

CMS Issues Final Rule on Covered Outpatient Drugs

by Constance A. Wilkinson, Alan J. Arville, Lesley R. Yeung, John S. Linehan, Richard H. Hughes IV, Meghan F. Weinberg, and James S. Tam*

January 2016

On January 21, 2016, the Centers for Medicare & Medicaid Services (“CMS”) released a final rule (“Final Rule”)¹ addressing key areas of Medicaid reimbursement for outpatient drugs and changes made to the Medicaid Drug Rebate Program (“MDRP”) by the Affordable Care Act (“ACA”).

I. BACKGROUND

Under the Medicaid program, states may provide coverage of prescribed drugs (covered outpatient drugs, or “CODs”) as an optional service under their state Medicaid plans. States may receive federal financial participation for CODs of manufacturers that enter into a national rebate agreement.

A number of statutory changes have been made in recent years to the Medicaid program that aim to assist states and the federal government in managing drug costs, to promote a fairer pharmacy reimbursement system, and to ensure the sustainability of the MDRP. CMS issued a Proposed Rule on February 2, 2012 (“Proposed Rule”), soliciting comments on the agency’s proposals to implement these changes to Medicaid reimbursement for CODs.² The Final Rule addresses public comments received from approximately 425 stakeholders in response to the Proposed Rule, finalizes definitions and clarifications of key terms, and provides regulatory guidance to ensure proper adherence to new requirements by states, drug manufacturers, and health care providers.

As discussed in more detail below, the Final Rule implements substantial changes to the Medicaid program that are aimed at improving beneficiary access to CODs and

¹ The Final Rule is available at <https://www.federalregister.gov/articles/2016/02/01/2016-01274/medicaid-program-covered-outpatient-drugs> and is scheduled to be published in the *Federal Register* on February 1, 2016.

² 77 Fed. Reg. 5,318 (Feb. 2, 2012).

addressing the rise in drug costs. The Final Rule creates a regulatory definition for “average manufacturer price” (“AMP”), updates the federal upper limit (“FUL”) formula for the payment of certain generic drugs, extends rebates to CODs provided by Medicaid managed care organization plans (“MMCOs”), and revises the definition of “states” to include the U.S. territories. The intent of these changes is to ensure that states and the federal government save money in managing Medicaid drug costs. Further, to better align pharmacy reimbursement with the acquisition cost of drugs, the Final Rule creates exceptions to the FUL calculation for multiple source drugs, identifies “actual acquisition cost” (“AAC”) as the basis for determining ingredient cost reimbursement, and establishes parameters for professional dispensing fees. The Final Rule also provides regulatory guidance to drug manufacturers on the proper calculation and reporting of drug product and pricing information for purposes of the MDRP.

The Final Rule is effective April 1, 2016, and states must submit state plan amendments (“SPAs”) by April 1, 2017, to comply with the requirements of the Final Rule. CMS previously estimated that savings from the implementation of the Medicaid COD regulations would reach \$17.7 billion over five years (2010 through 2014).³ Since most of the savings resulted from requirements that have been in effect since 2010,⁴ these savings estimates are already accounted for under the Medicaid program’s baseline spending projections. However, CMS estimates in the Final Rule that additional savings from the implementation of the FUL formula will reach \$2.735 billion over five years (2016 through 2020). In addition, states and drug manufacturers are expected to have increased costs totaling approximately \$432 million over the same five-year period related to the implementation of the new COD reimbursement provisions and participation in the MDRP.

II. ISSUES OF PARTICULAR INTEREST

A. AMP & Best Price Calculations

1. *“Presumed Inclusion” of Sales to Wholesalers in AMP Instead of “Buildup” of “Actual Sales” Data*

The Deficit Reduction Act of 2005 required manufacturers to include in the calculation of AMP those sales to wholesalers that they could not confirm with adequate documentation were sold subsequently to AMP-ineligible entities, an approach referred to as “presumed inclusion” that was reflected in the 2007 regulations. In the 2012 Proposed Rule, CMS proposed to discard “presumed inclusion” and require manufacturers to calculate AMP values based upon evidence of “actual sales” to “retail community pharmacies” and to wholesalers for drugs distributed to retail community pharmacies. Under this so-called “buildup” approach, the manufacturer includes in its AMP calculation only those prices where there is adequate, verifiable

³ 77 Fed. Reg. at 5,353 (estimating savings of \$17.7 billion, of which \$13.7 billion was expected to accrue to the federal government and \$4.0 billion was expected to accrue to the states).

⁴ The requirements that have been in effect since 2010 include increased minimum rebate percentages on brand-name drugs and the offsets of the total savings of the increased rebate percentage, treatment of new formulations, and the collection of rebates on drugs provided to MMCO enrollees.

documentation showing that the drug was actually distributed to a retail community pharmacy, either directly or indirectly through the wholesaler.

