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**MEMORANDUM**

**FROM:** Alan M. Kirschenbaum  
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**SUBJECT:** Summary of CMS Proposed Amendments to Medicaid Drug Rebate Program Regulations

In the Federal Register of Friday, June 19, 2020,<sup>1</sup> CMS published a proposed rule to implement recent statutory amendments to the Medicaid Drug Rebate Program (MDRP) statute and a not-so-recent issue pending since the 2010 Affordable Care Act. The proposed rule also goes beyond statutory implementation to add CMS's own policy proposals to encourage value-based purchasing arrangements and discourage patient savings programs. Comments on the proposed rule must be submitted by July 20, 2020.

The topics covered in this wide-ranging rule include:

- Best price changes and other measures to encourage value-based purchasing arrangements in Medicaid
- Additional regulations to implement the alternative rebate for line extensions, including an exceptionally broad definition of "new formulation" and a definition of "oral solid dosage form"
- Introduction of a new, problematic hurdle for claiming the best price exceptions for manufacturer coupon and other patient savings programs
- Clarification of the average manufacturer price (AMP) and best price treatment of rebates to Medicaid Managed Care plans that are not paid pursuant to a CMS-approved supplemental rebate program

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<sup>1</sup> 85 Fed. Reg. 37286 (June 19, 2020).

- Implementation of statutory amendments to exclude sales of authorized generics from the brand AMP, redefine single source and innovator multiple source drugs to remove references to “original NDAs,” and redefine multiple source drugs to include OTC drugs that are covered outpatient drugs.

The above topics are addressed in more detail below. Note that the focus of this summary is on provisions of the proposed rule that directly affect drug manufacturer price reporting under the MDRP. The proposed regulation also includes requirements for state Medicaid programs relating to opioid drug utilization review, drug utilization data reports to CMS, and payment of claims, but these provisions are outside of our scope here.

## I. VALUE BASED PURCHASING ARRANGEMENTS

CMS proposes to revise the best price regulation to remove impediments to value-based purchasing (VBP) arrangements in Medicaid. The proposed definition of VBP is “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) . . . .”<sup>2</sup> Two examples provided in the proposed rule are evidence-based measures, which substantially link cost to existing evidence of effectiveness and value for a specific use, and outcomes-based measures, which substantially link a drug’s cost to its actual performance or a reduction in medical expenses. An example of an evidence-based measure might be a multi-indication pricing arrangement with a payor to provide one price for a use of the drug that is supported by evidence of superior safety or effectiveness compared with other therapeutic alternatives, and a lower price for another indication for which the drug is one of several equally effective therapies. An example of an outcomes-based measure might be a refund on a drug if a patient does not achieve a specified clinical endpoint (e.g., blood pressure reduced to a specified level).

Manufacturers have long complained that best price restrictions discourage them from offering creative VBP discounts to commercial payors and Medicaid Managed Care Plans, both of which could affect best price. For example, in the outcomes based VBP arrangement described above, the refund of the drug for even one patient would arguably establish a best price of zero, increasing the unit rebate amount (URA) to an amount equal to the average price paid to the manufacturer by retail community pharmacies and wholesalers. The proposed rule offers two solutions to this best price dilemma.

First, CMS proposes to give its imprimatur to a methodology that some manufacturers have already adopted on their own: treating a VBP arrangement as a

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<sup>2</sup> Proposed 42 C.F.R. § 447.502.

bundled sale. Under CMS regulations, a bundled sale is, in essence, a sale in which a discount is conditioned on the purchase of the same drug or another product, or another performance requirement (e.g., placement on a formulary tier).<sup>3</sup> While a VBP arrangement might fall within the current definition if it is conditioned on a minimum purchase volume or a formulary tier placement, CMS proposes to explicitly clarify that a VBP arrangement may qualify as a bundled sale if it contains a performance requirement.<sup>4</sup> The advantage of a bundled sale is that the total discount is allocated among all of the items in the bundle in proportion to each item's undiscounted cost.<sup>5</sup> Thus, a full refund on one unit of drug, instead of resulting in a zero best price, may be allocated among all the units sold under the bundled arrangement, reducing the cost of each one by a small amount. The preamble offers an example of an arrangement requiring the purchase of 1,000 units of a drug at \$200 per unit, with a \$100 refund for each patient who does not meet the clinical outcome measure. If one patient failed to meet the outcome measure, the \$100 discount would be allocated across all 1,000 units, resulting in a 10 cent price reduction for each unit – a reduction that is unlikely to set a best price.<sup>6</sup>

