

**CMS FINAL RULE ON MEDICAID DRUG REBATE PROGRAM****Table of Contents**

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February 1, 2016

**MEMORANDUM**

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SUBJECT: CMS Final Rule On Medicaid Drug Rebate Program

In the February 1, 2016 Federal Register, the Centers for Medicare & Medicaid Services (CMS) published a Final Regulation With Comment Period to implement the Medicaid Drug Rebate Program (MDRP).<sup>1</sup> The regulation was a long time coming. It was primarily designed to implement amendments to the Medicaid Rebate statute made by the Patient Protection and Affordable Care Act (ACA) effective in 2010.<sup>2</sup> CMS issued a proposed rule in February 2012,<sup>3</sup> and this final regulation has followed nearly four years after that. During this period of approximately six years, drug manufacturers have been left, with negligible government guidance, to interpret and put into practice ACA provisions that are frequently cryptic and/or ambiguous. The Final Rule goes a long way toward clarifying ambiguities in the ACA amendments, the underlying Medicaid Rebate statute, and the proposed rule, and contains a number of favorable changes from the proposed rule. However, as this memorandum will point out, the Final Rule leaves certain questions unanswered and raises some new ones.

The effective date of the Final Rule is April 1, 2016, except that provisions relating to the expansion of the MDRP to U.S. Territories will have a delayed effective date of April 1, 2017. Although this is a final regulation, CMS is seeking comments on one issue: the treatment of line extensions of innovator, oral solid dosage form drugs. Comments may be submitted through April 1, 2016.

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<sup>1</sup> Medicaid Program; Covered Outpatient Drugs, 81 Fed. Reg. 5170 (Feb. 1, 2016) (to be codified at 42 C.F.R. pt. 447) [hereinafter "Final Rule"].

<sup>2</sup> Pub. L. No. 111-148 (Mar. 23, 2010). The MDRP provisions of the ACA were amended by Pub. L. No. 111-152 (Mar. 30, 2010) and Pub. L. 111-226 (Aug. 10, 2010). For convenience, these laws are referred to collectively as the ACA in this memorandum.

<sup>3</sup> Medicaid Program; Covered Outpatient Drugs, 77 Fed. Reg. 5318 (Feb. 2, 2012).

The remainder of this memorandum summarizes the most significant provisions of the Final Rule, pointing out where they differ from CMS' proposed rule and where questions remain. Although the regulation is final (except for the provisions relating to line extensions), readers are reminded that, following the issuance of the last major MDRP final regulation in 2007, CMS continued to answer questions in the form of sub-regulatory FAQ guidance for a limited period. Certain of the ambiguities in the Final Rule described in this memorandum would be appropriate subjects for such guidance.

I. DEFINITION OF COVERED OUTPATIENT DRUGS

Under the Medicaid Rebate statute, a manufacturer that has entered into a rebate agreement with the Department of Health and Human Services must pay rebates to states for its covered outpatient drugs (CODs) that are dispensed and paid for under Medicaid. Though the ACA made no changes to the statutory definition of a COD, CMS has added a definition to the MDRP regulations for the first time. While largely tracking the definition in the statute, the Final Rule adds that, in order for a drug to be considered a COD, the manufacturer must “submit[] to CMS evidence to demonstrate that the drug product satisfies the . . . definition.”<sup>4</sup> The preamble indicates that this evidence may consist of the COD status code (a code that identifies the type of FDA approval or other authority under which the drug is marketed), the FDA application number, or the FDA approval letter.<sup>5</sup> The first two items are routinely reported in the Medicaid Drug Data Reporting (DDR) system for every COD; the FDA approval letter is not. It is unclear in what instances, and in what manner, manufacturers may be required to submit copies of approval letters. The definition of a COD includes certain categories of unapproved drugs; for these, the preamble does not specify any evidence that must be submitted apart from identification of the status code in DDR.

CMS proposed adding a requirement that a drug be listed electronically with FDA in order to meet the definition of a COD, but did not include this requirement in the Final Rule. However, the preamble does state that CMS will use information listed with FDA as a means to verify that a drug is a COD, and CMS encourages manufacturers to ensure that their drugs are electronically listed. Should CMS not be able to verify that a product meets the definition of a COD, it will “delete these products from the MDR file after providing notice to manufacturers of these products and to states.”<sup>6</sup>

The preamble provides additional guidance on whether specific types of drugs meet the COD definition. Notably, CMS interprets the statute to provide that “prescription prenatal vitamins and fluoride preparations would qualify as CODs.”<sup>7</sup>

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<sup>4</sup> 42 C.F.R. § 447.502. All citations to 42 C.F.R. are to the Final Rule provisions set forth at 81 Fed. Reg. at 5347-56, unless otherwise indicated.

<sup>5</sup> 81 Fed. Reg. at 5186.

<sup>6</sup> *Id.* at 5184.

<sup>7</sup> *Id.* at 5188.

Approved radiopharmaceuticals are also CODs, but medical foods are not.<sup>8</sup> In a departure from past practice, CMS agreed with a comment “that there should be a process to evaluate a drug’s COD status and manufacturers may submit a request to CMS for reconsideration of their drug’s status.”<sup>9</sup>

## II. INCLUSION OF U.S. TERRITORIES

Since the establishment of the MDRP in 1991, manufacturers have not been required to pay rebates to the U.S. Territories (Puerto Rico, the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa), and sales to customers located in the Territories have likewise not been included in the average manufacturer price (AMP) or best price. However, over manufacturer objections, CMS has finalized its proposal to include the Territories in the Program by expanding the definition of “States” and “United States” to include them.<sup>10</sup> As authority for this expansion, CMS cites the general definitional provisions of the Social Security Act, which define “state” to include the Territories for purposes of Medicaid.<sup>11</sup>

Recognizing that the Territories currently may not have systems in place to adequately track Medicaid utilization and issue compliant rebate invoices, and that manufacturers will also have to change their transaction data systems and rebate payments systems to incorporate the Territories, CMS is delaying these definitional changes until one year after the effective date of the Final Rule – i.e., until April 1, 2017. Until that date, manufacturers will not be responsible for paying rebates to the Territories, nor for including sales to customers in the Territories in their AMP and best price calculations.<sup>12</sup> Territories that do not wish to assume the operational costs may elect not to participate in the MDRP.<sup>13</sup> The preamble explains that CMS will work with the Territories and manufacturers and issue further guidance to address implementation.<sup>14</sup>

Manufacturers would be well advised to review their pricing structure for sales to customers in the Territories to evaluate the impact that these prices could have on best price after the April 1, 2017 effective date.

## III. AVERAGE MANUFACTURER PRICE

The Final Rule clarifies many of the questions and ambiguities in the ACA and the proposed rule regarding AMP. In many cases, manufacturers will find the decisions made by CMS to be favorable, though some questions remain. Throughout the preamble,

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<sup>8</sup> *Id.* at 5185 and 5189.

<sup>9</sup> *Id.* at 5189.

<sup>10</sup> 42 C.F.R. § 447.502.

<sup>11</sup> *See* Social Security Act § 1101(a)(1), 42 U.S.C. § 1301(a)(1).

<sup>12</sup> 81 Fed. Reg. at 5204.

<sup>13</sup> *Id.* at 5205.

<sup>14</sup> *Id.* at 5206.

CMS continues to place emphasis on manufacturers' ability to use reasonable assumptions in making decisions regarding the calculation of AMP where guidance is absent.

