additional information, if necessary, regarding the fee waiver request. If the additional information is not received from the requester within 10 days of the FOIA Officer's communication with the requester, VA will assume that the requester does not wish to pursue the fee waiver request and the fee waiver request will be closed. If the request for waiver or reduction is denied or closed, the underlying FOIA request will continue to be processed in accordance with the applicable provisions of this Part. Requests for fee waivers are decided on a case-by-case basis; receipt of a fee waiver in the past does not establish entitlement to a fee waiver each time a request is submitted.

* * * * *

■ 12. In § 1.577, revise paragraphs (c) and (e) to read as follows:

§ 1.577 Access to Records.

* * * * *

(c) The VA component or staff office having jurisdiction over the records subject to the Privacy Act request will establish appropriate disclosure procedures, including notifying the individual who filed the Privacy Act request of the time, place, and conditions under which the VA will comply with the request, in accordance with applicable laws and regulations. Access requests for Privacy Act records or information must be sent to the staff office that maintains the records; the individual seeking access may consult the system of record notice (*https://www.oprm.va.gov/privacy/systems_of_records.aspx*) in order to identify the office to which the request should be sent. Each component has discretion to require that a requester supply additional information to verify his or her identity. If the Privacy Officer determines that the request does not reasonably describe the records being sought, the Privacy Officer will advise the requester how the request is insufficient; the Privacy Officer will provide an opportunity to discuss the request by documented telephonic communication or written correspondence in order to modify it to clearly identify the records being sought.

* * * * *

(e) Fees to be charged, if any, to any individual for making copies of his or her record shall not include the cost of and search for and review of the record. Fees under $25.00 shall be waived. Fees to be charged are as follows:

Activity	Fees
(1) Duplication of documents by any type of reproduction process to produce plain one-sided paper copies of a standard size (8½″ x 11″; 8½″ x 14″; 11″ x 14″).	$0.15 per page after first 100 one-sided pages or electronic equivalent.
(2) Duplication of non-paper records, such as microforms, audiovisual materials (motion pictures, slides, laser optical disks, video tapes, audio tapes, etc.), computer tapes and disks, diskettes for personal computers, and any other automated media output.	Direct cost to the Agency as defined in § 1.561(b)(3) of this part to the extent that it pertains to the cost of duplication.
(3) Duplication of document by any type of reproduction process not covered by paragraphs (e)(1) or (2) of this section to produce a copy in a form reasonably usable by the requester.	Direct cost to the Agency as defined in § 1.561(b)(3) of this part to the extent that it pertains to the cost of duplication.

■ 13. Revise § 1.580 to read as follows:

§ 1.580 Administrative review.

(a) Upon consideration and denial of a request under § 1.577 or § 1.579 of this part, the responsible VA official or designated employee will inform the requester *in writing* of the denial. The adverse determination notice must be signed by the component head or the component's Privacy Officer, and shall include the following:

(1) The name and title or position of the person responsible for the adverse determination;

(2) A brief statement of the reason(s) for the denial and the policy upon which the denial is based; and

(3) Notice that the requester may appeal the adverse determination under paragraph (b) of this section to the Office of General Counsel (providing the address as follows: Office of General Counsel (024), 810 Vermont Avenue NW, Washington, DC 20420), and instructions on what information is required for an appeal, which includes why the individual disagrees with the initial denial with specific attention to one or more of the four standards (*e.g.,* accuracy, relevance, timeliness, and completeness), and a copy of the denial letter and any supporting documentation that demonstrates why the individual believes the information does not meet these requirements.

(b) The final agency decision in appeals of adverse determinations described in paragraph (a) of this section will be made by the designated official within the Office of General Counsel (024).

(c) A written denial must have occurred to appeal to OGC. The absence of a response to an access *or* amendment request filed with a VA component is *not* a denial. If an individual has not received a response to a request for access to or amendment of records, the individual must pursue the request with the Privacy Officer of the administration office (*e.g.,* the VHA, VBA, or National Cemetery Administration Privacy Officer) or staff office (*e.g.,* the Office of Information Technology or Office of Inspector General Privacy Staff Officer) that has custody over the records.

[FR Doc. 2019–06101 Filed 3–29–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 447

[CMS–2345–F2 and 2345–IFC2]

RIN 0938–AT09

Medicaid Program; Covered Outpatient Drug; Line Extension Definition; and Change to the Rebate Calculation for Line Extension Drugs

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

ACTION: Final rule and interim final rule with comment period.