In the 2016 Final Rule, CMS has reversed its course and retained the “presumed inclusion” approach, under which “the manufacturer presumes, in the absence of adequate documentation to the contrary, that certain prices paid to manufacturers by wholesalers are for drugs distributed to retail community pharmacies, without data concerning that actual distribution.” CMS decided not to adopt the “buildup” approach because it would have been less practical due to the associated financial and operational difficulties in implementing the approach and it represented a significant change from the methodology manufacturers have traditionally used to calculate AMP. CMS has recognized that in the absence of specific guidance, manufacturers are allowed to make reasonable assumptions consistent with requirements and intent of the law when calculating AMP, and the “buildup” approach would have impeded this ability to make reasonable assumptions.

2. *“Specialty” and Other Pharmacies “Conducting Business as Wholesalers or Retail Community Pharmacies”*

The ACA revised the definition of “average manufacturer price” to require manufacturers to calculate it from sales (directly and through wholesalers) to “retail community pharmacies,” rather than to entities in the “retail pharmacy class of trade.” The statute defines “retail community pharmacy” 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” and explicitly excludes “pharmac[ies] that dispense prescription medications to patients primarily through the mail, nursing home pharmacies, long-term care facilities, hospital pharmacies, clinics, charitable or not-for-profit pharmacies, government pharmacies, or pharmacy benefit managers.”

In the Proposed Rule, CMS proposed to capture in the AMP calculations CODs that are not generally dispensed through traditional types of retail pharmacies named in the statute, as described above, such as “entities that conduct business as wholesalers or retail community pharmacies, which includes but is not limited to specialty pharmacies, home infusion pharmacies and home healthcare providers.”

In the Final Rule, CMS decided not to finalize the proposed definition of “retail community pharmacy” to include a separate category of “entities conducting business as wholesalers or retail pharmacies.” Nor did CMS expand the definition of “retail community pharmacies” to explicitly include home infusion, home health care, and specialty pharmacies, due to its understanding that these types of pharmacies may or may not qualify as retail community pharmacies, depending on the business model adopted. A specialty pharmacy, home health care pharmacy, or home infusion pharmacy may meet the definition of “retail community pharmacy” if it may dispense

medications to the general public and is not primarily a mail-order pharmacy. CMS considers the statutory definitions of “retail community pharmacy” and “wholesaler” to be adequate, and decided that an overly specific definition (entities “conducting business as”) may not accommodate a changing marketplace.

CMS expects sales to home infusion, home health care, and specialty pharmacies to be included in AMP to the extent that a pharmacy actually meets the definition of “retail community pharmacy.” This will require manufacturers to consider individual operational characteristics of these types of pharmacies and not solely their class of trade in determining whether sales to these entities are AMP-eligible.

In regards to assessing whether a “5i” drug (i.e., inhalation, infusion, instilled, implanted, or injectable drug) is “not generally dispensed through retail community pharmacies,” as discussed in more detail below, because CMS is not finalizing the “conducting business as” language, manufacturers will first need to determine if entities such as specialty pharmacies, home infusion pharmacies, and home health care providers meet the statutory definition of “retail community pharmacy” before applying the new 70-30 threshold test described below.

3. *Identification of 5i Drugs “Not Generally Dispensed” Through Retail Community Pharmacies—the 70/30 Standard*

The Proposed Rule included an alternative AMP calculation for 5i drugs that are not generally dispensed through retail community pharmacies, in order to ensure that an AMP could be calculated and Medicaid rebates could be collected from manufacturers for these drugs. CMS proposed a standard under which a manufacturer would determine that a 5i drug is “not generally dispensed” through retail community pharmacies if 90 percent or more of the sales of the 5i drug are to entities that are not retail community pharmacies. This “90-10 Rule” is adapted from guidance that the U.S. Department of Veterans Affairs has given in connection with the calculation of the Non-Federal Average Manufacturer Price.

In the Final Rule, CMS revised the standard by lowering the threshold to 70 percent. Accordingly, a 5i drug is not generally dispensed through retail community pharmacies if at least 70 percent of its sales are to entities other than retail community pharmacies (determined based on units at the NDC-9 level), in which case AMP will be based on those other sales. CMS agreed with commenters that the 90-percent threshold was overly restrictive, in that a limited amount of the product’s overall sales would have been used by the manufacturer to establish the AMP, and could result in a more volatile AMP. CMS concluded that the 70-percent standard better promotes stability and consistency in the AMP calculation and will ensure that sufficient sales are included in AMP while appropriately restricting the inclusion of 5i drugs to

those that are not generally dispensed through retail community pharmacies, consistent with the statute.

