proposed annual burden estimates.

TABLE 4—SUMMARY OF ANNUAL REQUIREMENT AND BURDEN

Section under Title 42 of the CFR	Number of respondents	Responses (per year)	Time per response (hours)	Total time (hours)	Labor rate ($/hr)	Total cost ($)	OMB Control No. (CMS ID No.)
§ 447.511	56	1	5	280	192.44	53,883	0938–0582 (CMS–R–144).
§ 447.511	56	4	0.5	112	192.44	21,553	0938–0582 (CMS–R–144).
§ 447.518(d)(1) and (2)	51	1	6	306	119.12	36,440	0938–TBD (CMS–10722).
§ 433.139(b)(2), (b)(3)(i) and (b)(3)(ii)(B).	56	4	1	224	34.10	7,638	0938–1265 (CMS–10529).
Total	56	13	Varies	1,432	Varies	180,276	n/a.

D. Submission of PRA-Related Comments

We have submitted a copy of this proposed rule to OMB for its review of the rule's information collection requirements. The requirements are not effective until they have been approved by OMB and a final rule is issued.

To obtain copies of the supporting statement and any related forms for the proposed collections discussed above, please visit the CMS website at *www.cms.hhs.gov/PaperworkReductionActof1995,* or call the Reports Clearance Office at 410–786–1326.

We invite public comments on these potential information collection requirements. If you wish to comment, please submit your comments electronically as specified in the **DATES** and **ADDRESSES** Section of this proposed rule and identify the rule (CMS–2482–P) the ICR's CFR citation, and OMB control number.

V. Response to Comments

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

VI. Regulatory Impact Statement

A. Statement of Need

This proposed rule would implement changes to:

- Section 1927 of the Act
- Statutory changes from the Medicaid Services Investment and Accountability Act of 2019 (Pub. L. 116–16, enacted April 18, 2019), BBA 2018 and the Affordable Care Act;
- Section 602 of BBA 2015, which amended section 1927(c)(3) of the Act;
- Section 2501(d) of the Affordable Care Act, which added section 1927(c)(2)(C) of the Act;
- Section 1927(b)(2)(A) of the Act requiring states to report to each manufacturer not later than 60 days after the end of each rebate period;
- Changes and additions to section 1927(g)(1) of the Act as set forth by section 1004 of the SUPPORT for Patients and Communities Act; and
- Title XIX of the Act and section 7 of the Medicaid Services Investment and Accountability Act of 2019 amending section 1902(a)(25)(E) of the Act ((§ 433.139(b)(2), (b)(3)(i) and (b)(3)(ii)(B)).
- Changes made by Public Law 116–59, the Continuing Appropriations Act, 2020, and Health Extenders Act of 2019 (Health Extenders Act), which made changes to section 1927(k)(1) and 1927(k)(11) of the Act.

B. Overall Impact

We have examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999) and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). This rule does not reach the economic threshold and thus is not considered a major rule.

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, small pharmaceutical manufacturers participating in the Medicaid Drug Rebate Program, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than $8.0 million to $41.5 million in any 1 year. Individuals and states are not included in the definition of a small entity. We are not preparing an analysis for the RFA because we have determined, and the Secretary certifies, that this proposed rule would not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603

of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this proposed rule with comment period would not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2020, that threshold is approximately $156 million. This rule would have no consequential effect on state, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a proposed rule (and subsequent final rule) that imposes substantial direct compliance costs on state and local governments, preempts state law, or otherwise has federalism implications. Since this regulation does not impose any substantial direct compliance costs on state or local governments, preempt state law, or otherwise have federalism implications, the requirements of Executive Order 13132 are not applicable.

Executive Order 13771 (January 30, 2017) requires that the costs associated with significant new regulations ''to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.'' This proposed rule is not subject to the requirements of E.O. 13771 because it is expected to result in no more than de minimis costs.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 433

Administrative practice and procedure, Child support, Claims, Grant programs-health, Medicaid, Reporting and recordkeeping requirements.

42 CFR Part 438

Grant programs-health, Medicaid, Reporting and Recordkeeping requirements.

42 CFR Part 447

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

42 CFR Part 456

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

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

PART 433—STATE FISCAL ADMINISTRATION

■ 1. The authority citation for part 433 is revised to read as follows:

Authority: 42 U.S.C. 1302.

■ 2. Section 433.139 is amended by—
■ a. Removing and reserving paragraph (b)(2); and
■ b. Revising paragraphs (b)(3)(i) and (b)(3)(ii)(B).

