

# CMS Publishes Final Rule Regarding Medicaid Drug Rebate Program

February 1, 2016

Health Care

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Today, the Centers for Medicare & Medicaid Services (CMS) published in the Federal Register the long-awaited Covered Outpatient Drugs Final Rule. [81 Fed. Reg. 5170 \(Feb. 1, 2016\)](#). The rule implements changes to the Medicaid Drug Rebate Program (MDRP) that were enacted by the Affordable Care Act (ACA) and addresses other key MDRP issues. With some exceptions, the rule will be applied prospectively effective April 1, 2016.

The rule was finalized four years after it was proposed. It was the subject of much comment and controversy. The Final Rule may have significant economic impact for drug manufacturers, both in terms of rebates payable and systems changes required to implement the rule.

This alert presents a summary of a lengthy and complicated rule. It is intended to give readers an overview of the most important areas covered by the rule but does not discuss many of the ambiguities and nuances of the Final Rule. We would be pleased to discuss with you in more detail any aspect of the Final Rule.

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## Brief Summary of Key Provisions

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### The Final Rule:

- Defines Average Manufacturer Price (AMP) as proposed, but allows for the continued use of a presumed inclusion methodology rather than mandating the “buildup” approach.
- Provides additional detail about the identification of so-called 5i drugs and the methodology for calculating AMP for these drugs.
- Permits restatement of base date AMP to reflect the requirements of the Final Rule until April 1, 2017.
- Revises the definition of a manufacturer’s “best price” and aligns it with the new AMP definition.
- Excludes from best price all sales to 340B covered entities, regardless of whether sales are made at the 340B price.
- Finalizes a four-part test for “bona fide service fees” (BFSFs) excludable from AMP and best price, but abandons the proposal to limit such fees to those paid only to wholesalers and retail community pharmacies (RCPs).
- Seeks comments on line extensions; finalizes two proposed provisions related to line extensions but delays finalizing the line extension definition.
- Revises the definition of “states” and “United States” to include the U.S. territories, meaning that sales in the territories will be included in the MDRP both for purposes of price reporting and payment of rebates, effective April 1, 2017.
- Finalizes the extension of rebates to Medicaid managed care organizations (MCOs).
- Sets Actual Acquisition Cost (AAC) as the basis for state Medicaid reimbursements based on ingredient cost.

## Calculation of Standard AMP

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The rule finalizes the definition of AMP as proposed. The AMP of a covered outpatient drug (COD) will be defined as “the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to retail community pharmacies and retail community pharmacies that purchase drugs directly from the manufacturer.” 42 C.F.R. § 447.504.

### Sales Included in Calculation of AMP

We address the sales included in the calculation of AMP below, highlighting any significant changes from the proposed rule.

#### Sales to Retail Community Pharmacies

CMS finalized the definition of an RCP as “an independent pharmacy, a chain pharmacy, a supermarket pharmacy, 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.” 42 C.F.R. § 447.504. The definition excludes “a pharmacy that dispenses prescription medications primarily through the mail, nursing home pharmacies, long-term care facility pharmacies,

hospital pharmacies, clinics, charitable or not-for-profit pharmacies, government pharmacies, or pharmacy benefit managers.” 42 C.F.R. § 447.504.

CMS clarified in the Final Rule that sales to home health care, home infusion, and specialty pharmacies may be included in the AMP calculation only to the extent they otherwise meet the definition of an RCP; e.g., such an entity that dispenses primarily through mail would not meet the definition of an RCP. CMS also clarified that sales by an RCP with an additional home delivery service to send prescriptions directly to a patient’s home would be included in AMP, as long as the pharmacy does not offer prescriptions primarily through the mail. If, however, a single entity owns both an RCP and a mail order pharmacy where medication is dispensed primarily through the mail, manufacturers may exclude the sales to the mail order pharmacy when determining AMP.

Sales to RCPs include any sales, payments, or other financial transactions that are “received by, paid by, or passed through retail community pharmacies.” 42 C.F.R. § 447.504(b)(3). CMS clarified in the Final Rule that manufacturers with evidence or knowledge of a discount, rebate, payment, or other financial transaction being passed through to an RCP must account for these transactions in calculating AMP. Absent this evidence or knowledge, manufacturers may continue to make reasonable assumptions about whether discounts are passed through to RCPs.

#### Sales to Wholesalers

The definition of wholesaler was finalized as proposed, as a “drug wholesaler that is engaged in wholesale distribution of prescription drugs to retail community pharmacies, including but not limited to manufacturers, repackers, distributors, own-label distributors, private-label distributors, jobbers, brokers, warehouses (including manufacturer’s and distributor’s warehouses, chain drug warehouses, and wholesale drug warehouses), independent wholesale drug traders, and retail community pharmacies that conduct wholesale distributions.” CMS clarified that the rule does not impose any requirements on wholesalers to report sales made to RCPs; rather, it is the manufacturer’s responsibility to calculate and report AMP to CMS.