CMS also revised its rule to remove the redundant reference to a quarterly determination of the “not generally dispensed” requirement. Manufacturers must make a determination of whether a 5i drug is not generally dispensed through a retail community pharmacy on a monthly basis, but not quarterly. Additionally, CMS will allow the use of a “smoothing” process (as discussed in more detail below) to permit manufacturers to determine general dispensing patterns of a drug over a period of time, such as over 12 months. Such smoothing would result in more consistency in the AMP calculation, by reducing the number of instances where the AMP-eligible sales change from the retail community pharmacy AMP to the 5i alternative based on fluctuations in the sales. CMS does not address how manufacturers would apply the smoothing methodology for lagged price concessions in periods in which the AMP methodology changes. CMS has confirmed that a manufacturer may establish only one base date AMP,⁵ regardless of whether its product fluctuates between a retail community pharmacy AMP calculation and a 5i AMP calculation.

4. *“Authorized Generic” Drugs*

CMS is finalizing its proposal regarding brand-name drugs with “authorized generic” versions. As a result, “primary” manufacturers will be required to include, in their AMP calculations for brand-name drugs, sales to “secondary” manufacturers (i.e., entities that are licensed to sell the authorized generic version but do not hold the new drug application (“NDA”)) that are acting as “wholesalers” engaged in wholesale distribution of drugs to retail community pharmacies. The primary manufacturer will be responsible for determining whether the secondary manufacturer is acting as a wholesaler, which would not pertain where the secondary manufacturer relabels the product before selling it to wholesalers or directly to retail community pharmacies. Nevertheless, CMS confirmed that manufacturers may continue to use a presumed inclusion approach when calculating AMP, thereby relieving manufacturers of any need to trace or document sales made by secondary manufacturers to downstream entities. Finally, CMS reaffirmed that the calculation of AMP must include transfer prices and fees paid by the secondary manufacturer to the primary manufacturer.

5. *“Bona Fide Service Fees”*

The ACA revised the AMP definition to exclude “bona fide service fees,” without defining them, and it provided a non-exhaustive list of the types of fees that might potentially qualify.⁶ In the Final Rule, CMS has come full circle

⁵ The “base date AMP” of a drug is generally the AMP for the first full quarter in which the drug is marketed.

⁶ The 2007 regulations required that such fees be excluded from AMP and “Best Price.”

to reinstitute the “four-part test” for purposes of determining whether a payment qualifies as a “bona fide service fee,” to be excluded from the calculation of AMP and Best Price,⁷ rather than as a price concession that must be included in those calculations. According to the test, a “bona fide service fee” is a payment: (i) for an itemized service; (ii) that the manufacturer would otherwise perform itself or engage a third party to perform; (iii) that reflects the fair market value of that service; and (iv) that the recipient does not pass on, in whole or in part, to another entity.

CMS decided to remove the proposed definition’s recipient limitation, which stated that the bona fide service fee exclusion applied only to fees paid by manufacturers to wholesalers and retail community pharmacies. In addition, CMS noted that with regard to the “not passed along” prong, manufacturers may presume, in the absence of any notice or evidence to the contrary, that the fee paid is not passed on to a client or customer of any entity—an adjustment that was designed to better align the test with the existing policy for bona fide service fees under the Medicare Average Sales Price (“ASP”) calculation. Having finalized the four-part test, CMS declined to provide any further examples of the types of payments that would constitute bona fide service fees but confirmed that the examples provided in the ACA amendment to the AMP definition are not exhaustive. The agency also declined to define “fair market value,” noting that manufacturers should have flexibility in determining fair market value in view of the complex and evolving pharmaceutical marketplace.

6. *“Smoothing” of Lagged Price Concessions*

CMS is finalizing its proposal to reestablish the requirement that manufacturers estimate the value of lagged price concessions related to AMP-eligible sales in a given calculation period (using a 12-month rolling average methodology, commonly referred to as “smoothing”).⁸ CMS has revised the Proposed Rule to specify that smoothing should be performed at the NDC-9 level and to add detailed instructions for the methodology for smoothing and an example, similar to the smoothing methodology established by regulation for the calculation of the ASP. The Final Rule requires the use of data from the most recent “12-month period,” as did CMS’s sub-regulatory guidance issued in February 2011⁹ and the Proposed Rule; CMS has revised the regulation to clarify that the 12-month period includes the current reporting period for which the AMP is being calculated. Smoothing of ineligible indirect sales is also permitted, according to CMS’s statements in the preamble to the Final Rule, although no specific methodology is prescribed.

⁷ “Best Price” is defined under 42 U.S.C. § 1396r-8(c)(1)(C) and section 447.505(a).

⁸ This requirement was technically withdrawn from the regulations in 2010. See 75 Fed. Reg. 69,591 (Nov. 15, 2010).

⁹ See CMS, Medicaid Drug Rebate Program Manufacturer Release No. 83 (Feb. 3, 2011), available at <http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Program-Releases.html>.