The revisions read as follows:

§ 433.139 Payment of claims.

* * * * *

(b) * * *

(2) [Reserved]

(3) * * *

(i) The claim is for preventive pediatric services, including early and periodic screening, diagnosis and treatment services provided for under part 441, subpart B of this chapter, that are covered under the State plan; or

(ii) * * *

(B) For child support enforcement services beginning February 9, 2018, the provider certifies that before billing Medicaid, if the provider has billed a third party, the provider has waited 100 days from the date of the service and has not received payment from the third party.

* * * * *

PART 438—MANAGED CARE

■ 3. The authority citation for part 438 continues to read as follows:

Authority: 42 U.S.C. 1302.

■ 4. Section 438.2 is amended by adding the definition of ''Managed care entities (MCEs) in alphabetical order to read as follows:

§ 438.2 Definitions.

* * * * *

Managed care entity (MCE) means a Medicaid managed care organization, as defined in section 1903(m)(1)(A) of the Act, that provides or arranges for services for enrollees under a contract pursuant to section 1903(m) of the Act or a primary care case manager, as defined in section 1905(t)(2) of the Act.

* * * * *

■ 5. Section 438.3 is amended by revising paragraphs (s) introductory text, (s)(4) and (5) to read as follows:

§ 438.3 Standard contract requirements.

* * * * *

(s) *Requirements for MCOs, MCEs, PIHPs, or PAHPs that provide covered outpatient drugs.* Contracts that obligate MCOs, MCEs, PIHPs or PAHPs to provide coverage of covered outpatient drugs must include the following requirements:

* * * * *

(4) The MCO, MCE, PIHP or PAHP must operate a drug utilization review program that complies with the requirements described in section 1927(g) of the Act and part 456, subpart K of this chapter, as if such requirement applied to the MCO, MCE, PIHP, or PAHP instead of the State.

(5) The MCO, MCE, PIHP or PAHP must provide a detailed description of its drug utilization review program activities to the State on an annual basis.

* * * * *

PART 447—PAYMENTS FOR SERVICES

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

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

■ 7. Section 447.502 is amended—
■ a. In the definition of ''Bundled sale'' by adding paragraph (3);
■ b. By adding the definition of ''CMS-authorized supplemental rebate agreement'' in alphabetical order;
■ c. By revising the definition of ''Innovator multiple source drug'';
■ d. By adding the definition of ''Line extension'' in alphabetical order;
■ e. By revising the definition of ''Multiple source drug'';
■ f. By adding the definition of ''New formulation'' in alphabetical order;
■ g. By revising the definitions of ''Oral solid dosage form'' and ''Single source drug'';
■ h. By adding the definitions of ''Value-based purchasing (VBP) arrangement'' in alphabetical order; and
■ i. By revising the definition of ''Wholesaler''.

The additions and revisions read as follows:

§ 447.502 Definitions.

* * * * *

Bundled sale * * *

(3) Value-based purchasing (VBP) arrangements may qualify as a bundled sale, if the arrangement contains a performance requirement such as an outcome(s) measurement metric.

* * * * *

CMS-authorized supplemental rebate agreement means an agreement 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 that are at least as large as the rebates set forth in the Secretary's national rebate agreement with drug manufacturers. Revenue from these rebates must be paid directly to the state and be used by the state to offset a state's drug expenditures resulting in shared savings with the Federal government.

* * * * *

Innovator multiple source drug means a multiple source drug, including an authorized generic drug, that is marketed under a new drug application (NDA) approved by FDA, unless the Secretary determines that a narrow exception applies (as described in this section or any successor regulation). It also includes a drug product marketed by any cross-licensed producers, labelers, or distributors operating under the NDA and a covered outpatient drug approved under a biologics license application (BLA), product license application (PLA), establishment license application (ELA) or antibiotic drug application (ADA).

* * * * *

Line extension means, for a drug, a new formulation of the drug, but does not include an abuse-deterrent formulation of the drug (as determined by the Secretary).

* * * * *

Multiple source drug means, 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 Act, 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/*).

(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.

* * * * *

New formulation means, 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. 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.

* * * * *

Oral solid dosage form means an orally administered dosage form that is not a liquid or gas at the time the drug enters the oral cavity.

* * * * *

Single source drug means 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 (as described in this section or any successor regulation), and includes a covered outpatient drug that is a biological product licensed, produced, or distributed under a biologics license application approved by the FDA.

* * * * *

Value-based purchasing (VBP) arrangement means an arrangement or agreement intended to align pricing and/or payments to an observed or expected therapeutic or clinical value in a population (that is, outcomes relative to costs) 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.