CMS's second proposed solution to the VBP best price dilemma is innovative but narrow in utility and difficult to administer. CMS proposes to permit manufacturers to report multiple best prices for a single dosage form and strength of a drug. For example, one best price could reflect the price under a VBP agreement and another could reflect the price under a non-VBP purchase agreement. This would necessarily result in two different URAs. CMS explains that one URA would apply to units dispensed to a Medicaid beneficiary under a VBP arrangement where the patient qualified for the VBP discount. The other URA would apply to units dispensed to all other Medicaid beneficiaries.<sup>7</sup>

This second proposal has limitations. First, it presumes that a manufacturer offers the VBP arrangement to a state Medicaid fee-for-service program or a Medicaid Managed Care plan sponsor, which is what CMS is trying to encourage. A VBP arrangement offered to commercial payors but not Medicaid might generate multiple best

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<sup>3</sup> 42 C.F.R. § 447.502.

<sup>4</sup> Proposed 42 C.F.R. § 447.502.

<sup>5</sup> *See* 42 C.F.R. § 447.502.

<sup>6</sup> *See* 85 Fed. Reg. at 37292.

<sup>7</sup> *Id.* at 37293.

prices, but which of them would apply to Medicaid-reimbursed units? Presumably the lower one, which would provide no relief to the manufacturer. Second, in order for the scheme to work, state Medicaid programs and Medicaid Managed Care plan sponsors would have to develop systems to track health outcomes, to distinguish units subject to one best price from units subject to another (since each would have a different URA), and to reflect these differences in their invoices and utilization reports to manufacturers and CMS. CMS seeks comments on the procedures that would be needed by states and manufacturers to implement this proposal.

To avoid discouraging VBP arrangements that involve evidence based or outcomes based measures that are measured in periods greater than three years, or installment payments over such longer periods, CMS proposes to permit manufacturers to restate AMP and best price beyond the otherwise applicable three-year limit if a VBP outcome must be measured outside of that period.<sup>8</sup> The proposed regulation would also provide for states to submit state plan amendments to establish VBP supplemental rebate programs, under which the state could enter into VBP agreements with manufacturers. States with such programs would have to submit annual reports to CMS, including data on administrative costs and total savings.<sup>9</sup>

## II. ALTERNATIVE REBATE FOR LINE EXTENSIONS

The alternative rebate for line extensions was enacted as part of the Affordable Care Act. The alternative rebate applies to “a line extension of a single source drug or an innovator multiple source drug that is an oral solid dosage form.”<sup>10</sup> The statute defines a line extension as “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.”<sup>11</sup> While CMS has promulgated regulations regarding the calculation of the alternative rebate, CMS has not provided a regulatory definition of a line extension.<sup>12</sup> Without a regulatory definition, CMS has directed manufacturers to

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<sup>8</sup> Proposed 42 C.F.R. § 447.510(b)(1)(vi).

<sup>9</sup> Proposed 42 C.F.R. § 447.518.

<sup>10</sup> 42 U.S.C. § 1396r-8(c)(2)(C)(i).

<sup>11</sup> *Id.* § 1396r-8(c)(2)(C).

<sup>12</sup> CMS proposed a definition in 2012, which it did not finalize. CMS requested further comments on the topic.

rely on the statutory definition of line extension and use reasonable assumptions in determining whether a drug qualifies.