A. Wholesaler Sales Included in AMP – Presumed Inclusion

The Medicaid Rebate statute defines AMP as “the average price paid to the manufacturer for the drug in the United States by (i) wholesalers for drugs distributed to retail community pharmacies [(RCPs)]; and (ii) [RCPs] that purchase drugs directly from the manufacturer.”<sup>15</sup> In the preamble to the proposed rule, CMS rejected the “presumed inclusion” approach reflected in long-standing CMS policy and in the previous AMP regulation, under which sales to wholesalers were presumed to be resold to AMP-eligible customers unless the manufacturer could document (e.g., by means of chargeback notices or rebate invoices) that the drug was subsequently sold by the wholesaler to an AMP-excluded entity. The proposed regulation sought to replace presumed inclusion with a so-called “buildup” approach, under which sales to wholesalers would be included only if the manufacturer had chargeback or other data documenting that the wholesaler subsequently sold the drug to an RCP.<sup>16</sup>

Manufacturers' objection to this change was widespread and vigorous. Among other concerns, manufacturers commented that although presumed inclusion generally results in higher rebate liability than would a buildup methodology, the challenges and costs of changes to policies, procedures, and automated systems would be enormous. In the Final Rule, CMS has listened to manufacturer concerns and rejected the proposed buildup approach, having been persuaded that it is “a less practical approach which would represent a significant change from the methodology [that] manufacturers have traditionally used to calculate AMP.”<sup>17</sup> In determining that a presumed inclusion approach is reasonable, CMS references its long-standing policy of permitting manufacturers to make reasonable assumptions in the absence of specific guidance, provided those assumptions are consistent with the requirements of the Medicaid Rebate statute. CMS states that it is reasonable for manufacturers to presume, in the absence of documentation to the contrary, that sales to wholesalers are for drugs distributed to RCPs.<sup>18</sup>

Note that the Final Rule itself provides only that AMP includes “[s]ales to wholesalers for drugs distributed to [RCPs].”<sup>19</sup> It does not mandate either presumed inclusion or the buildup approach. The preamble characterizes presumed inclusion as an “option” and a reasonable assumption that manufacturers are allowed to make, rather

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<sup>15</sup> 42 U.S.C. § 1396r-8(k)(1)(A).

<sup>16</sup> 77 Fed. Reg. at 5330.

<sup>17</sup> 81 Fed. Reg. at 5210.

<sup>18</sup> *Id.*

<sup>19</sup> 42 C.F.R. § 447.504(b)(1).

than a requirement.<sup>20</sup> Although CMS thinks that a buildup approach “has its weaknesses,”<sup>21</sup> it does not appear from the Final Rule or the preamble that the door is closed to a buildup approach if a manufacturer believes that approach is reasonable for its business. One potential effect of using the buildup approach, as recognized by CMS, is that it could result in lower AMPs and therefore lower rebates paid by manufacturers.<sup>22</sup>

#### B. Sales to Retail Community Pharmacies

CMS finalized a definition of “retail community pharmacy” that tracks the statutory definition.<sup>23</sup> In the preamble, CMS notes that it is modifying the regulatory text to include mass merchandisers, which were inadvertently omitted from the proposed definition.<sup>24</sup> CMS also states that a manufacturer may presume that an RCP is licensed and has no duty to investigate.<sup>25</sup>

*Mail order pharmacies:* With regard to the exclusion from the definition for pharmacies that dispense “primarily” through the mail, CMS purportedly declines to set a percentage of sales through the mail that would result in a pharmacy being considered one that dispenses primarily through the mail,<sup>26</sup> but then effectively suggests a 50 percent threshold by stating in the preamble that a manufacturer may reasonably assume that a pharmacy is an RCP “when the majority of the drugs are not dispensed through the mail.”<sup>27</sup> The preamble provides little guidance as to how a manufacturer should make such a determination. CMS believes that the information that manufacturers already have (e.g., chargebacks) will assist in verifying that drugs are not sold to mail order pharmacies.<sup>28</sup> This belief is ill-founded because, although wholesaler chargebacks identify a pharmacy, they typically will not assist in determining whether a majority of the pharmacy’s prescriptions are delivered through the mail. Nevertheless, it is helpful that CMS states that manufacturers are not required to query specialty pharmacies and chain pharmacies to determine overall percentage of purchases that are mail order or non-retail, and may use whatever information is known, along with reasonable assumptions, to determine whether sales to a pharmacy should be excluded from AMP.<sup>29</sup> CMS states that it will issue additional guidance or engage in rulemaking, if necessary, should business models evolve such that this issue needs to be addressed in the future.<sup>30</sup>

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<sup>20</sup> 81 Fed. Reg. at 5210-11.

<sup>21</sup> *Id.* at 5210.

<sup>22</sup> *Id.* at 5211.

<sup>23</sup> 42 C.F.R. § 447.504(a); *see also* 81 Fed. Reg. at 5214.

<sup>24</sup> 81 Fed. Reg. at 5215.

<sup>25</sup> *Id.*

<sup>26</sup> *Id.*

<sup>27</sup> *Id.*

<sup>28</sup> *Id.* at 5223.

<sup>29</sup> *Id.* at 5222-23.

<sup>30</sup> *Id.* at 5215.

*Specialty, home infusion, and home health care pharmacies:* The proposed rule would have included in AMP financial transactions to “entities conducting business as” RCPs, including specialty pharmacies, home infusion pharmacies, and home health care pharmacies.<sup>31</sup> However, in light of comments received, CMS has decided not to require that such transactions necessarily be included in AMP. CMS believes that:

[T]he definition of [RCP] could include some home infusion, home health care or specialty pharmacies because in certain situations, they operate as an independent, chain, supermarket, or a mass merchandiser pharmacy that is licensed as a pharmacy by the state and that dispenses medications to the general public at retail prices. In addition, they do not dispense prescription medications to patients primarily through the mail. Therefore, in such situations, these entities would qualify as [RCPs].<sup>32</sup>

CMS also states that an RCP need not have a “brick and mortar” store front and that modes of delivery such as delivery by a home health aide, pharmacy employee, or courier service would not necessarily render a pharmacy one that primarily dispenses prescription medications through the mail.<sup>33</sup> However, at least with regard to specialty pharmacies, the reality is that such pharmacies typically do primarily dispense through the mail, so sales to specialty pharmacies will usually be excluded from AMP.

*Discounts passed through to RCPs:* A manufacturer may make reasonable assumptions regarding whether discounts provided to an intermediary (such as a wholesaler) are passed through to RCPs.<sup>34</sup> The preamble indicates that, if a manufacturer has no knowledge regarding whether a discount is passed on to an RCP, it can exclude those discounts; however, “where manufacturers have evidence or other knowledge of chargebacks or other discounts being passed through to a retail community pharmacy, the manufacturer must appropriately account for these transactions in their calculation of AMP.”<sup>35</sup> Note that this approach is somewhat inconsistent with presumed inclusion because, while a sale to a wholesaler may be presumed (in the absence of contrary documentation) to be resold to an RCP, a discount to a wholesaler may be presumed (in the absence of contrary documentation) not to be passed through to an RCP. Like the presumed inclusion of sales to wholesalers, the “presumed exclusion” of discounts to wholesalers will tend to increase rebate liability.

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<sup>31</sup> Proposed 42 C.F.R. § 447.504(b)(4).

<sup>32</sup> 81 Fed. Reg. at 5216.

<sup>33</sup> *Id.* at 5221.

<sup>34</sup> *Id.* at 5219.

<sup>35</sup> *Id.*

### C. Transactions Excluded from AMP

The Final Rule, like the proposal, identifies numerous categories of sales that are excluded from AMP.<sup>36</sup> This memorandum does not discuss every category of AMP exclusion, but focuses rather on changes from the proposed rule or other noteworthy exclusions.

#### 1. Bona Fide Service Fees

*Correction of definition:* The proposed definition of “bona fide service fee” limited this term to fees paid to wholesalers or RCPs.<sup>37</sup> In response to comments, CMS has removed the reference to wholesalers and RCPs from the definition of bona fide service fees because the same definition is used for purposes of AMP and best price, and the latter includes numerous categories of customers besides wholesalers and RCPs.<sup>38</sup> However, in the provision excluding bona fide services fees from AMP, CMS specified that the exclusion applies to bona fide service fees paid by manufacturers to wholesalers or RCPs.<sup>39</sup>

*Four-part test:* The statutory definition of AMP, as amended by the ACA, excludes bona fide service fees, “including (but not limited to) distribution service fees, inventory management fees, product stocking allowances, and fees associated with administrative services agreements and patient care programs . . . .”<sup>40</sup> The Final Rule’s preamble explains that the identification in the statute of examples of fees excluded from AMP is instructive, but does not prohibit CMS from applying a general definition of bona fide service fees regardless of the type of recipient.<sup>41</sup> Accordingly, CMS affirms that the four-prong test remains applicable to all types of service fees.

*“Not passed on”:* With regard to the “not passed on” prong of the test, CMS has decided to revise its position so that the prong is more fully aligned with the policy articulated for purposes of average sales price (ASP). That is, CMS states that a manufacturer may presume, in the absence of evidence or notice to the contrary, that a service fee paid is not passed on to a client or customer of the entity to whom the fee is paid.<sup>42</sup> The preamble specifically discusses group purchasing organization (GPO) fees as an example of a fee that may be a bona fide service fee, unless the GPO agreement, or other evidence or knowledge, indicates that the fee is passed on to the GPO’s members.<sup>43</sup>

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<sup>36</sup> 42 C.F.R. § 447.504(c).