(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.

Wholesaler means a drug wholesaler that is engaged in wholesale distribution of prescription drugs to retail community pharmacies, including but not limited to repackers, distributors, own-label distributors, private-label distributors, jobbers, brokers, warehouses (including distributor's warehouses, chain drug warehouses, and wholesale drug warehouses), independent wholesale drug traders, and retail community pharmacies that conduct wholesale distributions.

■ 8. Section 447.504 is amended by—

■ a. Removing paragraph (b)(2);

■ b. Redesignating paragraph (b)(3) as paragraph (b)(2);

■ c. Revising paragraphs (c)(25) through (29); and

■ d. Revising paragraphs (e)(13) through (17).

The revisions read as follows:

§ 447.504 Determination of average manufacturer price.

* * * * *

(c) * * *

(25) Manufacturer coupons to a consumer redeemed by the manufacturer, agent, pharmacy or another entity acting on behalf of the manufacturer, but only to the extent that the manufacturer ensures the full value of the coupon is passed on to the consumer and the pharmacy, agent, or other AMP-eligible entity does not receive any price concession.

(26) Manufacturer-sponsored programs that provide free goods, including but not limited to vouchers and patient assistance programs, but only to the extent that the manufacturer ensures: The voucher or benefit of such a program is not contingent on any other purchase requirement; The full value of the voucher or benefit of such a program is passed on to the consumer; and the pharmacy, agent, or other AMP-eligible entity does not receive any price concession.

(27) Manufacturer-sponsored drug discount card programs, but only to the extent that the manufacturer ensures the full value of the discount is passed on to the consumer and the pharmacy, agent, or the other AMP eligible entity does not receive any price concession.

(28) Manufacturer-sponsored patient refund/rebate programs, to the extent that the manufacturer ensures that the manufacturer provides a full or partial refund or rebate to the patient for out-of-pocket costs and the pharmacy, agent, or other AMP eligible entity does not receive any price concession.

(29) Manufacturer copayment assistance programs, to the extent that the manufacturer ensures the program benefits are provided entirely to the

patient and the pharmacy, agent, or other AMP eligible entity does not receive any price concession

* * * * *

(e) * * *

(13) Manufacturer coupons to a consumer redeemed by the manufacturer, agent, pharmacy or another entity acting on behalf of the manufacturer, but only to the extent that the manufacturer ensures the full value of the coupon is passed on to the consumer and the pharmacy, agent, or other AMP-eligible entity does not receive any price concession.

(14) Manufacturer-sponsored programs that provide free goods, including, but not limited to vouchers and patient assistance programs, but only to the extent that the manufacturer ensures: The voucher or benefit of such a program is not contingent on any other purchase requirement; The full value of the voucher or benefit of such a program is passed on to the consumer; and the pharmacy, agent, or other AMP eligible entity does not receive any price concession.

(15) Manufacturer-sponsored drug discount card programs, but only to the extent that the manufacturer ensures the full value of the discount is passed on to the consumer and the pharmacy, agent, or the other AMP-eligible entity does not receive any price concession.

(16) Manufacturer-sponsored patient refund/rebate programs, to the extent that the manufacturer ensures the manufacturer provided a full or partial refund or rebate to the patient for out-of-pocket costs and the pharmacy agent, or other AMP eligible entity does not receive any price concession.

(17) Manufacturer copayment assistance programs, to the extent that the manufacturer ensures the program benefits are provided entirely to the patient and the pharmacy agent, or other AMP eligible entity does not receive any price concession

* * * * *

■ 9. Section 447.505 is amended—

■ a. In paragraph (a), by revising the definition of ''Best price'';

■ b. In paragraphs (c)(8) and (9), by removing the phrase ''extent that'' and adding in its place the phrase ''extent the manufacturer ensures that'';

■ c. In paragraphs (c)(10), (11) and (12), by removing the phrase ''that the'' and adding in its place the phrase ''that the manufacturer ensures the''; and

■ d. By revising paragraphs (d)(3).

The revisions reads 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. The lowest price available from a manufacturer may include varying best price points for a single dosage form and strength as a result of a value based purchasing arrangement (as defined at § 447.502).

* * * * *

(d) * * *

(3) The manufacturer must adjust the best price for a rebate period if cumulative discounts, rebates, or other arrangements subsequently adjust the prices available, to the extent that such cumulative discounts, rebates or other arrangements are not excluded from the determination of best price by statute or regulation.