To calculate AMP, manufacturers may continue to use the “presumed inclusion” approach where they may presume, in the absence of adequate documentation to the contrary, that certain prices paid to manufacturers by wholesalers are for drugs distributed to RCPs, without data concerning that actual distribution. The Final Rule abandons a proposal that manufacturers implement the “buildup methodology” approach, under which a manufacturer would have been able to include in AMP calculations only those prices where there was adequate, verifiable documentation showing that the drug was actually distributed to an RCP, either directly or indirectly through a wholesaler. In the Final Rule, CMS acknowledged that the buildup approach was less practical and would require a significant change from the methodology manufacturers have traditionally used to calculate AMP, and that the better alternative for calculating AMP is the presumed inclusion approach.

#### Other Sales Included in the Determination of AMP

In the Final Rule, CMS also identified specific “sales, nominal price sales, and associated discounts, rebates, payments or other financial transactions” that manufacturers should include in the determination of AMP. 42 C.F.R. § 447.504(b). CMS added the term “associated” in the regulatory language to clarify “that it is the sales themselves, as well as the discounts, rebates,

payment or financial transactions associated with the sales that are included in the AMP calculation, unless otherwise specifically excluded.”

CMS’s proposal to include in the calculation of AMP sales to other manufacturers who act as wholesalers for drugs distributed to RCP was finalized as proposed.

### **Transactions Excluded from the Calculation of AMP**

We address the transactions excluded from the calculation of AMP below, highlighting any significant changes from the proposed rule.

#### Bona Fide Service Fees

As discussed in more detail below, the Final Rule excludes from AMP any “bona fide service fees” that meet a four-part regulatory test.

#### Returned Goods

Excluded from AMP are reimbursements by manufacturers for recalled, damaged, expired, or otherwise unsalable returned goods, including (but not limited to) reimbursement for the cost of the goods and any reimbursement of costs associated with return goods handling and processing, reverse logistics, and drug destruction *only to the extent that such payment covers only those costs*. 42 C.F.R. § 447.504(c)(16). CMS left the terms “recalled,” “damaged,” “expired,” and “unsalable” undefined, stating that these terms are self-explanatory. CMS clarified that when a manufacturer faces difficulty in determining the purchase price of returned goods, it may rely on company records and reasonable assumptions to establish the value of the goods to be excluded from AMP. Notably, CMS removed the “good faith” requirement for the exclusion of returned goods set forth in its 2007 rule implementing the Deficit Reduction Act of 2005. Instead the agency stated that a good faith requirement was unnecessary, as returns designed to adjust prices or disguise price concessions would not be made in good faith since the reimbursement would cover more than the allowable costs.

#### Medicare Coverage Gap Discount

CMS finalized its proposal to exclude from AMP any discounts, rebates, or other price concessions provided under the Medicare coverage gap discount program. This is consistent with the statutory provision requiring that discounts provided by manufacturers under the Coverage Gap Discount program be excluded.

#### PBM Price Concessions

The exclusion of pharmaceutical benefit manufacturers (PBMs) from the definition of an RCP is finalized as proposed. 42 C.F.R. § 447.504(a). CMS proposed to exclude sales and price concessions to PBMs, including their mail order pharmacies’ purchases, from the calculation of AMP. In the Final Rule, CMS revised these exclusions to refer only to PBMs and removed the reference to mail order pharmacies because mail order pharmacies are already excluded from AMP. If a PBM sale is for its pharmacy line of business, the manufacturer must determine if such sale would be included based on the definition of RCP and the statutory and regulatory exclusions from AMP.

### Prices to Other Federal Programs

CMS proposed that prices to federal programs, including the TRICARE Pharmacy Program, should be excluded from AMP. In the Final Rule, CMS clarified that manufacturer sales to RCPs or wholesalers that distribute drugs to RCPs that are later reimbursed by TRICARE as a third-party payer should be included in AMP calculations. However, the rebates or refunds manufacturers pay to TRICARE should be excluded from AMP, because such rebates or refunds do not typically adjust the prices paid to manufacturers by RCPs or wholesalers for drugs distributed to RCPs. Similarly, sales to RCPs and wholesalers for drugs distributed to RCPs that are eventually reimbursed by Medicaid, state pharmaceutical assistance programs, and Medicare Part D are included in the AMP calculation, but the rebates or refunds paid to these programs are excluded from AMP.