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

<sup>38</sup> 81 Fed. Reg. at 5177.

<sup>39</sup> 42 C.F.R. § 447.504(c)(14).

<sup>40</sup> 42 U.S.C. § 1396r-8(k)(1)(B)(i)(II).

<sup>41</sup> 81 Fed. Reg. at 5178.

<sup>42</sup> *Id.*

<sup>43</sup> *Id.* at 5181.

The preamble confirms that if a manufacturer knows that even a portion of the fee is passed on, the entire fee may not be considered a bona fide service fee.<sup>44</sup>

*“Administrative service agreements”*: In response to a request for guidance on the meaning of the term “administrative service agreements,” CMS declines to provide a definition but states that it would consider such agreements “to include, but not be limited to, activities of a clerical, managerial, or processing nature that the manufacturer would otherwise perform (or contract for) in the absence of the administrative service agreement.”<sup>45</sup> CMS also believes that the list in the statute is sufficient to provide manufacturers with a general sense of the types of such fees, and therefore declines to provide further examples, an all-inclusive list, or additional types of bona fide service fees.<sup>46</sup>

*Fair market value*: As in the proposed rule, CMS declines to provide a definition of fair market value, preferring to continue to allow manufacturers the flexibility to determine the fair market value for a particular service in light of the continually changing marketplace for drugs.<sup>47</sup> Similarly, CMS declines to specify the type of documentation necessary to support a manufacturer’s determination of fair market value for a service, though CMS reiterates that it expects the determination to be made contemporaneously with the agreement to pay the fee.<sup>48</sup>

*Price appreciation credits*: As in the proposed rule, CMS addresses price appreciation credits in the preamble to the Final Rule, stating that it continues to believe that price appreciation credits would likely not meet the definition of a bona fide service fee. In CMS’ view, such credits are used to adjust the wholesaler’s purchase price for drugs remaining in inventory for which the manufacturer’s sale price has increased, and therefore amount to a subsequent price increase that affects the price paid to the manufacturer.<sup>49</sup>

## 2. Customary Prompt Pay Discounts

The Medicaid Rebate statute excludes from AMP “customary prompt pay discounts extended to wholesalers.”<sup>50</sup> CMS confirms in the preamble that, since the

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<sup>44</sup>

*Id.*

<sup>45</sup>

*Id.* at 5179.

<sup>46</sup>

*Id.*

<sup>47</sup>

*Id.*

<sup>48</sup>

*Id.* at 5180.

<sup>49</sup>

*Id.* at 5228. The treatment in AMP of price appreciation credits offset against distribution service fees paid to wholesalers is the subject of a *qui tam* False Claims Act lawsuit against several pharmaceutical manufacturers. See *United States ex rel. Streck v. Allergan et al.*, 894 F. Supp. 2d 584 (E.D. Pa. 2012).

<sup>50</sup>

42 U.S.C. § 1396r-8(k)(1)(B)(i)(I).

statute only refers to wholesalers, customary prompt pay discounts extended to RCPs must be included in AMP as discounts.<sup>51</sup>

### 3. Returned Goods

CMS finalized as proposed the exclusion from AMP for reimbursement by a manufacturer for returned goods. In the preamble, CMS declines to further define recalled, damaged, expired, or unsalable goods, as those “terms are self-explanatory within the standard industry practice.”<sup>52</sup> In addition, CMS has not adopted “returned in good faith” as a standard for excluding returns, as it was under the prior AMP regulation.<sup>53</sup> However, CMS believes that “the exclusion of reimbursement for returns designed to adjust prices or disguise price concessions would not be a return made in good faith because the reimbursement would cover more than the costs of goods and goods handling and processing, reverse logistics, and drug destruction.”<sup>54</sup>

### 4. Discounts or Benefits to Patients

In the proposed rule, CMS proposed five categories of discounts or benefits to patients that would be excluded from AMP under certain conditions: coupons, vouchers, prices negotiated under manufacturer drug discount programs, free goods under patient refund or rebate programs, and free goods under copayment assistance programs and patient assistance programs.<sup>55</sup> CMS has made several revisions to those exclusions to provide clarity and consistency among the programs, the more significant of which are as follows:

- For each category of patient benefit, CMS has included the requirement that the full value of the benefit (whether it be a coupon, voucher for free product, discount, refund/rebate, or copayment assistance) be passed on to the consumer, with the pharmacy, agent, or other AMP-eligible entity not receiving any price concession.<sup>56</sup>
- CMS has moved patient assistance programs into the voucher category in recognition that both types of programs are designed to offer free goods to patients, and has clarified that these programs must provide free goods not

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<sup>51</sup> 81 Fed. Reg. at 5229.

<sup>52</sup> *Id.*

<sup>53</sup> *Id.*

<sup>54</sup> *Id.*

<sup>55</sup> Proposed 42 C.F.R. § 447.504(c)(25)-(29).

<sup>56</sup> 42 C.F.R. § 447.504(c)(25)-(29). In the proposed rule, the concept that the pharmacy, agent, or other AMP-eligible entity not receive any price concessions was only present in the proposed exclusion pertaining to coupons; however, discussion of the requirement was in preamble discussions for other exclusions.

contingent on any other purchase requirement in order to be excluded from AMP.<sup>57</sup>

- In recognition that manufacturer-sponsored patient refund/rebate programs typically offer discounts or rebates rather than free goods, CMS has removed “free of charge” from the exclusion.<sup>58</sup>

The preamble provides additional clarifications regarding these programs. First, CMS clarifies that a benefit to a patient provided at the pharmacy counter is not a discount received by or passed through to the RCP.<sup>59</sup> Second, CMS states that it intends to issue guidance regarding the limitation that a free good may not be contingent on “any other purchase,” in order to provide consistency among treatment by manufacturers.<sup>60</sup> Third, CMS agrees that a fee paid to an RCP to process a voucher should be considered separately from the benefit to the patient and would likely meet the requirements for a bona fide service fee, though any determination would be fact-specific.<sup>61</sup> Fourth, CMS confirms that manufacturer vouchers for free goods that are provided by a provider to a patient are excluded regardless of whether the provider is made whole (i.e., reimbursed for the cost of the product) in cash or in kind.<sup>62</sup>

CMS has made the same revisions to the exclusions from 5i AMP and best price for these programs.<sup>63</sup>

## 5. Third Party Payors

In the Final Rule, as under the previous AMP regulation,<sup>64</sup> CMS has adopted a consistent approach to the treatment of rebates to third party payors, whether public or private: sales to wholesalers or RCPs that are ultimately reimbursed by third party payors are included in AMP, but the rebates to the payors are ignored. This approach applies to rebates paid to all government insurers, including Medicaid rebates, Medicaid supplemental rebates, rebates to State Pharmacy Assistance Programs (SPAPs), the TRICARE retail refund program, Medicare Part D, and AIDS Drug Assistance Programs (ADAPs), and rebates to commercial insurers.<sup>65</sup>

<sup>57</sup> 42 C.F.R. § 447.504(c)(26); *see also* 81 Fed. Reg. at 5234.

<sup>58</sup> 42 C.F.R. § 447.504(c)(28); *see also* 81 Fed. Reg. at 5234.

<sup>59</sup> 81 Fed. Reg. at 5235.

<sup>60</sup> *Id.*

<sup>61</sup> *Id.*

<sup>62</sup> *Id.* at 5236.

<sup>63</sup> 42 C.F.R. §§ 447.504(e)(13)-(17), 447.505(c)(8)-(12).

<sup>64</sup> 72 Fed. Reg. 39, 142 (July 17, 2007) (former 42 C.F.R. 447.504) (hereinafter the “DRA Rule”).

<sup>65</sup> 81 Fed. Reg. at 5226.