■ 10. Section 447.506 is amended by revising paragraph (b) to read as follows:

§ 447.506 Authorized generic drugs.

* * * * *

(b) *Exclusion of authorized generic drugs from AMP by a primary manufacturer.* 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 of that authorized generic drug.

* * * * *

■ 11. Section 447.509 is amended—

■ a. By revising paragraphs (a)(4)(i) introductory text, (a)(4)(i)(A), (a)(4)(ii) introductory text, (a)(4)(ii)(A), and (a)(5);

■ b. In paragraph (a)(6) introductory text, by removing word ''rebate'' and adding in its place the phrase ''basic rebate''; and

■ c. By adding paragraphs (a)(7), (8) and (9).

The revisions and additions read as follows:

§ 447.509 Medicaid drug rebates (MDR).

(a) * * *

(4) * * *

(i) In the case of 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, the rebate obligation for the rebate periods beginning January 1, 2010 through September 30, 2018 is the amount computed under paragraphs (a)(1) through (3) of this section for such new drug or, if greater, the product of all of the following:

(A) The AMP of the line extension of a single source drug or an innovator multiple source drug.

* * * * *

(ii) In the case of 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, the rebate obligation for the rebate periods beginning on or after October 1, 2018 is the amount computed under paragraphs (a)(1) through (3) of this section for such new drug or, if greater, the amount computed under paragraph (a)(1) of this section plus the product of all of the following:

(A) The AMP of the line extension of a single source drug or an innovator multiple source drug.

* * * * *

(5) *Limit on rebate.* In no case will the total rebate amount exceed 100 percent of the AMP of the single source or multiple source innovator drug.

* * * * *

(7) *Additional rebate for noninnovator multiple source drugs.* In addition to the basic rebate described in paragraph (a)(6) of this section, for each dosage form and strength of a noninnovator multiple source drug, the rebate amount will be increased by an amount equal to the product of the following:

(i) The total number of units of such dosage form and strength paid for under the State plan in the rebate period.

(ii) The amount, if any, by which:

(A) The AMP for the dosage form and strength of the drug for the period exceeds: (B) The base date AMP for such dosage form and strength, increased by the percentage by which the consumer price index for all urban consumers (United States city average) for the month before the month in which the rebate period begins exceeds such index associated with the base date AMP of the drug. The base date AMP has the meaning of AMP set forth in sections 1927(c)(2)(A)(ii)(II), 1927(c)(2)(B) and 1927(c)(3)(C) of the Act.

(8) *Total rebate.* The total rebate amount for noninnovator multiple source drugs is equal to the basic rebate amount plus the additional rebate amount, if any.

(9) *Limit on rebate.* In no case will the total rebate amount exceed 100 percent of the AMP for the noninnovator multiple source drug.

* * * * *

■ 12. Section 447.510 is amended by adding paragraph (b)(1)(vi) to read as follows:

§ 447.510 Requirement for manufacturers.

* * * * *

(b) * * *

(1) * * *

(vi) The change is a result of a VBP arrangement, as defined in § 447.502, requiring the manufacturer to make changes outside of the 12-quarter rule, when the outcome must be evaluated outside of the 12-quarter period.

* * * * *

■ 13. Section 447.511 is amended—

■ a. In paragraph (a) introductory text, by removing the phrase ''following data:'' and adding in its place the phrase ''following data and any subsequent changes to the data fields on the CMS–R–144 Medicaid Drug Rebate Invoice form:'';

■ b. By revising paragraph (b); and

■ c. By adding paragraphs (d) and (e).

The revision and additions read as follows:

§ 447.511 Requirements for States.

* * * * *

(b) *Data submitted to CMS.* On a quarterly basis, the State must submit drug utilization data to CMS, which will be the same information as submitted to the manufacturers on the CMS–R–144, as specified in paragraph (a) of this section. The state data submission will be due no later than 60 days after the end of each rebate period. In the event that a due date falls on a weekend or Federal holiday, the submission will be due on the first business day following that weekend or Federal holiday. Any adjustments to previously submitted data will be transmitted to the manufacturer and CMS in the same reporting period.

* * * * *

(d) *State data certification.* Each data submission in this section must be certified by one of the following:

(1) The State Medicaid Director (SMD);

(2) The Deputy State Medicaid Director (DSMD);

(3) An individual other than the SMD or DSMD, who has authority equivalent to an SMD or DSMD; or

(4) An individual with the directly delegated authority to perform the certification on behalf of an individual described in paragraphs (d)(1) through (3) of this section.