7. *Best Price Exclusion for Sales to Section 340B Covered Entities*

In 2012, CMS proposed that manufacturers exclude from their Best Price calculations “[p]rices to [section] 340B covered entities,” which include “[p]rices charged under the [section] 340B drug pricing program to a covered entity described in section 1927(a)(5)(B) of the [Social Security] Act” and “[a]ny inpatient prices charged to [disproportionate share] hospitals described in section 340B(a)(4)(L) of the [Public Health Service Act (“PHSA”).”

CMS received several comments opposing the proposed language as a departure from the statutory language exempting “any prices” charged to covered entities, and not just prices charged under the 340B program, from the Best Price calculations. One commenter specifically noted that the proposed language could potentially discourage manufacturers from offering discounted prices to safety net providers in order to avoid the inclusion of that low price in the Best Price calculation. As a result of these comments, CMS is not finalizing the changes to the Best Price calculation as proposed. Instead, the agency is adopting revised language to exclude from the Best Price calculation any prices charged to a covered entity described in section 1927(a)(5)(B) of the Social Security Act, including inpatient prices charged to hospitals under section 340B(a)(4)(L) of the PHSA.

B. Unit Rebate Amount (“URA”) Calculations

1. *Drugs Approved Under “Original New Drug Applications”*

The URA calculation for single source and innovator multiple source drugs differs from that for noninnovator multiple source drugs, in that innovator drugs are subject to a higher base rebate percentage, include an “additional rebate” akin to an inflation penalty, and include consideration of Best Price. The definitions of the two categories of innovator drugs, as finalized by CMS, include a reference to an “original NDA.” In the Proposed Rule, CMS proposed to define an “original NDA” as an NDA filed by the manufacturer for approval under section 505 of the Federal Food, Drug, and Cosmetic Act for purposes of approval by the U.S. Food and Drug Administration (“FDA”) for safety and effectiveness.

CMS has revised the proposed definition of “original NDA” to mean “an NDA, other than an Abbreviated New Drug Application (ANDA), approved by the FDA for marketing, unless CMS determines a narrow exception applies” (which requires the manufacturer’s written submission to CMS, and CMS’s response confirming that the exception applies). The limited exception applies where a drug may be more appropriately considered as if it were approved under an ANDA and classified as a noninnovator multiple source drug (a lack of exclusivity and patent protection being among such considerations). CMS intends to issue additional guidance on the scope of this exception.

The agency also clarified scenarios where the change in the definition of “original NDA” may require action. Drugs being reported to the MDRP on or

after the April 1, 2016, effective date of the Final Rule—which may include either (i) drugs newly marketed under an NDA other than an ANDA, or (ii) drugs previously marketed under an NDA other than an ANDA and newly reported to MDRP because the drug was not previously reported or the manufacturer entered into a new rebate agreement after the effective date—should be classified as single source or innovator multiple source drugs. As for drugs marketed under an NDA and currently reported in the MDRP as noninnovator multiple source drugs, CMS reminds manufacturers of these drugs that they must comply and report as innovator multiple source drugs or single source drugs, as applicable. CMS has established a timeframe of four quarters after the April 1, 2016, effective date of the Final Rule for a manufacturer to apply for the exception or make the required data changes to bring its reporting efforts into compliance before administrative action may be taken.

2. *Rebates for “Line Extensions”*

The ACA established that the “additional rebate” component of URAs for CODs would apply to a line extension (new formulation) of an oral solid dosage form. To implement this requirement, CMS proposed to define “line extension drugs” by reference to the chemical types assigned by the FDA: a new ester, salt, or other noncovalent derivative; a new formulation; a new combination; or a new indication.

In response to numerous comments, CMS decided not to finalize the proposed definition of “line extension.” Instead, CMS is requesting additional comments on this definition for future rulemaking. Until such time, manufacturers will have to rely on the current statutory definition of “line extension” in determining whether a drug qualifies as a line extension drug.

In the Proposed Rule, the methodology for identifying line extensions could have allowed for a drug to be considered a line extension even if it were manufactured by another manufacturer. In response to criticisms that this would have required manufacturers to collect pricing information from unrelated parties, in the Final Rule, CMS has limited the line extension provision so that a drug by one manufacturer will not be treated as a line extension of a drug by another manufacturer, unless there is a corporate relationship between the manufacturers.

In the Final Rule, CMS clarified that while the provisions in the Final Rule are effective on a prospective basis, the line extension provision was effective statutorily on January 1, 2010. Thus, the line extension requirements of the Final Rule apply to drugs that qualify as line extensions as of the statutory effective date of January 1, 2010.

C. Drugs Subject to MDRP Rebates

1. *Extending the MDRP to the U.S. Territories*

CMS is finalizing its proposal to extend the MDRP to the U.S. territories. Commenters challenged this proposal as inconsistent with CMS's authority and Congressional intent. Nonetheless, CMS believes the rebates will benefit the territories and that the change is consistent with its "reexamination" of the statutory definitions of "states" and the "United States," as applied to the MDRP.