SUMMARY: This interim final rule with comment period revises the regulatory text to accurately reflect the applicable statutory language describing the rebate calculation for line extension drugs, which was revised by the Bipartisan Budget Act (BBA) of 2018. In addition, we also are issuing a final rule which responds to comments on the definition and identification of line extension drugs for which we requested additional comments in the Covered Outpatient Drugs final rule with comment period

published in the February 1, 2016 **Federal Register**.

DATES: *Effective date:* April 1, 2019.

Comment date: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on May 31, 2019.

ADDRESSES: In commenting, please refer to file code CMS–2345–IFC2 when commenting on issues in the interim final rule with comment period. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. You may submit comments in one of 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–2345–IFC2, 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–2345–IFC2, 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 and identification of line extension drugs, and the rebate calculation for line extension drugs. Wendy Tuttle, (410) 786–8690, for all other inquiries.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *http://regulations.gov.* Follow the search instructions on that website to view public comments.

Provisions open for comment: We will consider comments that are submitted as indicated above in the **DATES** and **ADDRESSES** sections on the rebate calculation for line extension drugs discussed in the IFC.

I. Background

A. Introduction

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 Social Security Act (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 covered outpatient drugs (CODs). It also revised other requirements related to CODs, including key aspects of Medicaid coverage and payment and the Medicaid Drug Rebate (MDR) program under section 1927 of the Act. Additionally, the COD final rule did not finalize a regulatory definition of ''line extension'' but requested additional public comments on the definition and identification of line extension drugs.

B. Requesting Comments on Definition and Identification of Line Extension Drugs

We stated in the preamble to the COD final rule that we received numerous comments regarding our proposed definition of line extension drug. The comments addressed reasons why certain parameters should not be included in the definition of a line extension drug. For example, comments addressed why new combinations, new indications, and new ester, new salt or other noncovalent derivatives should not be included in the definition of a line extension. Other comments included concerns that our definition was too broad and not supported by legislative history and suggested alternative definitions of line extension drugs.

We stated that while we appreciated the comments that were provided, we had decided not to finalize the proposed regulatory definition of line extension drug at § 447.502. Instead, we requested additional public comments on the definition and identification of line extension drugs (81 FR 5197). The comment period for this additional request for public comments closed on April 1, 2016.

The Comprehensive Addiction and Recovery Act of 2016 (CARA) (Pub. L. 114–198, enacted on July 22, 2016) amended the last sentence of section 1927(c)(2)(C) of the Act. That statutory provision now reads, in this subparagraph, the term ''line extension'' means, with respect to 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. The amendment applies to drugs that are paid for by a state in calendar quarters beginning on or after the July 22, 2016, the date of enactment of CARA, which would be, October 1, 2016, the beginning of fourth quarter 2016. In short, CARA exempts certain abuse-deterrent formulations (ADFs) from the definition of line extension for purposes of the MDR program.

We issued Manufacturer Release No. 102 on November 17, 2016 to provide guidance on CARA. In that Manufacturer Release we described how we intend to verify if a drug is an ADF, and thus, should be excluded from the definition of line extension for purposes of the MDR program. This Manufacturer Release states that we intend to use information provided on the Drug Details page for the drug on *Drugs@FDA:* FDA Approved Drug Products to perform this verification process for the MDR program. For further details, please see the release which is available at *https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Prescription-Drugs/Downloads/Rx-Releases/MFR-Releases/mfr-rel-102.pdf.* Please note that FDA has subsequently updated the way in which it lists drug information on *Drugs@FDA*. The ''Drug Details'' section is no longer included but details about the drug are available based on the application number, including whether FDA has determined whether the drug has abuse-deterrent properties.

C. Statutory Change to the Rebate Calculation for Line Extension Drugs

Section 53104 of the BBA of 2018 (Pub. L. 115–123, enacted on February 9, 2018) amends section 1927 of the Act by providing a technical correction to the alternative rebate formula for line extension drugs that was established under the Affordable Care Act. Specifically, it amends section 1927(c)(2)(C) of the Act such that the rebate for a line extension drug is the greater of either (a) the standard rebate (calculated as a base rebate amount plus an additional inflation-based rebate), or (b) the base rebate amount increased by the alternative formula contained in section 1927(c)(2)(C)(i) through (c)(2)(C)(iii) of the Act. This amendment

applies to rebate periods beginning on or after October 1, 2018. We issued Manufacturer Release No. 109 and State Release No. 186 on August 9, 2018 to provide guidance to manufacturers and states on the statutory amendments to the alternative rebate formula for line extension drugs. For further details, please see the releases which are available at *https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/state-releases/state-rel-186.pdf* and *https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/mfr-releases/mfr-rel-109.pdf.* In addition, we have also included an interim final rule with comment period to revise § 447.509(a)(4) to accurately reflect the statutory amendments to section 1927(c)(2)(C) of the Act. The interim final rule with comment period includes a 60-day comment period.