The proposed definition of a line extension is consistent with that of the statute.<sup>13</sup> The proposed definition of a new formulation, however, is extremely broad and would encompass a number of situations that would not be obvious based on the statutory language. CMS proposes to define a new formulation as “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.”<sup>14</sup> The proposed definition includes the following examples of new formulations, but notes that the definition is not limited to that list:

- 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 new NDC number)
- Combination drugs, such as a drug that is a combination of two or more drugs or a combination of a drug and a device

In the preamble to the proposed rule, CMS noted that after several years of experience with manufacturers self-reporting line extensions, CMS has observed inconsistencies between the approach taken by different manufacturers and that manufacturers may have an incentive to be underinclusive in their identification of line extensions.<sup>15</sup> To mitigate this, CMS stated that it was interpreting the term “new formulation” broadly to ensure that the statute “is fully implemented and the universe of line extensions is identified consistent with our understanding of Congressional intent” so that manufacturers do not circumvent rebate liability by avoiding the inflation-based alternative rebate.<sup>16</sup>

As an initial matter, CMS stated in the preamble that interpreting the statutory text to require that both the initial brand name listed drug and the line extension be an oral solid dosage form would inappropriately limit the universe of line extension drugs. In coming to this conclusion, CMS stated that it believed that the statutory text could reasonably be interpreted to provide that only the initial brand name listed drug must be

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<sup>13</sup> Proposed 42 C.F.R. § 447.502.

<sup>14</sup> *Id.*

<sup>15</sup> 85 Fed. Reg. at 37294.

<sup>16</sup> *Id.*

an oral solid dosage form.<sup>17</sup> Accordingly, CMS is proposing that new dosage forms and routes of administration – even non-oral ones – may be considered new formulations.<sup>18</sup>

CMS is also proposing that a new strength be considered a new formulation, reversing its 2016 guidance.<sup>19</sup> CMS acknowledges that the base AMP provision of the statute permits a manufacturer to establish a new base AMP for a new strength of a drug.<sup>20</sup> That statutory provision reflects a Congressional intent that manufacturers should be able to introduce new strengths or dosage forms without penalty tied to the pricing of the predicate drug. In a statement startlingly contrary to this intent and to its former guidance, CMS explains that a new strength must be considered a line extension because otherwise, changing the strength “allows a manufacturer to establish a new base date AMP, thereby avoiding inflation based rebate liability.”<sup>21</sup> In other words, CMS proposes to interpret the line extension provision to prohibit manufacturers from doing precisely what the base AMP definition permits them to do – market a new strength without penalty tied to the existing strength’s pricing. Moreover, CMS arrives at this questionable interpretation despite acknowledging that “the line extension provision does not expressly contemplate that a new strength is a line extension.”<sup>22</sup>

With regard to a new indication, CMS is proposing that a drug that is approved with a new indication only be considered a new formulation if it is a separately identifiable drug product (for example, with a new NDC number) from the already approved drug.<sup>23</sup> CMS determined that it is not feasible for a drug to be identified as a line extension if it is not separately identifiable from the originally approved drug product. CMS is requesting comments on this proposal.

With regard to combination drugs, CMS is proposing that combinations of two or more drugs or drugs and devices be considered new formulations when the new drug contains at least one active ingredient in common with the initial brand name listed

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<sup>17</sup> *Id.* at 37295-96.

<sup>18</sup> Proposed 42 C.F.R. § 447.502.

<sup>19</sup> 81 Fed. Reg. 5170, 5267 (Feb. 1, 2016).

<sup>20</sup> 85 Fed. Reg. at 37295-96; 42 U.S.C. § 1396r-8(c)(2) (base AMP is calculated for a particular “dosage form and strength”).

<sup>21</sup> 85 Fed. Reg. at 37295-96.

<sup>22</sup> *Id.* at 37295.