## 6. Pharmacy Benefit Managers (PBMs)

In recognition of the fact that manufacturers do not “sell” drugs to PBMs but rather provide utilization rebates, the Final Rule excludes from AMP “rebates and discounts” to PBMs, rather than “sales” to PBMs as in the proposal.<sup>66</sup> If a PBM and a RCP are part of the same corporate enterprise, each entity should be considered for the AMP calculation separately based on its own activities.<sup>67</sup> If a manufacturer knows that a PBM is passing price concessions or discounts on to the corporate affiliate RCP, the manufacturer should include those price concessions in AMP, maintaining appropriate documentation that supports inclusion of the price concessions.<sup>68</sup> Otherwise, the manufacturer may make a reasonable assumption that PBM discounts or price concessions are not passed on to the PBM’s corporate affiliate RCP and may exclude such price concessions from its calculation of AMP.<sup>69</sup>

### D. Bundled Sales

CMS’ proposed definition of a “bundled sale” included a provision that “the discount in a bundled sale, including but not limited to those resulting from a contingent arrangement, are allocated proportionally to the total dollar value of the units of all drugs sold under the bundled arrangement.”<sup>70</sup> The underscored language suggested that CMS would require manufacturers to allocate non-contingent discounts, along with contingent discounts, on drugs included in a bundled sale agreement.<sup>71</sup> In response to manufacturer objections on this point, CMS removed the phrase “but not limited to” in the final rule.<sup>72</sup> The preamble clarifies that CMS did not intend to change the policy articulated in the DRA Rule; rather, it intended “to reiterate that when a bundled sale exists, manufacturers are required to allocate all discounts across all the products in the bundled arrangement.”<sup>73</sup>

CMS also confirms that a bundled arrangement is not created when a manufacturer offers discounts on multiple products under the same contract as long as all of the following conditions are met: (1) a price concession is established independently for each product within the contract; (2) the purchase price is not contingent upon any other product in the contract or some other performance requirement (e.g., achievement of market share or inclusion or tier placement on a formulary); and (3) the price concession

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<sup>66</sup> 42 C.F.R. § 447.504(c)(18); *see also* 81 Fed. Reg. at 5231.

<sup>67</sup> 81 Fed. Reg. at 5231.

<sup>68</sup> *Id.* at 5232.

<sup>69</sup> *Id.*

<sup>70</sup> Proposed 42 C.F.R. § 447.502 (emphasis added).

<sup>71</sup> 81 Fed. Reg. at 5181.

<sup>72</sup> 42 C.F.R. § 447.502.

<sup>73</sup> 81 Fed. Reg. at 5182.

under the contract is not greater than if the product was purchased outside of the contract.<sup>74</sup>

CMS also revised the definition of a bundled sale to include the term “product,” in order to make it clear that a bundled arrangement can include purchase requirements for products other than CODs and that any discounts should be allocated across all of the bundled products.<sup>75</sup>

#### E. 5i Drugs

The ACA added an alternative AMP calculation for inhalation, infusion, instilled, implanted, or injectable drugs that are not generally dispensed through RCPs (“5i drugs”).<sup>76</sup> CMS proposed a definition of the term “5i drug” that tracked the statutory language, but decided it was unnecessary and did not finalize it.<sup>77</sup>

*Route of administration:* CMS had proposed that a manufacturer must use FDA’s Routes of Administration list to determine whether a drug is an inhalation, infusion, instilled, implanted, or injectable drug. However, CMS decided not to mandate the source of information that manufacturers must use in this determination, explaining that “manufacturers will have the flexibility to determine whether their drug is a 5i drug based on reasonable assumptions,” since they are knowledgeable about how their drugs are administered.<sup>78</sup> The preamble suggests that sources could include, not only FDA’s Routes of Administration list, but also the manufacturer’s prescribing information or drug package insert.<sup>79</sup>

*Not generally dispensed through an RCP:* The proposed rule provided that a drug is not generally dispensed through an RCP if 90 percent or more of its sales were to entities other than RCPs or wholesalers for drugs distributed to RCPs, with the determination to be made on a monthly and quarterly basis.<sup>80</sup> In the Final Rule, CMS has changed the threshold from 90 percent to 70 percent.<sup>81</sup> CMS based the 70 percent threshold on comments and analyses suggesting that it would be “more likely than a 90 percent threshold to allow for an AMP calculation based on a sufficient number of sales, which would promote stability and consistency in the AMP calculation.”<sup>82</sup> The “not generally dispensed” determination should be made based on units, at the NDC-9 level.<sup>83</sup> Rejecting requests that manufacturers be permitted to make the “not generally dispensed”

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<sup>74</sup>

*Id.*

<sup>75</sup> 42 C.F.R. § 447.502; *see also* 81 Fed. Reg. at 5183.

<sup>76</sup> 42 U.S.C. § 1396r-8(k)(1)(B)(i)(iv).

<sup>77</sup> 81 Fed. Reg. at 5174.

<sup>78</sup> *Id.* at 5237.

<sup>79</sup> *Id.*

<sup>80</sup> Proposed 42 C.F.R. § 447.507.

<sup>81</sup> 42 C.F.R. § 447.507(b)(1).

<sup>82</sup> 81 Fed. Reg. at 5239.

<sup>83</sup> 42 C.F.R. § 447.507(b)(1).

determination on an annual basis, CMS finalized the requirement that the determination be made monthly,<sup>84</sup> but did drop the requirement that the determination also be made on a quarterly basis. In addition, CMS states in the preamble that manufacturers are permitted, but not required, to use a smoothing process in calculating whether the 70 percent unit threshold is met, in order to use data from a current, yet longer, period of time in making the “not generally dispensed” determination.<sup>85</sup>

*5i AMP methodology:* With regard to categories of transactions that are included in and excluded from 5i AMP, CMS decided in the Final Rule to follow the model of the standard AMP calculation and provide a list of inclusions and exclusions (the proposed rule listed only the inclusions).<sup>86</sup> The list of inclusions largely tracks the list proposed with changes for consistency of terminology between the standard AMP inclusions and the 5i AMP inclusions.<sup>87</sup> However, one noteworthy change was that CMS revised the provision regarding PBMs to clarify that all rebates and discounts provided to PBMs are to be included in the 5i AMP, regardless of whether the PBM is acting as an insurer or if it owns its own pharmacies.<sup>88</sup>

The new list of 5i AMP exclusions in the Final Rule includes sales to government, FSS, and 340B purchasers, bona fide service fees, customary prompt pay discounts, returned goods, free goods not contingent on purchases, sales to patients, patient discount and free goods programs, and charitable entities.<sup>89</sup> These exclusions mirror the corresponding exclusions from standard AMP.

*Other drugs not dispensed through RCPs:* A number of comments raised the question of how AMP should be calculated for oral CODs, such as certain REMS drugs, that may be dispensed only through entities that are not RCPs, with some comments suggesting that such drugs should use the 5i AMP calculation.<sup>90</sup> CMS disagrees with that suggestion, stating that it does “not find a basis for making this exception in the statute,”<sup>91</sup> but provides inadequate guidance regarding an alternative solution. CMS states that “when there are any AMP eligible sales, the calculation should be made based on those sales to entities that meet the definition of [an RCP],” and also believes the presumed inclusion approach will help reduce the instances where there are no includable sales.<sup>92</sup> However, CMS does not address the situation where, even with presumed inclusion, there are no sales to RCPs or wholesalers who sell to RCPs. The preamble

<sup>84</sup> *Id.* § 447.507(b)(2).

<sup>85</sup> 81 Fed. Reg. at 5240.

<sup>86</sup> 42 C.F.R. § 447.504(d) (included transactions), § 447.504(e) (excluded transactions).

<sup>87</sup> As with the proposed rule, in the Final Rule, 5i AMP includes the sales and associated price concessions from the standard AMP, as well as the transactions identified in the statute for 5i drugs. *See* 42 U.S.C. § 1396r-8(k)(1)(B)(i)(IV).

<sup>88</sup> 42 C.F.R. § 447.504(d)(2); *see also* 81 Fed. Reg. at 5249.

<sup>89</sup> 42 C.F.R. § 447.504(e).

<sup>90</sup> 81 Fed. Reg. at 5249.

<sup>91</sup> *Id.* at 5250.

<sup>92</sup> *Id.*

merely states that CMS “will continue to consider this issue and will provide additional guidance or rulemaking, if needed.” In the interim, manufacturers are to rely on reasonable assumptions.<sup>93</sup>

*Base date AMP for 5i drugs:* CMS has rejected suggestions that a manufacturer should have two baseline AMPs – one using the standard AMP calculation and one using the 5i AMP calculation – so that a drug that flip-flops between 5i and non-5i status in different quarters will be able to use the appropriate baseline AMP for the additional rebate calculation. CMS believes that there is no statutory basis for dual baseline AMPs, and that, in any event, reasonable assumptions and the option to use a unit-smoothing process in the “not generally dispensed” determination will reduce such flip-flops.<sup>94</sup> However, if the baseline AMP was calculated under the standard methodology for a drug that is now a 5i drug, or vice versa, the baseline AMP must be used regardless.<sup>95</sup> Similarly, where a drug flips between 5i and non-5i status among the three months of a quarter, the quarterly AMP is nevertheless calculated as the weighted average of the monthly AMPs. Manufacturers have the opportunity to restate an ACA base date AMP for each drug (*see* Section VII(B), below). If a manufacturer determines that it has a 5i drug that is not generally dispensed by RCPs, it can report an ACA base date AMP based on the 5i AMP calculation.