### Manufacturer-Sponsored Programs

CMS clarified that, for a discount or benefit from a voucher, manufacturer-sponsored program, or manufacturer-sponsored discount card to be excluded from AMP, the full value must be passed on to the consumer and the pharmacy or other intermediary must not receive any price concession. Similar requirements apply to manufacturer-sponsored patient refund or rebate programs. CMS clarified that “a benefit provided to a patient, even if it is provided at the pharmacy counter, is not a discount, rebate, payment or other financial transaction[] received by or passed through to the [RCP] that must be included in AMP.”

### Free Goods Provided by Manufacturers

AMP excludes free goods provided by manufacturers, as long as they are not contingent upon any purchase requirement. CMS intends to issue guidance “to provide consistency among manufacturers[] treatment of the ‘any purchase requirement’ of the free goods provision and to ensure that the discounts or benefits provided under programs being excluded from AMP and best price are programs that are designed to benefit or assist only the patient, without any purchase contingencies, rather than designed to increase manufacturer sales or profits.”

### Customary Prompt Pay Discounts

CMS finalized the proposal that customary prompt pay discounts extended to wholesalers should be excluded from the determination of AMP. However, if a manufacturer extends a customary prompt pay discount to an RCP that purchases drugs directly from the manufacturer, such discount should be included in calculating AMP.

## **Calculation of AMP for 5i Drugs**

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The Final Rule finalizes procedures to identify so-called 5i drugs, adopts a 70/30 quantitative threshold test to determine whether a 5i drug is “not generally dispensed through a retail pharmacy,” and more clearly sets forth the financial transactions included and excluded from the 5i AMP calculation.

### **Definition of 5i drug**

Pursuant to the Medicaid Rebate statute, a separate AMP must be calculated for inhalation, infusion, instilled, implanted, or injectable drugs (referred to as “5i” drugs) that are “not generally dispensed through an RCP.” The Final Rule does not adopt or finalize a definition for 5i drugs.

CMS noted that the “5i drug” nomenclature has gained widespread acceptance in the industry, and that a definition is unnecessary at this time.

### **Identification of 5i drugs**

Under the Final Rule, manufacturers are allowed to use “reasonable assumptions” to determine whether a drug meets the requirements of a 5i drug. 42 C.F.R. § 447.507(a). This is a significant shift from the proposed rule, which would have required manufacturers to use the FDA Routes of Administration in identifying 5i drugs. The Final Rule does not mandate reliance on any specific resource, and allows manufacturers to look to resources such as drug package inserts, prescribing information, and the FDA Routes of Administration, as long as the manufacturer’s reasonable assumptions are consistent with the requirements and intent of the Medicaid rebate statute and implementing regulations. 42 C.F.R. § 447.507(a). According to the preamble, CMS intends to shift responsibility for the identification of 5i drugs to manufacturers, believing them better suited to make such determinations. Manufacturers must identify to CMS “each covered outpatient drug that qualifies as a 5i drug.” 42 C.F.R. § 447.507(a).

### **Determination of a 5i drug’s status as “not generally dispensed”**

Manufacturers are required to exclude certain payments, rebates, and discounts received from sales for 5i drugs that are “not generally dispensed through retail community pharmacies” in calculating the drugs’ AMP.

#### The 70/30 Test

The Final Rule adopts a quantitative threshold to determine when 5i drugs are “not generally dispensed” through RCPs. The Final Rule excludes from the 5i AMP calculation any drug for which 30% or more of sales were to RCPs or wholesalers for drugs distributed to RCPs. 42 C.F.R. § 447.507(b)(1). This is a loosening of the 90/10 threshold test originally proposed by CMS, which would have excluded any drug for which 10% or more of sales were to RCPs. CMS believes that the 70/30 rule strikes a balance—it would capture a sufficient number of transactions to produce a stable AMP, unlike the 90/10 rule, but it would still exclude a sufficient number of transactions to meet the statutory requirement that a 5i drug is “not generally dispensed through a retail community pharmacy.”

The Final Rule clarifies that determination under the 70/30 rule should be based on units rather than dollars and should be calculated at the nine-digit National Drug Code (NDC) level. Manufacturers are already required to report unit data to CMS, and as such, CMS does not anticipate that this requirement would present an undue burden. Manufacturers may, but are not required to, use the smoothing process described in the Final Rule to calculate whether 30% or more of sales were to RCPs. Further details on the smoothing methodology are provided later in this alert.

#### Frequency of Determination

The Final Rule requires manufacturers to determine and report to CMS whether a 5i drug is “not generally dispensed” through an RCP on a monthly basis. 42 C.F.R. § 447.507(b)(2). Manufacturers would still be required to calculate quarterly AMP as a weighted average of the three monthly AMPs, even if the product’s status as a 5i drug varies from month to month. CMS expects to issue additional sub-regulatory guidance on this matter.