<sup>23</sup> Proposed 42 C.F.R. § 447.502.

drug.<sup>24</sup> CMS stated in the preamble that the statutory definition does not expressly exclude this interpretation.<sup>25</sup> CMS noted that previous concerns with identifying combination products as line extensions focused on the problem of sharing proprietary information among competitors, but that problem is resolved because the alternative rebate only applies when 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.<sup>26</sup> CMS also clarified that it believes it has the “discretion and authority to include a broad range of drugs as a line extension,” including the following situations:

- Where the initial brand name listed drug is a combination of a previously approved drug and a new molecular entity, subsequent approval of the new molecular entity alone would result in the new molecular entity being a new formulation.
- Where the initial brand name listed drug is a single entity, subsequent approval of the previously approved drug with a new molecular entity would result in the combination being a new formulation.
- Where the initial brand name listed drugs are two previously approved drugs, subsequent approval of the combination of the two previously approved drugs would result in the combination being a new formulation.
- Where the initial brand name listed drug is a previously approved drug, subsequent combination with a non-drug product such as a dietary supplement or a device would result in the combination being a new formulation.

CMS’s proposal would raise obvious apples-to-oranges problems in calculating of the alternative URA for such line extensions, which includes an additional rebate penalty based on the ratio of the additional rebate to the AMP of the predicate drug. Where a line extension is a combination of two previously approved drugs, which one’s AMP and additional rebate should be used to calculate the alternative URA? If both, how is the calculation to be done? Where a line extension is a combination of a previously approved drug and a new molecular entity, dietary supplement, or device, why would the approved drug’s AMP and additional rebate be a suitable measure for an additional rebate penalty for the line extension? The same question arises if the predicate drug was a

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<sup>24</sup> Proposed 42 C.F.R. § 447.502.

<sup>25</sup> 85 Fed. Reg. at 37295.

<sup>26</sup> *Id.*; 42 C.F.R. § 447.509(a)(4)(iii).

combination drug and the line extension is one of the components. These questions have not been addressed by CMS, but should be raised in comments.

CMS is also proposing a new definition of oral solid dosage form: “an orally administered dosage form that is not a liquid or gas at the time the drug enters the oral cavity.”<sup>27</sup> CMS clarified in the preamble that this would include, but not be limited to, a tablet or film administered sublingually and a drug that is orally inhaled.<sup>28</sup> CMS stated that it is making this change because there has been some confusion and inconsistency among manufacturers in how they were interpreting the term, with some apparently believing that the drug must be swallowed or otherwise enter the gastrointestinal tract.<sup>29</sup>

In short, from a statutory provision whose sole example of a line extension is an extended release formulation, CMS has fabricated an extraordinarily wide net that captures virtually every change that can be made to a drug. Whereas Congress intended the line extension provision to discourage manufacturers from making minor changes in an oral drug to evade rebate liability, CMS has interpreted the provision in an excessively blunt manner that threatens to discourage innovative changes to drug products.

### III. OTHER BEST PRICE ISSUES

#### A. Patient Assistance Exclusions Narrowed

Best Price and AMP currently exclude patient savings programs in the form of manufacturer discount cards, coupons, copayment assistance, patient rebates, and free-product vouchers (collectively, “patient savings programs”), provided that the full value of the benefit provided is received by the consumer.<sup>30</sup> Historically, manufacturers have reasonably assumed that their programs providing a certain dollar amount of savings to the patient at the point of sale (or rebates sent to the patient afterward) necessarily meet the requirement that the program benefits are provided entirely to the patient. The proposed rule would throw a wrench into that assumption.

In recent years, PBMs, commercial payors, and Medicare Part D plan sponsors have implemented so-called “accumulator programs” to discourage manufacturer copay assistance programs. Payors complain that these programs defeat the payor’s formulary

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<sup>27</sup> Proposed 42 C.F.R. § 447.502.

<sup>28</sup> 85 Fed. Reg. at 37296.

<sup>29</sup> *Id.*

<sup>30</sup> 42 C.F.R. §§ 447.504(c)(25) through (29) and 447.505(c)(8) through (12).

by causing patients to use more expensive non-preferred drugs instead of lower cost preferred or generic drugs. Under an accumulator program, manufacturer subsidies for patient copays and deductibles are not counted toward the patient's deductible or out-of-pocket limits. CMS recently issued a final rule expressly permitting Affordable Care Act exchange plans and individual and group health plans to implement accumulator programs.<sup>31</sup>