II. Responses to Public Comments on Definition and Identification of Line Extension Drugs

As discussed in the COD final rule, we decided not to finalize the proposed regulatory definition of line extension drug at § 447.502 and, instead, we requested additional comments on the definition of line extension drug noting that we may consider addressing this issue in future rulemaking (81 FR 5197). After the additional public comment period closed, CARA passed, and we issued guidance to the public on how we would apply section 1927(c)(2)(C) of the Act. While the additional comments that we received through the additional public comment period were insightful of the public's thoughts at a particular time, the comments are not informed by the current statutory framework. Therefore, we are not finalizing a definition of line extension in this final rule and interim final rule with comment period, but instead, are reiterating guidance provided in the COD 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 drug (81 FR 5265). Reasonable assumptions must be consistent with the purpose of section 1927 of the Act, federal regulations, and the terms of the MDR agreement; manufacturers must maintain adequate documentation explaining any such assumptions (83 FR 12770, 12785 (March 23, 2018)). If we later decide to develop a regulatory definition of line extension drug, we will do so through our established Administrative Procedures Act (APA) compliant rulemaking process and issue a proposed rule.

We received 31 public comments, some of which are beyond the scope of the request for comments on the definition of line extension drugs. Relevant public comments on the definition of line extension drugs related to the scope of the definition of line extension drug, included concerns regarding the process and establishment of a final definition of line extension drug, and proposed mechanisms suggested to define the term. We appreciate the comments and again note that we are not finalizing a definition of line extension drug at this time in this final rule or interim final rule with comment period.

III. Interim Final Rule With Comment Period To Address Statutory Change to the Rebate Calculation for Line Extension Drugs

A. Bipartisan Budget Act of 2018 Changes the Rebate Calculation for Line Extension Drugs

As stated previously, section 53104 of the BBA of 2018 amends the applicable statute by providing a technical correction to the alternative rebate formula for line extension drugs first established under the Affordable Care Act. Specifically, it amends section 1927(c)(2)(C) of the Act such that the rebate for a line extension drug is the greater of either (a) the standard rebate (calculated as a base rebate amount plus an additional inflation-based rebate), or (b) the base rebate amount increased by the alternative formula contained in section 1927(c)(2)(C)(i) through (c)(2)(C)(iii) of the Act. This amendment applies to rebate periods beginning on or after October 1, 2018. The interim final rule with comment period revises § 447.509(a)(4) to accurately reflect the statutory language of section 1927(c)(2)(C)(i) through (c)(2)(C)(iii) of the Act, as it applies beginning October 1, 2018.

B. Regulatory and System Change Required

For rebate periods occurring after the enactment of the Affordable Care Act and prior to the enactment of the BBA of 2018, that is, drugs paid for by a state after December 31, 2009 and prior to October 1, 2018, the unit rebate amount calculation (URA) for a line extension drug is the greater of: (1) Standard URA = the basic rebate plus the additional rebate for the line extension drug or (2) Alternative URA = the product of the average manufacturer price (AMP) of the line extension drug (for each dosage form and strength) and the highest additional rebate (calculated as a percentage of AMP) under section 1927(c) of the Act for any strength of the original single source drug or innovator multiple source drug (''initial brand name listed drug''.)

Effective for rebate periods beginning on or after October 1, 2018, the URA for a line extension drug will be the greater of: (1) Standard URA = the basic rebate plus the additional rebate for the line extension drug or (2) Alternative URA = *the basic rebate plus* the product of the quarterly AMP of the line extension drug (for each dosage form and strength) and the highest additional rebate (calculated as a percentage of AMP) under section 1927 of the Act for any strength of the original single source drug or innovator multiple source drug.

The proposed revisions to § 447.509(a)(4) are as follows: In § 447.509(a)(4)(i), the phrase ''for the rebate periods beginning January 1, 2010 through September 30, 2018'' is added between ''the rebate obligation'' and ''is the amount computed.