CMS agreed to include a flag in the DDR reporting system, allowing manufacturers to designate and track the type of AMP methodology (standard or 5i) used to calculate AMP for each month. CMS would allow manufacturers to report revisions to monthly AMPs within 36 months.

## **Financial Transactions Included and Excluded in the Determination of AMP for 5i Drugs**

### Inclusions

The 5i AMP includes all “sales, nominal price sales, and other associated discounts, rebates, payments, or other financial transactions” conducted with the standard entities eligible to be included in the AMP. 42 C.F.R. § 447.504(d). The 5i AMP additionally includes sales to:

- physicians;
- pharmacy benefit managers;
- health maintenance organizations (HMOs), including MCOs;
- insurers, hospitals, clinics and outpatient facilities;
- long-term care providers;
- hospices;
- mail order pharmacies; and
- entities that are not a wholesaler or RCP.

### Exclusions

Exclusions for the 5i AMP closely track the exclusions from the best price determination, with some exceptions. In addition to the sales and transactions excluded from best price, the 5i AMP excludes:

- customary prompt pay discounts to wholesalers;
- sales to government, and charitable and not-for-profit pharmacies;
- bona fide service fees paid to the entities listed in 42 C.F.R. § 447.504(d) (see above); and
- all sales to patients (both direct and indirect).

42 C.F.R. § 447.504(e). Conversely, financial transactions with PBMs are not excluded from the 5i AMP calculation, despite their exclusion from the best price.

## **Smoothing Methodology for Standard and 5i AMP**

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The Final Rule sets forth a “smoothing process” that is applied in several contexts in the Final Rule, including in the calculation of a monthly AMP under either the Standard or 5i AMP methodology. 42 C.F.R. § 447.510(d)(2). The Final Rule lays out a specific smoothing methodology for calculation of lagged price concessions in the monthly AMP, but it declines to adopt any specific smoothing methodology for calculating: (i) Federal Upper Limits; or (ii) whether a 5i drug is “not generally dispensed” through a community retail pharmacy.

### Calculation of Lagged Price-Concessions

The Final Rule first requires manufacturers to estimate the impacts of their lagged AMP-eligible price concessions using a 12-month rolling percentage. For NDC-9s that have at least 12 months of AMP-eligible sales, a lagged price-concession percentage is calculated using data from the most recent 12-month period (inclusive of the current reporting period), after adjusting for sales excluded from AMP. This formula is:

$$\frac{\text{total applicable lagged price concessions}}{\text{total dollars for AMP-eligible sales}}$$

For NDC-9s that do *not* have at least 12 months of AMP-eligible sales, the lagged-price concession percentage is calculated using the same formula but is applied for the time period equaling the total number of months of AMP-eligible sales.

### Calculation of the Monthly AMP

In order to calculate a monthly AMP using the smoothing process, the lagged price-concession percentage uses the following formula:

$$\frac{\text{total dollars for AMP-eligible sales in the month} \times \text{(lagged price-concession \%)}}{\text{(total dollars for AMP-eligible sales in the month)}} \div \text{number of units sold in the month}$$

CMS also noted that manufacturers may use a similar methodology to smooth “lagged ineligible AMP sales,” where the excluded sale is identified on a lagged basis. This approach is consistent with the 2007 Physician Fee Schedule Final Rule for Medicare Part B where, for calculations of Average Sales Price, CMS permits, but does not require, a smoothing methodology for lagged ineligible sales.

## AMP Reporting Issues

### Base Date AMP Revisions Permitted

CMS finalized the proposal to allow manufacturers the option to report a revised base date AMP to CMS within the first four full calendar quarters following the publication of the Final Rule. If submitting a revised base date AMP, manufacturers must have actual and verifiable documentation to support in any restatements. However, CMS is not requiring restatements to include the territories in the revised Base Date AMP calculations.

The Final Rule states that CODs may have only one base date AMP even if a product’s AMP is calculated using both the standard and 5i methodology, depending on the month.

## Civil Monetary Penalties Not Imposed for Late AMP

CMS did not finalize a proposal to impose a \$10,000 per day, per drug penalty for late reporting of AMP. Instead, CMS will refer late reporting instances to the Office of the Inspector General (OIG).

## Determination of Best Price

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The Final Rule establishes a regulatory definition of “best price,” seeks to more closely align the best price and AMP calculations, and clarifies what transactions are excluded from best price. Most significantly, the Final Rule abandons the proposal to include in best price any voluntary sub-ceiling prices to 340B entities, clarifies that bona fide service fees are broadly excluded from best price, and clarifies the types of manufacturer assistance excluded from best price. Unfortunately, the preamble to the Final Rule raises new questions about CMS’s treatment of “stacked” price concessions.