(e) *State data certification language.* Each data submission by a state must include the following certification language: ''I hereby certify, to the best of my knowledge, that the state's data submission is complete and accurate at the time of this submission, and was prepared in accordance with the state's good faith, reasonable efforts based on existing guidance from CMS, section 1927 of the Act and applicable federal regulations. I further certify that the state has transmitted data to CMS, including any adjustments to previous rebate periods, in the same reporting period as provided to the manufacturer. Further, the state certifies that it has applied any necessary edits to the data for both CMS and the labeler to avoid inaccuracies at both the NDC/line item and file/aggregate level. Such edits are to be applied in the same manner and in the same reporting period to both CMS and the manufacturer.''

■ 14. Section 447.518 is amended by adding paragraphs (d)(1) and (2) to read as follows:

§ 447.518 State plan requirements, findings, and assurances.

* * * * *

(d) * * *

(1) A State participating in value-based purchasing arrangements must report data described in paragraph (d)(2) of this section on an annual basis.

(2) Within 60 days of the end of each year, the State must submit all of the following data:

(i) State.

(ii) National drug code(s) (for drugs covered under the VBP).

(iii) Product FDA list name.

(iv) Number of prescriptions.

(v) Cost to the State to administer VBP (for example, systems changes, tracking outcomes, etc.).

(vi) Total savings generated by the supplemental rebate due to VBP.

PART 456—UTILIZATION CONTROL

■ 15. The authority citation for part 456 is revised to read as follows:

Authority: 42 U.S.C. 1302.

■ 16. Section 456.703 is amended by—

■ a. Redesignating paragraph (h) as (i); and

■ b. Adding a new paragraph (h).

The addition reads as follows:

§ 456.703 Drug use review programs.

* * * * *

(h) *Minimum standards for DUR programs.* (1) *Minimum standards.* In operating their DUR programs, states must include the following minimum standards:

(i) Prospective safety edit limitations for opioid prescriptions, as specified by the State, on:

(A) Days' supply for patients not currently receiving opioid therapy for initial prescription fills;

(B) Quantity of prescription dispensed for initial and subsequent prescription fills;

(C) Therapeutically-duplicative initial and subsequent opioid prescription fills; and

(D) Early refills, for subsequent prescription fills.

(ii) Prospective safety edit limitations for opioid prescriptions, as specified by the State, on the maximum daily morphine milligram equivalent for treatment of chronic pain, for initial and subsequent prescription fills.

(iii) A retrospective claims review automated process that indicates prescription fills of opioids in excess of the prospective safety edit limitations specified by the state under paragraphs (h)(1)(i) or (ii) of this section to provide for the ongoing review of opioid claims data to identify patterns of fraud, abuse, excessive utilization, inappropriate or medically unnecessary care, or prescribing or billing practices that indicate abuse or provision of inappropriate or medically unnecessary care among prescribers, pharmacists and individuals receiving Medicaid benefits.

(iv) 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:

(A) Benzodiazepines; or

(B) Antipsychotics.

(v) A program to monitor and manage the appropriate use of antipsychotic medications by children enrolled under the State plan, including any Medicaid expansion groups for the Children's Health Insurance Program (CHIP).

(vi) A process to identify potential fraud or abuse of controlled substances by individuals enrolled under the State plan, health care providers prescribing drugs to individuals so enrolled, and pharmacies dispensing drugs to individuals so enrolled.

(vii) Prospective safety edits, retrospective claims review automated processes, or a combination of these approaches as determined by the state, to identify when:

(A) A beneficiary is prescribed an opioid after the beneficiary has been prescribed one or more drugs used for Medication Assisted Treatment (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 new cancer diagnosis or entry into hospice care); and

(B) A beneficiary could be at high risk of opioid overdose and should be considered for co-prescription or co-dispensing of naloxone.

(2) *Exclusion.* The requirements in paragraphs (h)(1)(i) through (vii) of this section do not apply with respect to individuals receiving hospice or palliative care or treatment for cancer; individuals 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 other individuals the state elects to exempt. While States are not required to apply these requirements with respect to these individuals, States may elect to do so.

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■ 17. Section 456.712 is amended by adding paragraph (c) to read as follows:

§ 456.712 Annual report.

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(c) *Public availability.* All FFS and managed care DUR reports received by CMS under paragraph (b) of this section and, as applicable, pursuant to § 438.3(s) of this chapter, will be publicly posted on a website maintained by CMS for the sharing of reports and other information concerning Medicaid DUR programs.

Dated: February 6, 2020.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: June 11, 2020.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

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