Additionally, § 447.509(a)(4)(ii) is redesignated as § 447.509(a)(4)(iii) and § 447.509(a)(4)(ii) is changed to state that 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 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 the following:

- The AMP of the line extension of a single source drug or an innovator multiple source drug that is an oral solid dosage form;
- 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; and
- 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).

We will modify the rebate system to incorporate the revised line extension URA calculation as part of the quarterly rebate files beginning with the fourth quarter 2018 file that will be sent to the states in early February 2019. We will provide additional operational instructions to manufacturers and states regarding the status of the system modifications. As always, while we provide states with URA information as a courtesy, in accordance with section

1927(c)(2)(C) of the Act, manufacturers remain responsible for calculating the revised line extension URA in accordance with the BBA of 2018 effective fourth quarter of calendar year 2018.

C. Illustration and Example of Calculation

Below, we are providing an illustration of the steps for the calculation of the URA and unit rebate offset amount (UROA) [1] for a line extension drug, along with an example of each calculation.

Step 1: Calculate Standard URA = Basic Unit Rebate Amount + Additional Unit Rebate Amount.

Step 2: Calculate Alternative URA = Basic Unit Rebate Amount + Product of the AMP of the line extension drug and the highest additional rebate (calculated as a percentage of AMP) under section 1927 for any strength of the initial brand name listed drug.

Step 3: Determine the URA = Greater of (1) Standard URA or (2) Alternative URA.

Step 4: Determine if the URA is greater than 100 percent of the Quarterly AMP

a. If the URA is greater than or equal to 100 percent of the Quarterly AMP, then the URA = Quarterly AMP (consistent with section 1927(c)(2)(D) of the Act.)

b. If the URA is less than 100 percent of Quarterly AMP, then use the URA.

Step 5: Calculate the UROA

a. If the Alternative URA is greater than the Standard URA, then the UROA for the line extension drug will be the difference between the Alternative URA and the Standard URA plus the Basic UROA.[2]

b. If the Alternative URA is less than or equal to the Standard URA, then there is no UROA for the line extension portion; however, the Basic UROA still applies.

Example

Baseline AMP (line extension) = 100.00
Best Price (line extension) = 250.00
Quarterly CPI–U = 200.00
Quarterly AMP (line extension) = 300.00
Baseline CPI–U [3] = 170.00

Step 1: Calculate Standard URA

A. Basic Unit Rebate Amount is the greater of:
(a) Quarterly AMP × 23.1% = 300.00 × 23.1% = 69.30 or
(b) Quarterly AMP − Best Price = 300.00 − 250.00 = 50.00
The greater of the two results (69.30 or 50.00) is 69.30
Basic Unit Rebate Amount = 69.30

B. Additional Unit Rebate Amount = Quarterly AMP − [(Baseline AMP/Baseline CPI–U) × Quarterly CPI–U]
= 300 − [100/170 × 200]
= 300 − 117.65 = 182.35
Additional Unit Rebate Amount = 182.35
If the [(Baseline AMP/Baseline CPI–U) × Quarterly CPI–U] is equal to or greater than the Quarterly AMP, then the Additional Unit Rebate Amount is zero.
Standard URA = Basic Unit Rebate Amount + Additional Unit Rebate Amount = 69.30 + 182.35 = 251.65

Step 2: Calculate Alternative URA

Quarterly AMP (line extension) = 300.00
Best Price (line extension) = 250.00

A. Basic Unit Rebate Amount is the greater of:
(a) Quarterly AMP × 23.1% = 300.00 × 23.1% = 69.30 or
(b) Quarterly AMP − Best Price = 300.00 − 250.00 = 50.00
The greater of the two results (69.30 or 50.00) is 69.30
Basic Unit Rebate Amount = 69.30