Commenters raised concerns over the multiple administrative hardships on manufacturers and the territories, as well as the possibility that territories might implement the program before manufacturers are ready to pay rebates. In addition to substantial added administrative costs and challenges, manufacturers expressed concern over the wide variation in territorial drug coverage and reimbursement methodologies, as well as foreign pricing structures. CMS dismissed the variation issue as no different than the existing reality among the 50 states and the District of Columbia, and it downplayed other challenges as no different than those encountered when the MDRP was initially established. CMS has, however, imposed a one-year delay after the Final Rule becomes effective before the MDRP definitions will include territories or before manufacturers will be obligated to pay rebates to them.

CMS clarified that territories will have the ability to exercise waiver authorities, as they do now under Medicaid, to opt out of the MDRP or request additional time for implementation. The agency also addressed concerns that the cap on total territorial Medicaid spending would apply to setting up reporting systems necessary to implement the MDRP, explaining that Medicaid Management and Information Systems' costs are held harmless from the cap. Territories will receive support through their current CMS regional office assignments and additional guidance and technical assistance from CMS.

2. *Utilization by Enrollees in Medicaid Managed Care Organization Plans*

The ACA extended the MDRP to MMCOs, which had historically been exempted from the program requirements. As a result, manufacturers must pay rebates for COD utilization of MMCO enrollees where the MMCO is responsible for drug coverage. CMS is finalizing a new requirement under section 447.509(b)(1) that participating manufacturers pay rebates for CODs in the same manner. An exclusion applies to drugs purchased at 340B discounts that are dispensed to enrollees of Medicaid health plans, including MMCOs, to avoid the duplicate discount that would be caused by paying a Medicaid rebate on drugs sold at the 340B discounted price.

CMS declined to finalize its proposal that MMCOs submit detailed quarterly dispensing reports to states, recognizing the lack of improved effectiveness and potential added expense for states and MMCOs attendant upon this

approach. Instead, CMS finalized requirements at section 447.511 to require state reporting of relevant utilization to manufacturers, as described above.

CMS addressed many concerns over the carving out of MMCO drugs by 340B entities and the authority and ability of states to prevent double discounting. Some urged a requirement that states submit prescription-level data across Medicaid fee for service (“FFS”) and MMCO plans with a field for 340B identification. While noting that the issue is not within the scope of the Proposed Rule, CMS acknowledged commenter concerns and emphasized that states have the responsibility and flexibility to ensure that MMCOs exclude 340B drugs from utilization reporting. CMS declined to adopt any additional regulatory or reporting requirements but will continue to monitor and provide guidance to states, as needed. Similarly, with respect to dual eligibles, CMS believes adequate MMCO billing edits are in place to route drug claims to Medicare Part D.

Commenters also raised concerns over the typically longer difference in dates of payment and service in MMCOs relative to FFS plans, and the potential rebate period lag. CMS clarified that MMCO reporting should be based upon the date of service, while FFS reporting should continue to be based upon the date of payment. CMS also confirmed that manufacturer rebates are only applicable to CODs dispensed to MMCO enrollees on or after March 23, 2010.

Finally, CMS declined to address concerns over pharmacy reimbursement adequacy, stating that MMCOs are entitled to reimbursement flexibility to the extent necessary to achieve an adequate network.

D. Manufacturers’ Reporting Obligations

1. *“Covered Outpatient Drug” Status*

A manufacturer’s obligation to report information to CMS and to pay a rebate to state Medicaid programs is limited to drugs that meet the definition of “covered outpatient drug.” Although the ACA did not revise the long-standing statutory definition of “covered outpatient drug,”¹⁰ CMS had included in the Proposed Rule a new regulatory definition that a drug be considered a “covered outpatient drug” only if it is required to have an NDC assigned to it under applicable FDA regulations and it is electronically listed with the FDA. To facilitate CMS’s ability to confirm compliance with these proposed criteria, CMS further proposed to require manufacturers to report to CMS the reference number for the FDA-approved application under which each of its drugs is marketed and, for any drug that is permissibly marketed outside of an

¹⁰ The MDRP statute defines “covered outpatient drugs” to include prescription drugs and biologicals (except vaccines) marketed under NDAs, ANDAs, and biologics license applications (“BLAs”) approved by the FDA, drugs without FDA-approved applications that are subject to ongoing Drug Efficacy Study Implementation (“DESI”) review, and, at a state’s election, over-the-counter drugs when dispensed pursuant to physicians’ prescriptions.

FDA-approved application, evidence demonstrating that the product meets the definition of “covered outpatient drug.”

In finalizing the COD definition, CMS has eliminated the electronic FDA listing requirement (although it urges manufacturers to ensure that their drugs are accurately listed with FDA as CMS will continue to use FDA’s electronic database to confirm that products meet the COD definition). CMS clarifies in the preamble that evidence of COD status that manufacturers may provide would include FDA application number, letter of approval, and CMS’s COD status codes.