### Definition of “Best Price” and Prices Included in Best Price

Under the Final Rule, “best price” for single and innovator multiple source drugs means “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.” 42 C.F.R. § 447.505(a). Best price also includes the lowest price available for an authorized generic drug. *Id.* Best price includes all prices, “including applicable discounts, rebates, or other transactions” that adjust prices “directly or indirectly” to the best price-eligible entities specified above. 42 C.F.R. § 447.505(b).

### Prices Excluded from Best Price

The Final Rule seeks, where applicable, to apply the same methodology for best price as for AMP. Thus the rule expands the list of prices excluded from best price to include:

- **Patient Assistance.** The Final Rule excludes from best price various forms of manufacturer-sponsored patient assistance including: copayment assistance programs, 42 C.F.R. § 447.505(c)(10); patient refund or rebate programs. 42 C.F.R. § 447.505(c)(11); and vouchers, 42 C.F.R. § 447.505(c)(12). CMS clarifies that such assistance is excluded from best price only if the full value is passed on to the patient and the administering pharmacy, agent, or other entity does not receive any price concession. Manufacturer-provided free goods likewise are excluded from best price only if the benefit is not contingent on a purchase requirement, the full benefit is passed to the consumer, and the administering entity receives no price concession.
- **Direct-to-Patient Sales.** The Final Rule adds “direct sales to patients” to the list of sales excluded from best price. 42 C.F.R. § 447.505(c)(19).
- **State Pharmacy Assistance Programs (SPAPs).** Rebates and discounts to SPAPs (in addition to the prices paid by SPAPs) are excluded from best price as long as there is no contingency arrangement.
- **Clinical Trial Sales.** Sales to another manufacturer for clinical trial use generally will be excluded from best price, unless the purchasing manufacturer meets the definition of a

“wholesaler” and thus qualifies a best price-eligible entity. CMS “believe[s]” manufacturers likely will not meet this definition if using the drug in a clinical trial.

- Returns. Best price is not net of returns because reimbursement by the manufacturer for returns may be excluded. 42 C.F.R. §§ 447.505(c)(14), 447.505(d)(1).
- Bona Fide Service Fees (BFSFs). CMS clarified that there is a “broad exclusion” from best price for BFSFs and that the proposed rule’s apparent limitation on which BFSFs were excluded from best price was a drafting error.
- “Any Prices” to 340B Entities. CMS did not finalize its proposal to exclude from best price only prices charged “under the 340B program.” Many commenters objected to this as contrary to the plain language of the rebate statute. Instead, the Final Rule provides that “[a]ny prices charged” to a 340B covered entity are excluded from best price. CMS clarified that manufacturers are not required to oversee 340B entities’ compliance with 340B program requirements. Rather, to confirm that prices to such entities are excludable from best price, manufacturers may rely on the list of 340B entities through the online database on the Health Resources and Services Administration website.
- Coverage Gap Discounts. Discounts manufacturers provide under the Medicare coverage gap discount program are excluded. 42 C.F.R. § 447.505(c)(7).
- Nominal Price Sales. Nominal prices sales (i.e., sales at less than 10 percent of AMP) are excluded if made to certain entities. 42 C.F.R. §§ 447.505(c)(14), 447.508.

### **Stacking**

The proposed rule did not specifically address so-called “stacking” of price concessions, and many commenters asked CMS to clarify that manufacturers need only combine such concessions to any single entity on any single unit when the manufacturer has actual knowledge of the price concessions. Other commenters sought to clarify when separate but related entities are considered to be a “single entity” for purposes of stacking.

CMS stated that manufacturers must include “all price concessions that adjust the price realized by the manufacturer.” Thus, if a manufacturer offers price concessions to two entities “for the same drug transaction, such as rebates to a PBM where the rebates are designed to adjust prices at the retail or provider level and discounts to an RCP’s final drug price, all discounts related to that transaction which adjust the price available from the manufacturer should be considered in the manufacturer’s final price of that drug when determining the best price to be reported for the drug.” CMS suggested that this approach is consistent with current 42 C.F.R. § 447.505(e)(3) regarding cumulative discounts and with the provision CMS finalized at 42 C.F.R. § 447.505(c)(17) specifying that best price “includes PBM rebates, discounts or other financial transactions, including their mail order pharmacy purchases, where such rebates discounts or price concessions are designed to adjust prices at the retail or provider level.”

### **Value-Based Purchasing**

CMS noted that certain arrangements, such as value-based purchasing agreements, may benefit patients and that these and others could adjust the prices available from the manufacturer. CMS is considering how to provide more guidance regarding such arrangements.