B. Alternative Additional Unit Rebate Amount:
Product of the Quarterly AMP of the line extension drug and the highest additional rebate (calculated as a percentage of AMP) for any strength of the initial brand name listed drug.
Additional Unit Rebate Amount (initial brand name listed drug) strength A = 200.00
Additional Unit Rebate Amount (initial brand name listed drug) strength B = 125.00
Additional Unit Rebate Amount (initial brand name listed drug) strength C = 110.00
Quarterly AMP (initial brand name listed drug) strength A = 280.00
Quarterly AMP (initial brand name listed drug) strength B = 275.00
Quarterly AMP (initial brand name listed drug) strength C = 270.00
Additional rebate ratio strength A = 200/280 = 0.7143
Additional rebate ratio strength B = 125/275 = 0.4545
Additional rebate ratio strength C = 110/270 = 0.4074
Quarterly AMP of line extension drug × highest additional rebate ratio for any strength of the initial brand name listed drug = 300 × 0.7143 = 214.29
Alternative Additional Unit Rebate Amount = 214.29
Alternative URA = Basic Unit Rebate Amount + Alternative Additional Unit Rebate Amount = 69.30 + 214.29 = 283.59

Step 3: Determine the URA = the greater of:
(Step 1) Standard URA = 251.65 or
(Step 2) Alternative URA = 283.59
URA = 283.59

Step 4: Determine if the URA is greater than or equal to 100 percent of the Quarterly AMP
100 percent of Quarterly AMP = 100% × 300.00 = 300.00
URA = 283.59
If the URA is greater than or equal to 100 percent of the Quarterly AMP, then URA = Quarterly AMP.
If the URA is less than 100 percent of the Quarterly AMP, then use the URA
283.59 is less than 300.00
URA is equal to 283.59

Step 5: Calculate total UROA = Line Extension UROA + Basic UROA of line extension drug

A. Line Extension UROA = Alternative URA − Standard URA = 283.59 − 251.65 = 31.94
If the Alternative URA is less than or equal to the Standard URA, then there is no Line Extension UROA, however, the Basic UROA still applies.

B. Basic UROA—
If Quarterly AMP − BP is greater than Quarterly AMP × 15.1% and less than Quarterly AMP × 23.1%
Quarterly AMP (line extension) = 300.00
Best Price (line extension) = 250.00
Quarterly AMP − BP = 300.00 − 250.00 = 50.00
Quarterly AMP × 15.1% = 300.00 × 15.1% = 45.30
Quarterly AMP × 23.1% = 300.00 × 23.1% = 69.3
Quarterly AMP − BP (50.00) is greater than Quarterly AMP × 15.1% (45.30) and less than Quarterly AMP × 23.1% (69.3)
Then, the Basic UROA= Quarterly

[1] Drug products are identified and reported using a unique, three-segment number, called the National Drug Code (NDC), which serves as a universal product identifier for drugs. The amount per unit of a drug at the 9-digit NDC level that is returned to the federal government is attributable to the increased amount of rebates that manufacturers are required to pay under the Medicaid drug rebate program due to changes in the rebates made in the Affordable Care Act.

[2] See SMDL #10–019 for additional information on CMS policy on Federal offset of rebates which is based on the increase in the minimum rebate percentage effectuated by the Affordable Care Act.

[3] A measure of the average change over time in the prices paid by urban consumers for a market basket of consumer goods and services.

AMP × 23.1% − (Quarterly AMP − BP) = 69.30 − 0.00 = 19.30

Consistent with our reading of the statutory offset provision in section 1927(b)(1)(B) of the Act, we have calculated the offset amount to reflect the amount attributable to the increase in the percentages affected by the Affordable Care Act amendments. In this scenario, this NDC would have both a Line Extension UROA of 31.94 and a Basic UROA of 19.30, the sum of which equals 51.24.

D. Waiver of Proposed Rulemaking and Waiver of Delay in Effective Date for Changes to the Rebate Calculation for Line Extension Drugs

Under 5 U.S.C. 553(b) of the Administrative Procedure Act (APA), the agency is required to publish a notice of the proposed rule in the **Federal Register** before the provisions of a rule take effect. Section 553(b)(B) of the APA authorizes an agency to dispense with normal rulemaking requirements for good cause if the agency makes a finding that the notice and comment process is impracticable, unnecessary, or contrary to the public interest.

Section 553(d) of the APA ordinarily requires a 30-day delay in effective date of final rules after the date of their publication in the **Federal Register**. This 30-day delay in effective date can be waived, however, if an agency finds for good cause that the delay is impracticable, unnecessary, or contrary to the public interest, the agency may incorporate a statement of the findings and its reasons in the rule issued.