CMS has also made other revisions to track more closely the statutory definition of “covered outpatient drug,” such as revising the definition to include a drug that is “commercially *used or sold* in the United States.” Similarly, in the limiting definition, which excludes drugs from the COD definition if they are provided incident to, and in the same setting as, specified services, CMS has revised section 447.502, paragraph (2) of the COD definition to “and for which payment *may be* made as part of that service.” In this context, in the preamble, CMS has clarified that it is the state’s responsibility to collect and report information to manufacturers for all CODs for which payment was made under the state plan, which may vary from state to state.

2. *Base Date AMP Recalculations*

CMS proposed to allow manufacturers to recalculate the base date AMP for a COD to account for changes in the AMP calculation made by the ACA, but only if the manufacturer uses “actual and verifiable pricing records.” In light of CMS rejecting the buildup methodology in favor of the presumed inclusion method (described above), CMS will allow manufacturers to recalculate the base date AMP using the presumed inclusion method. Although manufacturers may use the presumed inclusion method, CMS is finalizing its requirement that manufacturers must maintain actual and verifiable documentation that otherwise supports such calculations. CMS also is finalizing the requirement that the base date AMP must be recalculated within four calendar quarters after the April 1, 2016, effective date of the Final Rule.

3. *Restatements*

The recalculation provisions set forth in the Proposed Rule represented a substantial change from the current regulatory reporting requirements. Manufacturers have been encouraged by the prospect of new procedures that would permit the reporting of revisions to AMP and Best Price data beyond the existing three-year (12-quarter) window. CMS will finalize the procedure for a manufacturer to request permission to revise reported information in the following five circumstances: (i) when the change is to a drug’s “drug category” or “market date”; (ii) when the change would relate to an initial product submission; (iii) when the information relates to a drug deleted from

CMS's database following termination of its manufacturer from the MDRP, upon that manufacturer's reentry to the program; (iv) when the change involves a technical error, which does not involve changes in the data originally used to calculate that information; and (v) when the change involves specific rebate adjustments to states by manufacturers as required by CMS or court order, or under an internal investigation, or an investigation conducted by the Office of Inspector General ("OIG") or the U.S. Department of Justice. CMS did make one adjustment to the proposed procedures by changing the language of the fifth prong to clarify that change requests will be considered where they involve an overpayment to the state as well as when there has been an underpayment. CMS noted that the exception will apply to each change request submission as a whole (reflecting the net impact), and revisions will not be permitted based on a per drug, or partial change, request submission. The Final Rule does not impose any additional recalculation deadlines extending beyond the 12-quarter timeframe.

On the other hand, CMS is not finalizing its second proposed "good cause" exception that would have permitted manufacturers to submit a recalculation request for "other good cause reasons" relating to a change in the manufacturer's methodology for calculating AMP and/or Best Price. The agency did not receive sufficient comments discussing the sorts of situations that would constitute "good cause" and noted that there was confusion expressed about the relationship between the "good cause" exception and the fifth prong, noted above, concerning the restatement for underpayment exception. Nonetheless, CMS may revisit the idea of a broader "good cause" exception in future rulemaking.

4. Timeliness of Submissions & Compliance with Other Program Requirements

Manufacturers may be relieved that CMS is not finalizing its proposal that any manufacturer that fails to submit and certify quarterly and monthly AMP and monthly AMP units within the 30-day timeframe will be reported to the OIG and subjected to civil monetary penalties ("CMPs") of \$10,000 for each day that information on a particular drug is late. Some observers have voiced concerns that the proposal to impose penalties for each drug was based on an unduly broad interpretation of the statutory penalty.¹¹ Nevertheless, CMS noted that as a matter of practice, it will continue to refer to the OIG those manufacturers that fail to report on a timely basis. In recent years, CMS has taken steps to bolster its enforcement of the timeliness requirement. CMS previously announced in 2010 that it would work in closer collaboration with the OIG to oversee reporting.¹² Therefore, even without an automatic referral

¹¹ 42 U.S.C. § 1396r-8(b)(3)(C)(i).

¹² See CMS, Medicaid Drug Rebate Program Manufacturer Release No. 81 (Aug. 11, 2010); HHS Special Advisory Bulletin, Average Manufacturer Price and Average Sales Price Reporting Requirements (Sept. 2010), available at: <http://www.oig.hhs.gov/compliance/alerts/bulletins/index.asp>.

and CMP penalty for tardy reporting, manufacturers will need to maintain rigorous controls to ensure reporting timeliness.

CMS announced that, at the present time, it will not be promulgating any additional guidance relating to suspension or termination procedures for manufacturers that fail to submit quarterly reports or otherwise comply with their rebate obligations.

