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
(Final Rule – December 2020)

> ***Note**: This document shows how the final rule differs from the proposed rule. Additions are in blue text. Deletions are in red text. Please see the accompanying client alert for a summary of these changes.*

PART 447—PAYMENTS FOR SERVICES

~~6~~5. The authority citation for part 447 continues to read as follows:

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

~~7~~6. 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~~"Multiple source drug"~~;~~.

~~e. By revising the definition of ''Multiple~~and"Single 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~~d. 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.~~
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~~*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.

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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 select 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 covered outpatient drug to existing evidence of effectiveness and potential value for specific uses of that product~~.~~; and/or

(2) Outcomes-based measures, which substantially link payment for the covered outpatient 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.

7. Section 447.502 is further amended, effective January 1, 2022, by—

a. Adding the definitions of "Line extension", and "New formulation" in alphabetical order; and

b. Revising the definition of "Oral solid dosage form".

The additions and revision read as follows:

§ 447.502 Definitions.

* * * * *

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).

* * * * *

New formulation means, for a drug, a change to the drug, including, but not limited to: an extended release formulation or other change in release mechanism, a change in dosage form, strength, route of administration, or ingredients.

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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.

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§ 447.504 [Amended]

8. Section 447.504 is amended by—
removing paragraph (b)(2) and redesignating ~~a. Removing paragraph (b)(2);~~
~~b. Redesignating~~ paragraph (b)(3) as paragraph (b)(2)~~;~~.

9. Section 447.504 is further amended, effective January 1, 2023, by revising paragraphs
~~c. Revising paragraphs~~ (c)(25) through (29)~~;~~ and
~~d. Revising~~ paragraphs (e)(13) through (17)~~.~~
to ~~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~~the voucher or benefit of such a program is not contingent on any other purchase requirement;
~~The~~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~~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: Thethe voucher or benefit of such a program is not contingent on any other purchase requirement; Thethe 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-sponsoredManufacturer –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

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910. Section 447.505 is amended—

a. Effective January 1, 2022, iIn 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

b. Effective [Insert date 60 days after date of publication in the **Federal** Register], bBy revising paragraphsparagraph (d)(3).

The revisions readsread 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. TheIf a manufacturer offers a value based purchasing arrangement (as defined at § 447.502) to all states, the lowest price available from a manufacturer may include varying best price points for a single dosage form and strength as a result of athat value based purchasing arrangement (as defined at § 447.502).

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(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~~11. Section ~~447.506~~447.505 is amended by revising ~~paragraph (b~~paragraphs (c)(8) through (12) to read as follows:

§ 447.505 Determination of best price.

* * * * *

(c) * * *

(8) Manufacturer-sponsored drug discount card programs, but only to the extent the manufacturer ensures 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.

(9) Manufacturer coupons to a consumer redeemed by a consumer, agent, pharmacy, or another entity acting on behalf of the manufacturer; but only to the extent the manufacturer ensures 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.

(10) 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 entity does not receive any price concession.

(11) Manufacturer-sponsored patient refund or rebate programs, to the extent that the manufacturer ensures 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.

(12) 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 entity does not receive any price concession.

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12. Section 447.506 is amended—

a. In paragraph (a) by revising the definition of “Secondary manufacturer of an authorized generic drug”; and

b. By revising paragraph (b).

The revisions read as follows:

§ 447.506 Authorized generic drugs.

(a) * * *

Secondary manufacturer of an authorized generic drug means a manufacturer that is authorized by the primary manufacturer to sell the drug.

(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.

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~~11~~13. Section 447.509 is amended—

a. Revising paragraph (a)(5);

~~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~~revision 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.~~

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~~(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.~~

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(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.
AMP of the single source or multiple source innovator drug.

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(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.

(B) 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.

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14. Section 447.509 is further amended, effective January 1, 2023, by—

a. By revising paragraphs (a)(4)(ii) introductory text;

b. By redesignating paragraph (a)(4)(iii) as paragraph (a)(4)(iv); and

c. Adding a new paragraph (a)(4)(iii).

The revision and addition read as follows”

§ 447.509 Medicaid drug rebates (MDR).

(a) * * *

(4) * * *

(ii) 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, the rebate obligation for the rebate periods beginning on October 1, 2018 through December 31, 2021 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:

* * * * *

(iii) 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 and after January 1, 2022 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.

(B) The highest additional rebate (calculated as a percentage of AMP) under this section for any strength of the original single source drug or innovator multiple source drug.

(C) The total number of units of each dosage form and strength of the line extension product paid for under the State plan in the rebate period (as reported by the State).

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~~12~~15. 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.

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~~13~~16. Section 447.511 is amended, effective January 1, 2022—

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.

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(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.

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(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 ~~f~~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~~manufacturer 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."

13. Section 447.518 is amended , effective January 1, 2022, by—

a. Redesignating the text of paragraph (d) introductory text as paragraph (d)(1); and

~~14. Section 447.518 is amended by adding~~b. Adding paragraphs (d)(~~1~~2) and (~~2~~3) ~~to read as follows:~~.

The additions read as follows:

§ 447.518 State plan requirements, findings, and assurances.

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(d) * * *

(~~1~~2) A State participating in ~~value-based purchasing~~VBP arrangements approved under a CMS-authorized supplemental rebate agreement (SRA) must report data described in paragraph (d)(~~2~~3) of this section on an annual basis.

(~~2~~3) Within 60 days of the end of each year, the State must submit all of the following data, including cumulative data to date:

(i) State.

(ii) National drug code(s) (for drugs covered under the CMS-authorized VBP SRA).

(iii) ~~Product~~Product's FDA list name.

(iv) Number of prescriptions.

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

(vi) Total savings generated by the supplemental rebate due to the CMS-authorized VBP SRA.