#### F. Smoothing

The proposed rule stated that a manufacturer must use a smoothing methodology in its calculation of monthly AMP to estimate the impact of lagged price concessions, but it did not set forth the details of the smoothing methodology.<sup>96</sup> In response to comments, CMS added to the regulation the specific details of the smoothing methodology for lagged price concessions, which are consistent with the method in the ASP regulations.<sup>97</sup> The Final Rule also contains an example of how to smooth lagged price concessions.<sup>98</sup>

The Final Rule, like the proposal, does not mandate smoothing of ineligible indirect sales identified through lagged data (e.g., chargebacks), but the preamble explains that manufacturers may do so, using the same or similar methodology used for ASP calculations.<sup>99</sup>

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<sup>93</sup>

*Id.*

<sup>94</sup>

*Id.* at 5243.

<sup>95</sup>

*Id.*

<sup>96</sup>

Proposed 42 C.F.R. § 447.510(d)(2)(iii).

<sup>97</sup>

42 C.F.R. § 447.510(d)(2)(iii); *see also* 81 Fed. Reg. at 5285.

<sup>98</sup>

42 C.F.R. § 447.510(d)(2)(vi); *see also* 81 Fed. Reg. at 5285-86.

<sup>99</sup>

81 Fed. Reg. at 5287.

### G. Quarterly AMP

Although CMS did not revise the text of the regulation regarding the calculation of quarterly AMP, the preamble states that the appropriate method for calculating the “weighted average of monthly AMPs in that quarter” is the following:<sup>100</sup>

$$\frac{(\text{month 1 AMP} \times \text{month 1 units}) + (\text{month 2 AMP} \times \text{month 2 units}) + (\text{month 3 AMP} \times \text{month 3 units})}{\text{month 1 units} + \text{month 2 units} + \text{month 3 units}}$$

## IV. BEST PRICE

### A. Definition and Prices Included

The Medicaid Rebate statute defines best price to include prices to “any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity” in the U.S., with certain exclusions.<sup>101</sup> The definition of best price in the Rebate Agreement and the DRA Rule considerably exceeded the statute, encompassing prices to “any entity in the U.S.” Although the ACA made no changes to the statutory list of included entities, the Final Rule narrows the regulation so that it is consistent with the statute. Under the Final Rule, best price means:

[F]or 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.<sup>102</sup>

Rather than listing best-price eligible entities, as under the DRA Rule, the new Final Rule merely provides that best price includes all prices and associated rebates, discounts, or other transactions that adjust prices either directly or indirectly to the best-price eligible entities identified above, except for prices identified in the list of excluded prices.<sup>103</sup>

### B. Stacking of Discounts

Although both the statute and the Final Rule define best price as a price to an individual customer, the preamble suggests that price concessions offered to two unrelated entities for the same drug unit may be required to be added together when determining best price. As a basis for this approach, the preamble cites the requirement

<sup>100</sup> *Id.* at 5251.

<sup>101</sup> 42 U.S.C. § 1396r-8(c)(1)(C).

<sup>102</sup> 42 C.F.R. § 447.505(a).

<sup>103</sup> *Id.* § 447.505(b).

to adjust best price “if cumulative discounts, rebates, or other arrangements subsequently adjust the prices available from the manufacturer.”<sup>104</sup> An example is provided of a rebate to a PBM where the rebates are designed to adjust prices at the retail or provider level, and a discount to an RCP on the same transaction.<sup>105</sup> This example is less than helpful, since CMS provides no clarity – and has never provided clarity – on when a rebate to a PBM is considered to adjust prices at the retail or provider level.

### C. Exclusions from Best Price

In the list of price categories excluded from best price, the Final Rule contains additions and clarifications that do not appear in the current best price regulation. These include specific mention of TRICARE prices, Medicare Part D coverage gap discounts, direct sales to patients, and exclusions for patient discount, coupon, voucher, and free drug programs that parallel the corresponding exclusions from AMP.<sup>106</sup> In addition, the preamble clarifies that sales of a drug to a manufacturer for use in a clinical trial are excluded from best price.<sup>107</sup> As discussed in Section III(C)(1) in connection with AMP, bona fide service fees to any best price-eligible entity are excluded.

CMS initially proposed to exclude from the determination of best price the prices charged “under the 340B program” to covered entities. If finalized, this language would have required manufacturers to include in best price any sub-340B discounts, discounts on orphan drugs, and other discounts to 340B covered entities that are not required under the 340B program, which would have discouraged manufacturers from providing such voluntary discounts. In response to comments, CMS has revised the exclusion to apply to “any prices charged” to a 340B covered entity, including inpatient prices charged to disproportionate share hospitals.<sup>108</sup>

### V. AUTHORIZED GENERICS

Although the ACA did not amend the provisions of the Medicaid Rebate statute relating to authorized generics, CMS has made largely organizational changes to the current authorized generic regulations, and provided guidance on how the agency interprets the provisions. CMS has added definitions of a primary manufacturer and secondary manufacturer, which remain unchanged from the proposed rule. A “primary manufacturer” is “a manufacturer that holds the NDA of the authorized generic drug,” and a “secondary manufacturer” is “a manufacturer that is authorized by the primary manufacturer to sell the drug but does not hold the NDA.”<sup>109</sup>

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<sup>104</sup> 81 Fed. Reg. at 5253.

<sup>105</sup> *Id.*

<sup>106</sup> 42 C.F.R. § 447.505(c).

<sup>107</sup> 81 Fed. Reg. at 5255.

<sup>108</sup> *Id.* at 5256-67.

<sup>109</sup> 42 C.F.R. § 447.506(a).

A. Inclusion of Authorized Generic Sales in AMP

The Final Rule provides that the primary manufacturer must include in AMP its sales of authorized generics “that have been sold or licensed to a secondary manufacturer, acting as a wholesaler for drugs distributed to retail community pharmacies, or when the primary manufacturer holding the NDA sells directly to a wholesaler.”<sup>110</sup> It would be reasonable to conclude, based on the regulatory text alone, that the transfer price of an authorized generic sold by a primary manufacturer to a secondary manufacturer should be included in the AMP of the former, because a secondary manufacturer in the usual case would fall within the statutory and regulatory definition of a “wholesaler” – i.e., an entity “engaged in wholesale distribution of prescription drugs to [RCPs], including [among other things] manufacturers, repackers [and] distributors . . . .”<sup>111</sup> Moreover, under the Final Rule, manufacturers may presume that prices paid by wholesalers are for drugs distributed to RCPs, in the absence of guidance and adequate documentation to the contrary.<sup>112</sup>

However, in the preamble, CMS takes an inexplicably narrow view of whether a secondary manufacturer may be a wholesaler. For example, CMS states that the “primary manufacturer should not include the price . . . of the authorized generic drug in its AMP when the secondary manufacturer is relabeling the product with its own or a different NDC . . . . In situations when the secondary manufacturer relabels the product with a different NDC, the secondary manufacturer would be acting as a manufacturer. . . .”<sup>113</sup> The preamble adds that the sale of an authorized generic to the secondary manufacturer would not be included in the primary manufacturer’s AMP “[i]f the secondary manufacturer does not qualify as a wholesaler (for example, the secondary manufacturer relabels the product and then sells it to wholesalers or directly to [RCPs]).”<sup>114</sup> Every authorized generic is relabeled from the brand version, and CMS does not explain why this has any bearing on whether the secondary manufacturer meets the definition of a wholesaler. Moreover, there is no explanation why the fact that a secondary manufacturer might sell to wholesalers and RCPs (as many do) disqualifies it from being a “wholesaler,” as defined. The treatment of transfers of authorized generics in AMP would be a question ripe for further, sub-regulatory guidance from CMS.

CMS does provide clear guidance on situations where a brand and its authorized generic version are both sold by a single manufacturer. In such cases, the sales of both drugs would be “blended for AMP, even if . . . the manufacturer may have given the drug a different product code.”<sup>115</sup>

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<sup>110</sup> *Id.* § 447.506(b).

<sup>111</sup> *Id.* § 447.502.

<sup>112</sup> 81 Fed. Reg. at 5210.

<sup>113</sup> *Id.* at 5261.