In the new proposed rule, CMS has taken the view that, where a plan has a copay accumulator, a manufacturer patient copay assistance program does not benefit the patient, who still has to pay the same amount out of pocket to meet his/her deductibles and out-of-pocket limits. Instead, it benefits the plan, which gets to delay payment for drugs until the patient works his/her way through the deductible or out-of-pocket maximum without the help of the manufacturer subsidy. From this, CMS concludes that a manufacturer cannot reasonably assume that its copay subsidy program meets the best price exclusions' requirement that the patient must receive the full benefit of the patient savings program.<sup>32</sup> CMS's proposed solution is to permit a manufacturer patient savings subsidy to be excluded from best price (and AMP) only "to the extent that the manufacturer *ensures* that" the full value of the benefit is received by the patient.<sup>33</sup> In other words, a manufacturer may no longer reasonably assume that the benefit is received by the patient, but now must "ensure" it.

As to how manufacturers are supposed to "ensure" that the benefit is received by the patient, CMS states casually and without explanation that it "believe[s] that manufacturers have the ability to establish coverage criteria around their manufacturer assistance programs to ensure that the benefit goes exclusively to the consumer or patient."<sup>34</sup> If CMS contemplates that a manufacturer exclude patients whose plans have accumulator programs from eligibility, this would require the manufacturer to find out whether a particular patient's plan has an accumulator program, which typically is not publicly available information and may not be known to the patient. If CMS contemplates other ways for manufacturers to "ensure" that a patient receive the full benefit of copay assistance, CMS does not explain what these ways might be. Obviously, manufacturers are not in a position to prohibit a plan from applying a copay accumulator to a particular patient. In practice, CMS's proposed changes to these exclusions will make them unusable, so that subsidies under patient savings programs will have to be

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<sup>31</sup> See 45 C.F.R. § 156.130(h), 85 Fed. Reg. 29164, 29261 (May 14, 2020).

<sup>32</sup> 85 Fed. Reg. at 37298-99.

<sup>33</sup> Proposed 42 C.F.R. § 447.505(c)(8)-(12) (emphasis added).

<sup>34</sup> 85 Fed. Reg. at 37299.

taken into account in best price. CMS welcomes comments on this proposal, and we encourage drug manufacturers to oblige.

B. AMP/Best Price Treatment of Supplemental Rebates to Medicaid Managed Care

Under the Medicaid Rebate statute, states are permitted to enter into separate supplemental drug rebate agreements with manufacturers, subject to CMS approval of a state plan amendment.<sup>35</sup> Such agreements often offer manufacturers eligibility for placement of their drugs on the state's preferred drug list in exchange for the supplemental rebates. Supplemental rebate agreements may require rebates to be paid, not only on Medicaid fee-for-service utilization, but also units dispensed to Medicaid Managed Care Organization (MMCO) enrollees. With regard to the latter, some states directly collect supplement rebates for units dispensed to MMCO enrollees, while others require MMCOs to collect and share the rebates with the state Medicaid agency. Still other states permit MMCOs to negotiate their own rebates with manufacturers outside of any CMS-authorized supplemental rebate agreements, which allows the MMCO to keep the savings generated by the supplemental rebates.

Under current CMS regulations, rebates paid under "CMS-authorized State supplemental rebate agreements" are excluded from both AMP and best price.<sup>36</sup> However, CMS explains that some manufacturers have mistakenly assumed that all rebates paid to MMCOs are rebates paid under CMS-authorized agreements. To clarify this point, CMS is proposing a new definition of a "CMS-authorized supplemental rebate agreement," which would specify that such agreements must be approved by CMS through a state plan amendment, and the revenues therefrom must be passed through to the state.<sup>37</sup> Accordingly, rebates paid to MMCOs that are not under a CMS-authorized supplemental rebate agreement may not be excluded from AMP or best price.

IV. IMPLEMENTATION OF OTHER STATUTORY CHANGES

A. Exclusion of Authorized Generic Sales From Brand AMP

In Section 1603 of Continuing Appropriations Act, 2020, and the Health Extenders Act of 2019,<sup>38</sup> Congress revised the AMP definition so that the AMP of a

<sup>35</sup> 42 U.S.C. § 1396r-8(a)(1).