## Other Provisions Related to AMP and Best Price

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The Final Rule also addresses several important issues for pharmaceutical manufacturers: the allocation of bundled sales, the treatment of BFSFs, the determination of fair market value, the submission of restatements, and the handling of authorized generic drugs.

### Bundled Arrangements

The Final Rule eliminates the proposed requirement that discounts in a bundled sale, “including, *but not limited to*, those discounts resulting from a contingent arrangement” must be proportionally allocated when calculating AMP and best price (emphasis added). Under the Final Rule, “discounts in a bundled sale, including those discounts resulting from a contingent arrangement, are allocated proportionally to the total dollar value of the units of all drugs or products sold under the bundled arrangement.” 42 C.F.R. § 447.502.

The Final Rule also revises the definition of bundled sale to add the term “product” because, CMS stated, “bundled arrangements can include CODs, as well as other product purchases as part of the bundled sale requirement.” 42 C.F.R. § 447.502.

### Bona Fide Service Fees

CMS finalized a four-part test for “bona fide service fees” in the context of AMP and abandoned its proposal to limit such fees to those paid to wholesalers or RCPs versus other entities.

BFSFs excludable from best price are defined as fees paid by a manufacturer to “an entity” that: (1) “represent fair market value” of (2) a “bona fide, itemized service actually performed on behalf of the manufacturer” (3) that the manufacturer “would otherwise perform (or contract for) in the absence of the service arrangement,” and (4) that “are not passed on in whole or in part to a client or customer of an entity.” 42 C.F.R. § 447.502.

The ACA excluded BFSFs from the calculation of AMP and provided particular examples of BFSFs. In the Final Rule, CMS stated that there was no indication that Congress had intended to limit the definition of BFSFs to fees paid to particular entities and thus did not finalize its original proposal.

The Final Rule enacts a harmonized four-part definition of a BFSF for both best price and AMP and establishes in regulation the examples of BFSFs listed in the ACA. CMS noted that, for purposes of the fourth prong of the BFSF test, the agency would allow manufacturers to “presume, in the absence of any evidence or notice to the contrary, that the fee paid is not passed on.” However, if even a portion of a service fee is passed on, the entire fee will not be considered a BFSF.

The final regulatory definition of a BFSF (for purposes of both AMP and best price) is:

a fee paid by a manufacturer to an entity that represents fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that is not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug. The fee includes, but is not limited to, distribution

service fees, inventory management fees, product stocking allowances, and fees associated with administrative service agreements and patient care programs (such as medication compliance programs and patient education programs).

42 C.F.R. § 447.502.

CMS did not state whether it intended that the four examples of BFSFs listed in the ACA and in the Final Rule will be considered BFSFs automatically or whether manufacturers must subject them to the four-part test and corresponding documentation requirements.

### **Fair Market Value**

CMS declined to define “fair market value” (FMV). Instead, CMS noted that the determination is “by nature subjective” and therefore “can be a range of values.” CMS added that “manufacturers should retain flexibility in determining whether service fees are paid at [FMV] in light of constant changes in the pharmaceutical marketplace.” “[A]ny documentation” may be used to support FMV, but the documentation must (1) “make[] clear the methodologies and factors the manufacturer used in making its [FMV] determination,” (2) “be made contemporaneously with the manufacturer’s agreement to pay the fee,” and (3) be maintained consistent with rebate agreement requirements. CMS refused to establish any safe harbors for what constitutes reasonable FMV, noting that the OIG is responsible for issuing advisory opinions on health care fraud and abuse.

### **Restatements**

CMS amended 42 C.F.R. § 447.510(b)(1) to allow manufacturers to submit a request to restate pricing data beyond the 12-quarter deadline if the change is due to:

- a drug category or market date change;
- initial submission for a product;
- a resubmission required to reenter the MDRP after termination for failure to submit pricing data;
- a technical correction (such as a keying error) “not based on any changes in sales transactions or pricing adjustments from such transactions; or
- specific rebate adjustments to states by manufacturers, as required by CMS or court order, or under an internal investigation, or an OIG or Department of Justice (DOJ) investigation.

These restatements would be permitted for AMP, best price, customary prompt pay discount, or nominal price calculations. CMS may consider additional scenarios under which manufacturers could resubmit pricing data after the 12-quarter deadline and may issue guidance or rulemakings on the subject.

CMS did not finalize the proposal to permit pricing restatements after the 12-quarter limit for “good cause.” Rather the agency cited the myriad concerns raised regarding what would constitute “good cause,” confusion about the overlap between the good cause provision and the exception for specific underpayments or potential liability, and a lack of recommendations regarding what situations should qualify as “good cause.” CMS noted that it will continue to consider the good cause provision for future rulemakings.