<sup>114</sup> *Id.*

<sup>115</sup> *Id.* at 5260.

Addressing situations where the primary and secondary manufacturers are corporate affiliates, CMS provides little useful guidance, other than recommending that the manufacturer determine whether the secondary manufacturer meets the definition of a “wholesaler,” and use reasonable assumptions.<sup>116</sup>

#### B. Inclusion of Authorized Generic Sales in Best Price

CMS did not make significant changes to the current rule that a primary manufacturer must include in the brand best price the price of an authorized generic sold to a secondary manufacturer, or any other manufacturer, wholesaler, retailer, provider, HMO, nonprofit entity, or governmental entity in the United States.<sup>117</sup> Where the primary and secondary manufacturers are the same company, CMS does “not believe the manufacturers . . . should determine a separate best price for each NDC . . . .”<sup>118</sup> The preamble (though not the regulation) makes clear that best price is adjusted for royalties, licensing fees, or profit-sharing payments made by the secondary to the primary manufacturer.<sup>119</sup>

### VI. DETERMINING REBATES

Under the Medicaid Rebate statute as amended by the ACA, effective January 1, 2010, the rebate per unit (RPU) for a single source or innovator multiple source drug is the sum of the basic rebate and an additional rebate triggered by price increases greater than inflation. The basic rebate is the greater of: (1) the difference between the best price and the AMP, or (2) the AMP multiplied by 17.1 percent for a clotting factor, 17.1 percent for a drug approved exclusively for pediatric indications, and 23.1 percent for all other innovator drugs. The RPU for a noninnovator multiple source drug is the AMP multiplied by 13 percent.<sup>120</sup> These statutory provisions are reflected in the Final Rule without change from the proposal.<sup>121</sup>

#### A. Innovator Versus Noninnovator Drugs

*Original NDAs:* In the Medicaid Rebate statute and current regulations, the definitions of both an innovator multiple source drug and a single source drug refer to a drug marketed under an “original new drug application.”<sup>122</sup> In its regulatory definitions

<sup>116</sup>

*Id.*

<sup>117</sup>

42 C.F.R. § 447.506(c).

<sup>118</sup>

81 Fed. Reg. at 5260.

<sup>119</sup>

*Id.* at 5261.

<sup>120</sup>

42 U.S.C. § 1396r-8(c). Under an amendment to the Medicaid Rebate statute enacted in section 602 of the Bipartisan Budget Act of 2015, Pub. L. No. 114-74, noninnovator multiple source drugs will also be subject to an additional rebate effective January 1, 2017. This amendment was enacted on November 2, 2015 – too recently to be addressed in the Final Rule.

<sup>121</sup>

42 C.F.R. § 447.509(a).

<sup>122</sup>

42 U.S.C. § 1396r-8(k)(7)(A)(ii) and (iv); 42 C.F.R. § 447.502 (2015) (emphasis added).

of these terms, CMS proposed to delete the word “original” from the regulations, so that an original NDA would simply be defined as an NDA.

Many commenters objected that CMS does not have authority to read a term out of the statute, and that Congress did not intend all NDAs to be considered original. For example, products approved under FDA’s paper NDA policy prior to the Hatch-Waxman amendments of 1984, when ANDAs were added to the statute, were equivalent to generics. Similarly, many drugs approved through section 505(b)(2) applications under the Federal Food, Drug, and Cosmetic Act based on literature pertaining to a reference brand drug are functionally equivalent to generics. Many commenters pointed out that Congress presumably did not consider such applications to be “original,” and did not intend such drugs to be subject to higher rebates applicable to innovator drugs.

CMS did not agree that it was disregarding the term “original” in the statute. However, CMS conceded that, while “original NDA” typically means an NDA, “[t]here may be very limited circumstances where . . . certain drugs might be more appropriately treated as if they were approved under an ANDA and classified as a noninnovator multiple source drug.”<sup>123</sup> Accordingly, the word “original” has been added back into the final definitions of innovator multiple source drug and single source drug, and these definitions have also been revised to add that an “original NDA” means an NDA “unless CMS determines that a narrow exception applies.”<sup>124</sup>

The preamble describes the process for such a determination. The “narrow exception” will not apply to a drug unless it was approved under either FDA’s pre-1984 paper NDA policy or a literature-based 505(b)(2) application, and did not receive patent protection or statutory exclusivity. A manufacturer who markets a drug that is approved under an NDA but is currently reported to the MDRP as a noninnovator drug, and who believes it has approval from CMS to do so, or believes that the drug qualifies for the narrow exception, must submit supportive materials to CMS. CMS will issue a written decision on whether the narrow exception applies. Such manufacturers will have until March 31, 2017 to apply for the narrow exception, and, if it is denied, change the drug category in DDR. Until that date, CMS will not take any administrative action against such a manufacturer. CMS cautions, however, that this exercise of administrative enforcement discretion does not relieve manufacturers of other liability.<sup>125</sup>

*Delayed compliance date:* CMS rejected comments that the revised definition of innovator multiple source drug should have prospective application only, asserting that the revised definitions are clarifications of existing policy.<sup>126</sup> Therefore, if a manufacturer has reported a COD as a noninnovator multiple source drug in the past and now needs to change the drug category to innovator, the manufacturer will be liable for

<sup>123</sup> 81 Fed. Reg. at 5191.

<sup>124</sup> 42 C.F.R. § 447.502.

<sup>125</sup> 81 Fed. Reg. at 5191-92.

<sup>126</sup> *Id.* at 5193.

underpaid rebates for past periods. However, recognizing that such a manufacturer will need to make operational changes to calculate a baseline AMP and best price for prior periods, CMS will allow manufacturers until March 31, 2017 “to make the necessary data changes before CMS takes any administrative action, if appropriate.”<sup>127</sup>

*Change from “N” to “I” and baseline AMP:* The preamble addresses data gaps that may arise when a drug category is changed from noninnovator (“N”) to innovator (“I”) multiple source drug in order to bring a COD into compliance with the final definition of an “innovator multiple source drug.” If a manufacturer changes the drug category but, because it acquired the drug from another manufacturer, it does not have access to the original market date or baseline AMP, CMS advises that the reporting manufacturer should enter the purchased product date (PPD) – i.e., the date on which the manufacturer acquired the drug – and the DDR system will supply the base date AMP from data submitted by the original owner.<sup>128</sup> This appears to be a helpful change from the policy articulated by CMS in manufacturer releases, where CMS stated that it will not provide such historical data.<sup>129</sup>

If a manufacturer obtains approval of an NDA for a drug that was previously reported as a N drug, the baseline AMP is the first full quarter after the market date of the newly approved drug – not the original N drug.<sup>130</sup>

#### B. Clotting Factors

Without change from the proposed rule, the Final Rule defines a “clotting factor” as a “hemophilia clotting factor for which a separate furnishing payment is made under” Medicare Part B and which is included on a list of such factors maintained on the CMS web site.<sup>131</sup> A list of clotting factors is also posted on the Medicaid DDR system. The preamble explains that the 17.1 percent rebate percentage applies beginning the later of the first quarter of 2010 or the market date quarter.<sup>132</sup>

#### C. Drugs with Exclusively Pediatric Indications

For purposes of applying the 17.1 percent rebate percentage, the proposed rule defined a “pediatric indication” as an indication for individuals from birth through 16 years of age (i.e., before the 17<sup>th</sup> birthday), as stated in the Indications and Usage section of the approved labeling. Despite numerous comments that the age limit should be higher, the Final Rule adheres to the 16 year age limit, which is consistent with FDA drug labeling regulations.<sup>133</sup> However, CMS did agree with comments that the age limit does

<sup>127</sup>

*Id.*

<sup>128</sup>

*Id.* at 5194.

<sup>129</sup>

*See* Manufacturer Release 59, at 4 (June 23, 2003).