We find that there is good cause to waive the notice and comment requirements under sections 553(b)(B) of the APA as it would be unnecessary and impracticable to undergo notice and comment procedures before finalizing, on an interim basis with an opportunity for public comment, the policies described herein because the provisions of section 53104 of the BBA of 2018 are otherwise self-implementing as of the effective date required by statute, that is, for rebate periods beginning on or after October 1, 2018. The interim final rule with comment period simply revises § 447.509(a)(4) to accurately reflect the amended statutory language of section 1927(c)(2)(C)(i) through (iii) of the Act. Further, such procedures would be unnecessary, as we are not altering the calculations required expressly in statute. Rather, we are simply implementing the calculation for rebates for line extension drugs adopted by Congress. Moreover, we note that the statute, as amended by section 53104 of the BBA of 2018, already requires these rebate calculations to apply. Thus, we are exercising no discretion in this interim final rule with comment period and emphasize that it is intended solely to ensure there is no confusion as to the rebate calculations that apply for such drugs for rebate periods beginning on or after October 1, 2018, as required by statute.

Finally, undertaking notice and comment procedures to incorporate the statutory amendments to section 1927 of the Act would be contrary to the public interest because it is in the public's interest to ensure that manufacturers are paying appropriate rebates on covered outpatient drugs, and the state Medicaid programs and the federal Medicaid program are receiving appropriate rebates to ensure efficient and economical functioning of the programs.

Therefore, we find good cause to waive the notice of proposed rulemaking as provided under section 553(b)(B) of the APA and to issue this interim final rule with an opportunity for public comment. We are providing a 60-day public comment period as specified in the **DATES** section of this document.

We are also waiving the 30-day delay in effective date for this interim final rule with comment period. We believe that a delay in the effective date is unnecessary as we are complying with statutory requirements. It is also contrary to the public interest to delay the effective date for this interim final rule with comment period beyond the statutorily mandated effective date, that is, applicability to rebate periods beginning on or after October 1, 2018. Therefore, we also find good cause to waive the 30-day delay in effective date.

IV. Provisions of the Final Rule

This final rule responds to comments on the definition and identification of line extension drugs for which we requested additional public comments in the COD final rule published on February 1, 2016. Therefore, we are reiterating our guidance provided in the COD 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 and consistent with the requirements of the MDR agreement, are permitted to use reasonable assumptions in their determination of whether their drug qualifies as a line extension drug (81 FR 5265).

V. Provisions of the Interim Final Rule With Comment Period

The interim final rule with comment period revises § 447.509(a)(4) to accurately reflect the applicable statutory language describing the rebate calculation for line extension drugs, which was revised by section 53104 of the BBA of 2018.

VI. Collection of Information Requirements

The actions in this final rule and interim final rule with comment period do not impose any new or revised information collection, reporting, recordkeeping, or third-party disclosure requirements or burden on manufacturers. Manufacturers must continue to report product and pricing data to CMS using the CMS–367 forms approved by the Office of Management and Budget (OMB) under control number 0938–0578. The forms' requirements and burden figures are unaffected by this rule. Consequently, there is no need for review by OMB under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

VII. 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.

VIII. Regulatory Impact Analysis

A. Statement of Need

As stated previously, section 53104 of the BBA of 2018 amends section 1927 of the Act by providing a technical correction to the alternative rebate formula for line extension drugs that was established under the Affordable Care Act. Specifically, it amends section 1927(c)(2)(C) of the Act such that the rebate for a line extension drug is the greater of either (a) the standard rebate (calculated as a base rebate amount plus an additional inflation-based rebate), or (b) the base rebate amount increased by the alternative formula contained in section 1927(c)(2)(C)(i) through (iii) 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 Social Security 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 the Congressional Review Act (5 U.S.C. 804(2).

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). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) Having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. The interim final rule has been designated as an economically significant rule, under section 3(f)(1) of Executive Order 12866. We estimate that the interim final rule is ''economically significant'' as measured by the $100 million threshold, and hence also a major rule under the Congressional Review Act. Accordingly, we have prepared a Regulatory Impact Analysis that to the best of our ability presents the costs and benefits of the rulemaking. OMB has reviewed these proposed regulations, and the Departments have provided the following assessment of their impact.