E. Pharmacy Reimbursement

1. *Actual Acquisition Cost and Cost to Dispense*

CMS finalized its proposal to establish AAC rather than “estimated acquisition cost” (“EAC”) as the basis by which states should determine their ingredient cost reimbursement for drugs, other than multiple source drugs that are subject to upper limits (discussed in the subsection below). Citing previous OIG reports, CMS has taken the position that AAC more accurately reflects purchase price and that EAC, which is based on average wholesale price or wholesale acquisition cost, is less accurate because it fails to include discounts and other price concessions. States must submit SPAs by June 30, 2017, to be effective no later than April 1, 2017, if needed to implement the change.

In response to numerous comments expressing concern with the change to AAC, CMS noted that states have the flexibility to establish an AAC reimbursement in their state plan based on several different pricing benchmarks, for example, the National Average Drug Acquisition Cost (“NADAC”) files, a state survey of retail pharmacy providers, or AMP-based pricing. In addition, CMS revised proposed section 447.518(d) to require states to consider both the ingredient cost reimbursement and the professional dispensing fee reimbursement when proposing changes to these components of reimbursement. Under the Final Rule, the professional dispensing fee includes pharmacy costs associated with the transfer of the drug to the beneficiary. The fee also includes, but is not limited to, reasonable costs associated with a pharmacist’s time in checking an individual’s coverage, performing drug utilization review and preferred drug list review activities, measurement or mixing of the drug, filling the container, counseling, physically providing the completed prescription of the Medicaid beneficiary, delivery, special packaging, and overhead with maintaining the facility and equipment necessary to operate the pharmacy.

The provisions of the Final Rule related to AAC do not apply to MMCOs, which establish their own reimbursement methodologies, in accordance with their contractual arrangement with the state agency.

2. *Federal Upper Limits for Multiple Source Drugs*

Under the Medicaid program, certain multiple source drugs are subject to a FUL, which is the maximum amount that a state Medicaid agency can

reimburse a pharmacy for dispensing the multiple source drug. As required by the ACA, CMS finalized its proposal that a FUL be calculated for each multiple source drug for which the FDA has rated three or more products therapeutically and pharmaceutically equivalent. In addition, CMS finalized its proposal to calculate the FUL as an aggregate upper limit at 175 percent of the weighted average of monthly AMPs, to use the most recently reported monthly AMPs and AMP units, and to eliminate single source drugs from the FUL calculation. To address situations where the FUL is less than the average retail community pharmacies' acquisition cost, CMS revised its proposal to establish the FUL using a higher multiplier so that the FUL amount would equal the most current average retail community pharmacies' acquisition cost as determined by the most current national survey of such costs. To implement this provision, CMS intends to use the most current monthly NADAC pricing file values to estimate the average retail community pharmacies' acquisition cost.

Consistent with the Final Rule, CMS issued a notice on January 22, 2014, that it intends to publish the draft FULs for two months beginning in January 2016. According to the notice, the FULs will be published in late March 2016 and will be effective on April 1, 2016, to coincide with the effective date of the Final Rule.

3. Impact on Pharmacy Reimbursement

In the preamble, CMS recognized that retail community pharmacies will be affected by the Final Rule, because it will result in ingredient cost reimbursement that is closer to the acquisition cost of the drug. However, the finalized definition of "professional dispensing fee" may be beneficial to pharmacies, since it includes the costs of a number of specific pharmacist activities. Thus, the Final Rule's impact on pharmacy reimbursement will depend on whether, and the extent to which, states, as a result of being required to assess pharmacy costs, raise dispensing fees that mitigate the effects of any lower, AAC-based reimbursements.

4. Impact on 340B Covered Entity Reimbursement

Under the 340B Drug Pricing Program, discounted drug prices are available to a broad range of participating "safety net" providers, known as "covered entities" (including disproportionate share hospitals, federally qualified health centers, and other types of hospital and non-hospital entities with federal designations or that receive funding from federal programs). Under the Final Rule, ingredient cost reimbursement for 340B covered entities, as with other providers, will shift to the acquisition cost of the drug. Because states may not have access to "subceiling prices" (prices below the statutory 340B ceiling price), CMS states that it will consider reimbursement at the statutory 340B ceiling price for the ingredient cost component of reimbursement in addition to an adequate professional dispensing fee.

DATES OF INTEREST

Although the provisions of the Final Rule are effective on April 1, 2016, CMS mentioned other specific dates and deadlines of interest:

- **“Original NDA” Exception:** CMS has granted manufacturers up to four quarters to apply for the limited exception to the “original NDA” definition.
- **Line Extensions Provisions:** CMS stated that the line extension provisions in the ACA were effective on January 1, 2010. However the provisions in the Final Rule will be implemented only on a prospective basis, effective April 1, 2016.
- **U.S. Territories:** In order to allow manufacturers and territories sufficient time to prepare for implementation of the Final Rule, CMS will delay the implementation of the new definitions of “states” and “United States” to include the territories of the United States until April 1, 2017—one year after the effective date of the Final Rule. As a consequence, certain revised definitions that apply to manufacturers under section 447.504 (“Determination of AMP”), section 447.505 (“Determination of best price”), section 447.509 (“Medicaid Drug Rebates”), and section 447.510 (“Requirements for manufacturers”) will not immediately be applicable to the territories as of the effective date of the Final Rule.
- **Base Date AMP Recalculation:** Manufacturers will have four calendar quarters from the April 1, 2016, effective date of the Final Rule to report the recalculated base date AMP.
- **State Plan Amendment:** CMS has allowed states four quarters from the effective date of the Final Rule to submit an SPA to comply with the FUL provisions.