<sup>130</sup>

81 Fed. Reg. at 5198.

<sup>131</sup>

42 C.F.R. § 447.502.

<sup>132</sup>

81 Fed. Reg. at 5264.

<sup>133</sup>

*See* 21 C.F.R. §§ 201.57 and 201.80.

not necessarily have to be in the Indications and Usage section of the labeling, so the final definition has been amended to provide that the age limit may alternatively appear “in an explanation elsewhere in the labeling that makes it clear that the drug is for use only in a pediatric age group, or a subset of this group.”<sup>134</sup>

#### D. New Formulations

The ACA established an alternative method of calculating the Medicaid rebate for a “line extension” of an existing oral solid dosage form innovator drug. The statute defines a line extension as “a new formulation of the drug, such as an extended release formulation.”<sup>135</sup> For these drugs, the unit rebate is the greater of: (1) the unit rebate calculated under the standard rules, or (2) the highest additional rebate for any strength of the original drug, expressed as a percentage of AMP, multiplied by the AMP of the line extension drug.<sup>136</sup> To implement this provision, CMS proposed a complex methodology that involved the use of FDA’s Chemical Type classifications for marketing applications, the Orange Book, the NDC Directory, Drugs@FDA, and the CMS MDRP drug data file. The proposal would have included in the definition of “line extension” not only an extended release formulation, but also any other new formulation, new indication, or new combination. In addition, the proposed definition would have included a line extension drug whose corresponding initial drug is marketed by an unrelated manufacturer, and would have required sharing of pricing data in such instances.<sup>137</sup>

Pharmaceutical industry commenters vigorously argued that the proposal was unworkable, extended well beyond the language of the statute, and involved inter-company sharing of pricing data that was of questionable feasibility and lawfulness. CMS listened and has retreated from its proposal, which is not being finalized in the Final Rule. Instead, the Final Rule sets forth the alternative rebate calculation without defining a line extension or describing how to identify one. CMS is requesting additional comments on the definition of line extensions and how to identify new formulations, which CMS “may consider addressing . . . in future rule making.”<sup>138</sup> Comments may be submitted through April 1, 2016. In the interim, CMS advises manufacturers to rely on the statutory definition of a line extension, and use reasonable assumptions.<sup>139</sup>

In addition, CMS has added to the regulation the important limitation that an alternative rebate will only be required if the manufacturer of the line extension drug also manufactures the initial brand name drug, or has a corporate relationship with the

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<sup>134</sup> 42 C.F.R. § 447.502.

<sup>135</sup> 42 U.S.C. § 1396r-8(c)(2)(C).

<sup>136</sup> *Id.*

<sup>137</sup> Proposed 42 C.F.R. § 447.509(a)(4).

<sup>138</sup> 81 Fed. Reg. at 5265.

<sup>139</sup> *Id.*

manufacturer of the initial brand name drug.<sup>140</sup> This will obviate the need for sharing of pricing data sharing between competitors.

The following additional favorable guidance is provided in the preamble:

- As in the proposed regulation, no alternative rebate requirement will apply to a line extension if the initial brand name drug is not active in the MDRP.<sup>141</sup>
- A drug whose sole change from the initial brand name drug is the strength will not be treated as a line extension drug. However, a new strength of a line extension drug will, like the initial line extension drug, also be treated as a line extension.<sup>142</sup>
- An authorized generic may also be a line extension drug. If so, this presumably would mean that: (1) sales of the authorized generic are taken into account in the AMP (if applicable) and best price of the brand version in accordance with the authorized generic rules, and (2) both the brand version and the authorized generic, as line extensions of another brand name drug, would be subject to the alternative rebate calculation for line extensions, which would be calculated based on the AMP and additional rebate of the other brand name drug.<sup>143</sup>
- A sample alternative rebate calculation is provided.<sup>144</sup>

Manufacturers are responsible for identifying their line extension drugs in DDR, and also for identifying the initial brand name drug with the highest additional-rebate-to-AMP ratio. Manufacturers will not submit the ratio itself or the alternative unit rebate amount (URA), which will be calculated by CMS. However, CMS cautions that manufacturers are also responsible for calculating their own URAs.<sup>145</sup> Also, CMS makes clear that the alternative rebate for line extensions applies to all line extension drugs marketed as of the ACA effective date of January 1, 2010, not just those marketed after the effective date of the Final Rule.<sup>146</sup>

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<sup>140</sup> 42 C.F.R. § 447.509(a)(4)(ii); *see also* 81 Fed. Reg. at 5266.

<sup>141</sup> 81 Fed. Reg. at 5267.

<sup>142</sup> *Id.*

<sup>143</sup> *Id.* at 5267-68.

<sup>144</sup> *Id.* at 5269-70.

<sup>145</sup> *Id.* at 5269.

<sup>146</sup> *Id.*

E. Rebates for Drugs Dispensed by Medicaid Managed Care Organizations (MCOs)

Under an ACA amendment to the Medicaid Rebate statute, manufacturers are required to pay rebates on covered outpatient drugs dispensed by Medicaid MCOs on or after March 23, 2010, except where the drug was purchased under the 340B drug discount program.<sup>147</sup> The Final Rule incorporates this requirement with only one change from the proposed rule. CMS has deleted a provision specifying the data elements that MCOs must include in their dispensing reports to the state, in favor of a future guidance or rulemaking concerning such requirements.<sup>148</sup> The preamble reminds states of their obligation to identify fee-for-service and MCO utilization separately on manufacturer rebate invoices beginning with the second quarter of 2012.<sup>149</sup> CMS also instructs that utilization for MCO reporting should be based on the dispensing date (unlike fee-for-service Medicaid, where utilization is reported based on the date on which the claim was paid).<sup>150</sup> This requirement will present a challenge to states, many of which do not currently report utilization based on dispensing date.

F. Rebates for Investigational Drugs

As under the proposed regulation, where states elect to provide Medicaid coverage for investigational drugs covered under an IND, manufacturers are not required to pay rebates on such drugs provided they do not meet the definition of a COD.<sup>151</sup> An unapproved investigational drug would be unlikely to meet such definition.

VII. REQUIREMENTS FOR MANUFACTURERS

A. Reporting Requirements and Restatements

The Final Rule's requirements to submit quarterly reports of AMP, best price, customary prompt pay discounts, and nominal prices and monthly reports of AMP and AMP units, as well as the requirements for certification of price reports, remain substantively unchanged from the proposed regulation.<sup>152</sup>

As under the current regulations, manufacturers must report revisions to AMP, best price, customary prompt pay discounts, and nominal prices for a period not to exceed 12 quarters from the quarter in which the original reports were due, and also must report revisions to monthly AMP (other than revisions pertaining to lagged price concessions) within 36 months from the month the reports were due.<sup>153</sup> However, the provisions for

<sup>147</sup> 42 U.S.C. § 1396r-8(b)(1)(A).

<sup>148</sup> 81 Fed. Reg. at 5272.

<sup>149</sup> *Id.*

<sup>150</sup> *Id.* at 5275.

<sup>151</sup> 42 C.F.R. § 447.522(e).

<sup>152</sup> *Id.* § 447.510(a), (d)(1), and (e).

<sup>153</sup> *Id.* § 447.510(b)(1) and (d)(3).

revising the quarterly data beyond the 12-quarter window have changed from the proposed rule. Under the Final Rule, such revisions may be made on request to CMS for one of the following reasons:

- (1) The change is a result of a drug category change or a market date change;
- (2) The change is an initial submission for a product;
- (3) The change is due to termination of a manufacturer from the MDRP for failure to submit pricing data and the manufacturer must submit pricing data to reenter the program;
- (4) The change is due to a technical correction; that is, not based on any changes in sales transactions or pricing adjustments from such transactions;
- (5) The change is to address specific rebate adjustments to States by manufacturers, as required by CMS or court order, or under an internal investigation, or an investigation of the Office of the Inspector General of the Department of Health and Human Services (OIG) or Department of Justice.<sup>154</sup>

The proposed rule had provided for an additional “good cause” exception to the 12-quarter limitation. However, commenters expressed confusion between the good cause exception and exception (5), above, and CMS concluded that the two exceptions were somewhat duplicative. Therefore, CMS did not finalize the good cause exception, though the agency will continue to consider that option and address it in a future rulemaking, if appropriate.<sup>155</sup>

Importantly, whereas the proposed rule limited exception (5) to corrections of rebate “underpayments,” the Final Rule substitutes the term “adjustments,” reflecting CMS’ recognition that CMS should not “cherry pick” among revision requests but instead should permit pricing changes for both overpayments and underpayments to states.<sup>156</sup> The preamble clarifies that the “internal investigation” referred to in that exception is intended to mean a manufacturer’s internal investigation.<sup>157</sup> CMS also explains that a manufacturer should revise its quarterly AMP submissions within the 12-quarter window even if one or two months of a quarter are outside that period, but should then submit a revision request for the month(s) that exceed the 36 month window.<sup>158</sup>

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<sup>154</sup> *Id.* § 447.510(b)(1).

<sup>155</sup> 81 Fed. Reg. at 5278-79.

<sup>156</sup> *Id.* at 5279.