## Authorized Generics

CMS finalized the definitions of “authorized generic drug,” “primary manufacturer,” and “secondary manufacturer” of an authorized generic drug as proposed:

- An authorized generic drug is “any drug sold, licensed, or marketed under a new drug application (NDA)” that is “marketed, sold or distributed under a different labeler code, product code, trade name, trademark, or packaging (other than repackaging the listed drug for use in institutions) than the brand name drug.” 42 C.F.R. § 447.502.
- A primary manufacturer is “a manufacturer that holds the NDA of the authorized drug.” 42 C.F.R. § 447.506(a).
- A secondary manufacturer is a manufacturer “authorized by the primary manufacturer to sell the drug but does not hold the NDA.” 42 C.F.R. § 447.506(a).

Sales of an authorized generic drug must be included in the primary manufacturer’s calculation of AMP when the drug is sold directly to a wholesaler. 42 C.F.R. §447.506(b). The Final Rule slightly amends the proposed rule to direct a primary manufacturer to also include sales of an authorized generic drug in its AMP calculations if the drug is sold or licensed to a secondary manufacturer, “acting as a wholesaler for drugs distributed to retail community pharmacies.” 42 C.F.R. § 447.506(b). CMS clarified that, when the secondary manufacturer is relabeling the product with its own or a different NDC, the primary manufacturer should not include sales of the authorized generic drug in its AMP. In this context, the secondary manufacturer would be acting as a manufacturer rather than as a wholesaler.

CMS also finalized its proposal to require primary manufacturers to include the best price of an authorized generic drug in its determination of best price by considering prices to any manufacturer, wholesaler, retailer, provider, HMO, non-profit entity, or governmental entity in the United States. 42 C.F.R. § 447.506(c). The Final Rule requires a secondary manufacturer to calculate AMP and best price for its authorized generic NDCs and provide a rebate based on its sales of authorized generics. 42 C.F.R. § 447.506(d).

## Line Extensions

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CMS provided additional guidance regarding the treatment of line extensions for MDRP purposes but left open the issue of the definition of “line extension.” The agency is accepting comments on how to define this category of drugs.

### Identification of Line Extension Drugs

The ACA provided for an alternative rebate calculation for “line extensions” that takes into account the prices of other drugs in the line and that may result in a higher rebate amount than that for other innovator drugs. Although the ACA defined a “line extension” as a “new formulation of [a] drug, such as an extended release formulation,” CMS’s proposed rule would have expanded this definition to include a “new version of the previously approved listed drug, such as a new ester, a new salt, or other noncovalent derivative; a new formulation of a previously approved drug; a new combination of two or more drugs; or a new indication for an already marketed drug.” CMS proposed to designate a drug meeting these criteria as a line extension regardless of whether the drug is approved under an NDA or supplemental NDA.

In response to “numerous comments,” CMS did not finalize the proposed line extension definition. Instead, the agency is requesting additional comments by April 1, 2016, regarding how to identify line extension drugs. CMS “may consider addressing this in a future rulemaking.” In the meantime, CMS indicated that new strengths of existing formulations, without more, are not line extensions.

### **Unit Rebate Amount (URA) Methodology for Line Extensions**

The Final Rule establishes (without change from the proposed rule), the URA calculation for line extensions as the greater of: (1) the standard URA; or (2) the alternative URA (product of the line extension AMP and the highest additional rebate of any strength of the original drug). If no brand drugs are active in the Medicaid program, the alternative URA cannot be calculated.

### **Corporate Relationship for Line Extensions**

The Final Rule also provides that a drug manufactured by one manufacturer is not a line extension of a drug manufactured by a second manufacturer unless there is a “corporate relationship” between the two manufacturers. “Corporate relationship” is undefined in the rule. If a corporate relationship exists, manufacturers must identify line extension drugs and the initial brand name listed drug with the highest additional rebate ratio. Manufacturers are not required to submit URAs or additional rebate-to-AMP ratios.

## **Covered Outpatient Drugs: Definition and Categories**

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### **Definition of “Covered Outpatient Drug”**

The Final Rule revises and clarifies certain aspects of the definition of CODs on which manufacturers would be obligated to pay a rebate.

Specifically, CMS decided not to finalize the requirement that a drug must be listed electronically with the FDA in order to be considered a COD, but it encouraged manufacturers to so list their drugs, since CMS will be consulting the list with respect to eligibility and categorization of a drug for MDRP purposes.

Drugs that are billed as part of a bundled service are CODs if the state Medicaid plan provides for a separate payment for the drug. Since some states may opt for separate reimbursement, the manufacturer must submit AMP and best price reports for the drug, but need only pay rebates in those states where the drug receives separate reimbursement. Therefore, a drug can be COD in one state and not in another.