C. Anticipated Effects

1. Effects on Drug Manufactures of Line Extension Drugs

Manufacturers of Line Extension Drugs will be impacted by the technical correction that was made by section 53104 of the BBA of 2018 to the alternative rebate formula for line extension drugs that was established under the Affordable Care Act. During the drafting of this legislation, the Congressional Budget Office (CBO) scored an estimated savings for the revised line extension rebate calculation of $1.877 billion over 5 years and $5.65 billion over 10 years. Table 1 shows the CMS Office of the Actuary's (OACT's) estimated savings of $1.64 billion over 5 year and $3.95 billion over 10 years. OACT utilized second quarter 2018 rebate data along with first through fourth quarter 2017 state drug utilization data to conduct their analysis. Since OACT's estimate is based on more current data we will use these estimated savings figues in the remaining regulatory impact analysis discussion. This savings will be the result of additional rebates being paid by these drug manufacturers to the federal government.

TABLE 1—SAVINGS OF THE LINE EXTENSION UNIT REBATE AMOUNT CALCULATION REVISIONS UNDER BBA 2018 *

Fiscal Year	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	Total
Federal Impact (million)	280	300	330	350	380	400	430	460	490	530	3,950

* Source: OACT, September 2018.

The Regulatory Flexibility Act (RFA) requires agencies to analyze options for regulatory relief of small entities if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, 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 $7.5 million to $38.5 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 final rule and interim final rule with comment period will 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 a regulatory impact analysis 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 604 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 final rule and interim final rule with comment period will 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 2018, that threshold is approximately $150 million. This final rule and interim final rule with comment period will 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 requirement costs on State and local governments, preempts state law, or otherwise has federalism implications. Since this regulation does not impose any costs on state or local governments, the requirements of Executive Order 13132 are not applicable.

2. Effects on Medicaid Program

The Federal Medicaid program will benefit from the technical correction that was made by section 53104 of the BBA of 2018 to the alternative rebate formula for line extension drugs that was established under the Affordable Care Act. As stated above, OACT estimated a savings of $1.64 billion over 5 year and $3.95 billion over 10 years. This savings will be the result of additional rebates being paid to the federal government by these drug manufacturers.

D. Alternatives Considered

The interim final rule with comment period simply revises § 447.509(a)(4) to accurately reflect the amended statutory language of section 1927(c)(2)(C)(i) through (iii) of the Act. We considered

the notice and comment rulemaking process, but as described in section III.D., Waiver of Proposed Rule Making and Waiver of Delay in Effective Date for Changes to the Rebate Calculation for Line Extension Drugs, we find that there is good cause to waive the notice and comment requirements under sections 553(b)(B) of the APA as it would be unnecessary and impracticable and contrary to the public interest to undergo notice and comment procedures before finalizing, on an interim basis with an opportunity for public comment, the policies described herein because the provisions of the section 53104 of the BBA of 2018 are otherwise self-implementing as of the effective date required by statute, that is, for rebate periods beginning on or after October 1, 2018. The interim final rule with comment period simply revises § 447.509(a)(4) to accurately reflect the amended statutory language of section 1927(c)(2)(C)(i) through (iii) of the Act.

E. Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars_a004_a-4*), we have prepared an accounting statement in Table 2 showing the classification of the transfers associated with the provisions of this final rule and interim final rule with comment period.

TABLE 2—ACCOUNTING STATEMENT

Category	Estimates	Units		
		Year dollar	Discount rate	Period covered
Transfers				
Annualized	324.6	2018	7%	2019–2023
Monetized ($million/year)	326.5	2018	3%	2019–2023
From Whom To Whom	Drug Manufacturers to Federal Government			

F. Regulatory Reform Analysis under E.O. 13771

Executive Order 13771, entitled ''Reducing Regulation and Controlling Regulatory Costs,'' was issued on January 30, 2017 and requires that the costs associated with significant new regulations ''shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.'' It has been determined that this final rule and interim final rule with comment period are actions that primarily result in transfers and thus are not a regulatory or deregulatory action for the purposes of Executive Order 13771.

G. Conclusion

The estimated savings of the revised line extension rebate calculation is $1.64 billion over 5 years and $3.95 billion over 10 years. This savings will be the result of additional rebates being paid by drug manufacturers, as applicable. The analysis above, together with the remainder of this preamble, provides a Regulatory Impact Analysis. This final rule and interim final rule with comment period are subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*) and have been transmitted to the Congress and the Comptroller General for review. In accordance with the provisions of Executive Order 12866, this final rule and interim final rule with comment period was reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 447

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

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

PART 447—PAYMENTS FOR SERVICES

■ 1. The authority citation for part 447 is revised to read as follows:

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

■ 2. Section 447.509 is amended by revising paragraph (a)(4) to read as follows:

§ 447.509 Medicaid drug rebates (MDR).