<sup>157</sup> *Id.* at 5284.

<sup>158</sup> *Id.* at 5280.

## B. Base Date AMP

The Final Rule permits manufacturers to recalculate the base date AMP for a COD using the AMP methodology in the Final Rule (the “Affordable Care Act base date AMP”), so that the additional rebate calculations will compare quarterly AMPs calculated under the same methodology. This recalculation must be completed within four quarters after the effective date of the Final Rule – i.e., before April 1, 2017. Manufacturers may choose whether to submit such a recalculation on a product-by-product basis.<sup>159</sup> The base date recalculation must use “actual and verifiable pricing records,” but need not include sales to the U.S. Territories.<sup>160</sup> If a base date AMP is recalculated, it may be used to calculate the additional rebate beginning with the April 1, 2016 effective date of the Final Rule.<sup>161</sup>

CMS clarifies that the Final Rule is effective on a prospective basis only, so AMP and best price need not be restated to comply with the Final Rule back to the fourth quarter of 2010, when the ACA amendments to the AMP definition became effective.<sup>162</sup>

## C. Civil Monetary Penalties

The proposed rule provided that a manufacturer who failed to submit a timely quarterly or monthly AMP report within 30 days after the end of the reporting period would be subject to civil monetary penalties of \$10,000 per day.<sup>163</sup> CMS has not finalized this provision, recognizing that this language implied the automatic imposition of late penalties, when, in fact, the OIG decides whether to impose such penalties. However, CMS affirms that it will continue to refer to the OIG manufacturers who do not submit timely pricing reports.<sup>164</sup>

## VIII. REQUIREMENTS FOR STATES

CMS finalized without change new regulations codifying existing reporting requirements for states. The Final Rule requires that, within 60 days after the end of each quarter, states must provide manufacturers an invoice that includes, among other items, information about the product, the URA, the number of prescriptions, the rebate amount claimed, and amounts reimbursed.<sup>165</sup> States must also submit the same information to CMS on a quarterly basis. However, the statute imposes no penalties on states for late

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<sup>159</sup> 42 C.F.R. § 447.510(c)(3) and (4).

<sup>160</sup> *Id.* § 447.510(c)(4)(iii).

<sup>161</sup> 81 Fed. Reg. at 5284.

<sup>162</sup> *Id.*

<sup>163</sup> Proposed 42 C.F.R. § 447.510(a)(5) and (d)(7).

<sup>164</sup> 81 Fed. Reg. at 5276.

<sup>165</sup> 42 C.F.R. § 447.502.

reporting, and the preamble affirms that a state’s failure to meet the 60-day deadline for invoicing does not absolve manufacturers of the obligation to provide rebates.<sup>166</sup>

## IX. MEDICAID DRUG PAYMENT

### A. Payment Based on Actual Acquisition Cost

At least since 1978, CMS regulations have required state Medicaid programs to base payment for brand drugs and generics that are not subject to a federal upper limit (FUL) on an “estimated acquisition cost” plus a dispensing fee.<sup>167</sup> Under current regulations, “estimated acquisition cost” is defined as the State’s “best estimate” of the price paid by providers,<sup>168</sup> and States generally have based their estimates on published prices such as average wholesale price (AWP) minus a specified percentage, or wholesaler acquisition cost (WAC) plus a specified percentage, or some combination of these. The unreliability of these published benchmarks has been the subject of multiple reports by the OIG and extensive litigation against drug manufacturers and price publishing services.

To make Medicaid drug payment more reflective of actual prices paid, CMS has finalized its proposal to require States to convert to “actual acquisition cost” (AAC) as a benchmark for drug ingredient cost reimbursement.<sup>169</sup> The Final Rule defines AAC as “the [State Medicaid] agency’s determination of the pharmacy providers’ actual prices paid to acquire drug products marketed or sold by specific manufacturers.”<sup>170</sup> The preamble explains that states have flexibility to use various methods to determine AAC, such as CMS’ survey-based National Average Drug Acquisition Cost (NADAC) data, state surveys, AMPs (which will be provided by CMS to states), or other reliable data.<sup>171</sup> If a state uses AMPs to determine AAC, CMS cautions that the state must treat AMPs confidentially and not disclose them in a form that discloses the identity of a particular manufacturer or particular prices.<sup>172</sup>

The Final Rule requires states (including the U.S. territories) to submit to CMS a state plan amendment describing the state’s AAC payment methodology, as well as its methodology for determining the dispensing fee.<sup>173</sup> The Final Rule itemizes pharmacy costs that should be covered by the dispensing fee, including time for checking insurance coverage, performing drug utilization review, counseling, measurement, mixing, and other activities and overhead.<sup>174</sup> The state plan amendment must be submitted by June

<sup>166</sup> 81 Fed. Reg. at 5289.

<sup>167</sup> 42 C.F.R. § 447.512(b) (2015).

<sup>168</sup> *Id.* § 447.502 (2015).

<sup>169</sup> 42 C.F.R. § 447.512(b).

<sup>170</sup> *Id.* § 447.502.

<sup>171</sup> 81 Fed. Reg. at 5293-94.

<sup>172</sup> *Id.* at 5315.

<sup>173</sup> 42 C.F.R. § 447.518.

<sup>174</sup> *Id.* § 447.502.

30, 2017 and be effective no later than April 1, 2017.<sup>175</sup> The AAC requirements of the Final Rule do not apply to Medicaid MCOs – they have flexibility to determine their own reimbursement methodologies.<sup>176</sup>

### B. Federal Upper Limits

Under the statute, CMS must establish FULs for multiple source drugs for which there are at least three versions available on a nationwide basis that are A-rated in FDA’s Orange Book. A state’s payment for such drugs may not exceed, in the aggregate, the FULs for these drugs plus a dispensing fee.<sup>177</sup> Until now, FULs have been set at 150 percent of the published price for the least costly therapeutic equivalent (using all available national compendia). The ACA provided that the FUL shall be calculated “as no less than 175 percent of the weighted average (determined on the basis of utilization) of the most recently reported monthly [AMPs] . . . .”<sup>178</sup> CMS has been publishing draft FULs calculated in this manner, but has delayed implementation of final FULs until the Final Rule becomes effective. Accordingly, CMS announced on January 22, 2016 that it will publish the first final FULs in March, to become effective April 1, 2016 – the same effective date as the Final Rule.

The proposed rule reflected the ACA FUL amendments, and the Final Rule contains no substantive changes, with one important exception.<sup>179</sup> In response to pharmacy concerns that the new AMP-based FULs would not cover their ingredient costs, CMS compared the NADAC with the FUL value obtained using the 175 percent formula and found that about 40 percent of the FUL values were lower than the NADAC each month. In order to ensure adequate pharmacy reimbursement, CMS has added a provision under which the NADAC will be a floor for the FULs. In other words, if the 175 percent formula results in an amount lower than the most current NADAC, CMS will substitute a higher percentage such that the FUL equals the NADAC.<sup>180</sup>

FUL calculations will not include 5i drugs, nor will they include drugs for which a termination date has been reported but, prior to the termination date, no AMP units are reported.<sup>181</sup> Moreover, FULs will not be retroactively adjusted when an AMP is restated.<sup>182</sup>

CMS has provided unsatisfactory guidance on whether an authorized generic may be included in the calculation of a FUL. The preamble states that an authorized generic will be included in the calculation of a FUL if the drug has been “found by the FDA to be

<sup>175</sup> 81 Fed. Reg. at 5170.

<sup>176</sup> *Id.* at 5293.

<sup>177</sup> 42 U.S.C. § 1396r-8(e)(4) and (5).

<sup>178</sup> *Id.* § 1396r-8(e)(5).

<sup>179</sup> 42 C.F.R. § 447.514.

<sup>180</sup> *Id.* § 447.514(b)(2); *see also* 81 Fed. Reg. 5295.

<sup>181</sup> 81 Fed. Reg. at 5299-5300.

<sup>182</sup> *Id.* at 5309.

therapeutically and pharmaceutically equivalent to the reference listed drug,” based on a review of FDA’s Orange Book.<sup>183</sup> This statement reflects an ignorance of the fact that authorized generics are not rated in the Orange Book, so that if this approach were applied, authorized generics would never be included in FULs. However, our understanding is that CMS has, in fact, been including authorized generics in the draft FULs. Therefore, the guidance in the preamble is of questionable foundation and accuracy. This would be an appropriate subject for additional, sub-regulatory guidance from CMS.

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<sup>183</sup> *Id.* at 5297.