<sup>36</sup> 42 C.F.R. §§ 447.504(c)(19) and (e)(9) (AMP) and 447.505(c)(7) (best price).

<sup>37</sup> Proposed 42 C.F.R. § 447.502.

<sup>38</sup> Pub. L. 116-59 (Sept. 27, 2019).

brand drug that has an authorized generic excludes sales of the authorized generic. This change became effective for rebate periods beginning October 1, 2019.<sup>39</sup> CMS issued guidance to implement these amendments in Manufacturer Releases 111 (Oct. 17, 2019) and 112 (May 18, 2020). In the latter Release, CMS clarified that the exclusion from AMP not only applies to sales of an authorized generic by the NDA holder to an unaffiliated entity, but also applies where the same company or two corporate affiliates market both the brand version and the authorized generic.

CMS now proposes to revise its regulations consistent with the statutory amendments. Among other things, CMS proposes to revise its authorized generic regulation to state that the primary manufacturer (i.e., NDA holder) must exclude from its calculation of the brand AMP any sales of authorized generic drugs to wholesalers for drugs distributed to retail community pharmacies. Instead, the brand drug will have an AMP exclusive of any authorized generic sale, and the authorized generic will have its own separate AMP. The preamble also reiterates the guidance in Release 112 – that the exclusion of authorized generic sales from the brand AMP applies even when the brand and the authorized generic are marketed by the same company or by two corporate affiliates.<sup>40</sup> As CMS explains, this change will likely result in higher AMPs and increased rebates for the brand drugs.

Manufacturers that have been including authorized generic sales in the AMP of the brand version are expected to revise their AMP calculations for rebate periods beginning with 4Q 2019, but will have a 12 quarter window (i.e., until January 30, 2023) in which to restate their prior period AMPs.

**B. Revising the Definitions of Single Source, Innovator Multiple Source, and Multiple Source Drugs**

Until April 2019, single source drugs and innovator multiple source drugs, which are subject to a substantially higher per-unit rebate than non-innovator drugs, were defined in the statute as drugs approved under an “original new drug application.” This undefined term generated confusion until February 2016, when CMS issued a regulation defining an “original new drug application” as simply an approved NDA, “unless CMS determines that a narrow exception applies.”<sup>41</sup> In the preamble to the 2016 rule, CMS

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<sup>39</sup> See our blog post on this subject at <http://www.fdalawblog.net/2019/10/continuing-appropriations-act-changes-treatment-of-authorized-generics-in-medicaid-rebate-average-manufacturer-price/> .

<sup>40</sup> 85 Fed. Reg. at 37300.

<sup>41</sup> 42 C.F.R. § 447.502.

advised that narrow exceptions would only be granted for drugs that were approved under FDA's paper NDA policy prior to 1984 or under literature-based 505(b)(2) applications, and that had no patent protection or statutory exclusivity.<sup>42</sup>

In Section 6(c)(2) of the Medicaid Services Investment and Accountability Act of 2019 ("MSIAA"),<sup>43</sup> Congress codified CMS's interpretation by deleting the word "original" before "new drug application" in the statute and codifying the narrow exception process. Accordingly, the Medicaid rebate statute now defines a single source drug and an innovator multiple source drug, in part, as a drug that is marketed under an NDA approved by the FDA, "unless the Secretary determines that a narrow exception applies (as described in § 447.502 (or any successor regulation))."<sup>44</sup> CMS is now proposing to make conforming changes in the definitions of single source drug and innovator multiple source drug by deleting the term "original" altogether.

Also to conform to amendments in the MSIAA, CMS is proposing to revise the definitions of "single source drug" and "multiple source drug" to include non-prescription drugs that qualify as covered outpatient drugs, and that meet the other conditions of those definitions.<sup>45</sup>

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<sup>42</sup> 81 Fed. Reg. at 5191; *see also* Manufacturer Release 98 (May 2, 2016).

<sup>43</sup> Pub. L. 116-16, April 18, 2019.

<sup>44</sup> 42 U.S.C. § 1396r-8(k)(7).

<sup>45</sup> Proposed 42 C.F.R. § 447.502.