(a) * * *

(4) *Treatment of new formulations.* (i) 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 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 that is an oral solid dosage form.

(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).

(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 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 that is an oral solid dosage form.

(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).

(iii) The alternative rebate is required to be calculated if the manufacturer of the line extension drug also manufactures the initial brand name listed drug or has a corporate relationship with the manufacturer of the initial brand name listed drug.

* * * * *

Dated: October 3, 2018.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: December 18, 2018.

Alex M. Azar, II,

Secretary, Department of Health and Human Services.

[FR Doc. 2019–06274 Filed 3–28–19; 4:15 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Part 202

[Docket DARS–2019–0013]

RIN 0750–AK20

Defense Federal Acquisition Regulation Supplement: Repeal of Certain Defense Acquisition Laws (DFARS Case 2018–D059)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: DoD is issuing a final rule amending the Defense Federal Acquisition Regulation Supplement (DFARS) to implement a section of the National Defense Authorization Act for Fiscal Year 2019.

DATES: Effective April 1, 2019.

FOR FURTHER INFORMATION CONTACT: Ms. Kimberly R. Ziegler, telephone 571–372–6095.

SUPPLEMENTARY INFORMATION:

I. Background

DoD is amending the DFARS to implement section 812 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2019. Section 812 repeals more than 60 obsolete Defense acquisition laws, most of which have been completed, have expired, or do not impact the procurement regulations. Of the obsolete laws listed in section 812, only one was implemented in the DFARS: section 815(b) of the NDAA for FY 2008 (Pub. L. 110–181). Section 815(b) required modification of the DFARS to clarify that the terms ''general public'' and ''non-governmental entities'', with regard to sales of commercial items, do not include the Federal Government or a State, local, or foreign government. The clarification with regard to the terms ''general public'' and ''non-governmental entities,'' as used in the definition of ''commercial item,'' was added to DFARS 202.101, Definitions, via a final rule published in the **Federal Register** at 75 FR 51416 on August 20, 2010 (DFARS Case 2008–D011).

Since section 812 of the NDAA for FY 2019 repealed section 815(b) of the NDAA for FY 2008, this final rule removes the clarification of the terms ''general public'' and ''non-governmental entities'' at DFARS 202.101. No other changes are required to implement section 812 of the NDAA for FY 2019.

II. Publication of This Final Rule for Public Comment Is Not Required by Statute

The statute that applies to the publication of the Federal Acquisition Regulation (FAR) is 41 U.S.C. 1707 entitled ''Publication of Proposed Regulations.'' Paragraph (a)(1) of the statute requires that a procurement policy, regulation, procedure or form (including an amendment or modification thereof) must be published for public comment if it relates to the expenditure of appropriated funds, and has either a significant effect beyond the internal operating procedures of the agency issuing the policy, regulation, procedure, or form, or has a significant cost or administrative impact on contractors or offerors. This final rule is not required to be published for public comment, because the rule merely removes a clarification to an existing definition in the FAR.

III. Applicability to Contracts at or Below the Simplified Acquisition Threshold and for Commercial Items, Including Commercially Available Off-the-Shelf Items

This rule only removes the definition of ''general public'' and non-governmental'' entities at DFARS 202.101 Definitions. This rule does not create or revise any solicitation provisions or contract clauses.

IV. Executive Orders 12866 and 13563

Executive Orders (E.O.) 12866 and E.O. 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). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

V. Executive Order 13771

This rule is not subject to E.O. 13771, because this rule is not a significant regulatory action under E.O. 12866.

VI. Regulatory Flexibility Act

Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this rule under 41 U.S.C. 1707(a)(1) (see section II. of this preamble), the analytical requirement of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) are not applicable. Accordingly, no regulatory flexibility analysis is required, and none has been prepared.

VII. Paperwork Reduction Act

The rule does not contain any information collection requirements that require the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. chapter 35).

List of Subjects in 48 CFR Part 202

Government procurement.

Jennifer Lee Hawes,

Regulatory Control Officer, Defense Acquisition Regulations System.

Therefore, 48 CFR part 202 is amended as follows:

PART 202—DEFINITIONS

■ 1. The authority citation for part 216 continues to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

202.101 [Amended]

■ 2. Amend section 202.101 by removing the definition ''General public'' and ''non-governmental entities''.

[FR Doc. 2019–06249 Filed 3–29–19; 8:45 am]

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