Separately reimbursed radiopharmaceuticals approved under a new drug application (NDA) or an abbreviated new drug application (ANDA) and biologics approved under a biologics license application (BLA) are CODs.

### **Issues Relating to Categorization of Covered Outpatient Drugs**

The Final Rule also addresses issues of classification of certain CODs as innovators or noninnovators, a categorization that affects the level of rebate that must be paid on the drug.

### Biosimilars

A drug approved under a BLA, including a biosimilar, falls within the definition of a single source drug. This classification is consistent with CMS's March 30, 2015, policy statements on national payment policies for covered biosimilars dispensed to individuals enrolled in Medicare and Medicaid, which noted that biosimilar products fall within the definition of "single source drugs."

### Original NDA

The Medicaid rebate statute provides that a drug that is approved under an "original NDA" is a single source drug if it has no generic competitors and an innovator multiple source drug if it has generic competitors. There has long been confusion and controversy over what constitutes an original NDA. In the proposed rule, CMS proposed to define "original NDA" to mean an NDA under section 505(b) of the Food, Drug and Cosmetic Act (FDCA), as opposed to an ANDA under section 505(j) of the FDCA. CMS elected to finalize this proposal, notwithstanding many objections, including the objection that CMS has ignored the word "original" in the statute.

CMS created an exceptions process for manufacturers who believe that a product approved under an NDA should be considered a noninnovator and has indicated that it will give manufacturers four quarters to go through the process and bring reporting into compliance with the results of the exceptions process. CMS stated that it will issue additional guidance about the exceptions process, but it indicated that it might be willing to issue an exception for drugs approved under a paper NDA prior to the Hatch-Waxman amendments of 1984, for drugs approved under certain types of literature-based 505(b)(2) NDAs, and for certain parenteral drugs in immediate plastic containers where the need to obtain approval under an NDA related to the plastic container. There is some ambiguity as to whether CMS considers its definition to apply only prospectively or to constitute a clarification of existing law.

## **Sales in U.S. Territories**

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Sales outside the United States are specifically excluded from the determination of AMP and best price. 42 C.F.R. § 447.504(c), 447.505(c)(18). The proposed definition of "states" and "United States" included the 50 states, the District of Columbia, and the U.S. territories, meaning that sales in the territories would no longer be considered "outside of the United States." CMS retained this definition in the Final Rule but delayed the inclusion of the territories in the definitions of states and United States until April 1, 2017, to give more time to territories and manufacturers to adjust to these new definitions. Effective on April 1, 2017, the territories, will also be included in the MDRP for purposes of rebates.

## **Rebates to Medicaid Managed Care Organizations**

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The ACA required manufacturers to begin paying rebates on drugs covered by Medicaid MCOs. In the proposed rule, CMS considered requiring MCOs to submit a list of data elements to states within 30 days of the end of each quarter. However, CMS did not finalize this requirement in the Final Rule.

The requirement that states avoid duplicate discounts and rebates on 340B drugs also applies to Medicaid MCO utilization. States must "ensure that procedures are in place with their MCOs to exclude [340B] utilization for drugs."

## Use of Actual Acquisition Cost by States

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Under current regulations, states may base reimbursement for CODs on the estimated acquisition cost (EAC) of the drug. OIG, however, has had a longstanding concern that states overpay for Medicaid CODs, as states traditionally use published compendia prices such as the average wholesale price (AWP) to establish the EAC. In the Final Rule, CMS finalized its proposal to replace EAC with “actual acquisition cost,” defined as “the agency’s determination of the pharmacy providers’ actual prices paid to acquire drug products marketed or sold by specific manufacturers.” 42 C.F.R. § 447.502. States are instructed to establish AAC reimbursement based on prices actually available to pharmacies in the marketplace, but retain the flexibility to adopt the benchmarks of their choice to do so. Such benchmarks include, but are not limited to, a national survey of AACs, a state survey of retail pharmacy providers, or AMP data.

CMS proposed that states reimburse 340B providers at their cost for 340B drugs as part of the implementation of AAC. However, because CMS recognized that 340B entities may be able to negotiate discounts below the statutory 340B ceiling price, it will accept methodologies that reimburse the statutory 340B ceiling price for the ingredient cost component in addition to an adequate professional dispensing fee. CMS noted that states might decide to use “different professional dispensing fee rates for different entities and providers,” including 340B providers. “While we do not mandate any specific professional dispensing fee methodologies that states must use, states are required to provide data which indicates that the methodology is consistent with the regulation and ensures access.”

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If you have any questions concerning the material discussed in this client alert or would like assistance in commenting on the line extension provisions (comments are due by April 1, 2016), please contact the following members of our Health Care Practice Group:

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