In response to several comments expressing that state dispensing fees to 340B covered entities are inadequate, CMS recognized that there may be unique circumstances for 340B covered entities that states should consider when establishing their professional dispensing fees. CMS discusses in the preamble that 340B covered entities may have additional costs associated with dispensing compared to a retail pharmacy and may also consider those dispensing costs when looking at overall payment to these covered entities. The Final Rule expressly requires state plans to describe their payment methodologies for 340B covered entities and their contract pharmacies.

Although many state Medicaid programs already reimburse 340B covered entities based on acquisition cost, establishing a national limit on reimbursement based on costs could potentially diminish the differential between drug cost and reimbursement relied upon by 340B covered entities to generate 340B program savings. For example, in the preamble, CMS suggested that it would not make an exception to the AAC provisions for “shared savings” programs that create an incentive for 340B covered entities to dispense 340B discounted drugs to Medicaid beneficiaries.

Ultimately, the impact on 340B covered entities will depend on whether, and the extent to which, state agencies establish increased dispensing fees unique to 340B covered entities and their contract pharmacies. Except where prohibited by state law, a 340B covered entity will continue to have the option to “carve in” or “carve out” Medicaid patients from its 340B program.

III. REQUEST FOR ADDITIONAL COMMENTS

CMS *specifically* requests comment on the issue of line extensions. The agency has decided not to finalize the proposed regulatory definition of “line extension drug” at section 447.502. Instead, CMS has invited another round of comments on the definition of “line extension drug” for consideration in a future rulemaking.

Comments are due by April 1, 2016—60 days after publication of the Final Rule in the *Federal Register*.

IV. NEXT STEPS

Manufacturers, pharmacies, and other key stakeholders should consider the potential implications of the Final Rule with respect to their products and implementation costs, including the potential impact of the Final Rule on their operations, systems, policies, and financial projections/budgeting. Given the significant delay between the issuance of the Proposed Rule and the Final Rule, manufacturers should review their current practices to determine whether any changes made in the interim should be reconsidered and whether additional changes are required to bring their methodology into compliance with the Final Rule. Manufacturers, in particular, may want to take advantage of the opportunity to comment on the line extension issue noted above.

Epstein Becker Green is available to assist with drafting and submitting comments to the Final Rule as well as providing a more detailed understanding of its implications and the manner in which particular requirements may be implemented effectively.

* * *

*This Client Alert was authored by **Constance A. Wilkinson, Alan J. Arville, Lesley R. Yeung, John S. Linehan, Richard H. Hughes IV, and Meghan F. Weinberg.** For additional information about the issues discussed in this Client Alert, please contact one of the authors or the Epstein Becker Green attorney who regularly handles your legal matters.*

****James S. Tam**, a Law Clerk – Admission Pending (not admitted to the practice of law) in the Health Care and Life Sciences practice, in the firm’s Washington, DC, office, contributed to the preparation of this Client Alert.*

This document has been provided for informational purposes only and is not intended and should not be construed to constitute legal advice. Please consult your attorneys in connection with any fact-specific situation under federal law and the applicable state or local laws that may impose additional obligations on you and your company.

About Epstein Becker Green

Epstein Becker & Green, P.C., is a national law firm with a primary focus on health care and life sciences; employment, labor, and workforce management; and litigation and business disputes. Founded in 1973

HEALTH CARE & LIFE SCIENCES

as an industry-focused firm, Epstein Becker Green has decades of experience serving clients in health care, financial services, retail, hospitality, and technology, among other industries, representing entities from startups to Fortune 100 companies. Operating in offices throughout the U.S. and supporting clients in the U.S. and abroad, the firm's attorneys are committed to uncompromising client service and legal excellence. For more information, visit www.ebglaw.com.

IRS Circular 230 Disclosure

To ensure compliance with requirements imposed by the IRS, we inform you that any tax advice contained in this communication (including any attachments) is not intended or written to be used, and cannot be used, for the purpose of: (i) avoiding any tax penalty, or (ii) promoting, marketing or recommending to another party any transaction or matter addressed herein.

If you would like to be added to our mailing list or need to update your contact information, please contact Lisa C. Blackburn at lblackburn@ebglaw.com or 202-861-1887.

BALTIMORE Helaine I. Fingold Joshua J. Freemire Thomas E. Hutchinson* John S. Linehan	NEW YORK Jeffrey H. Becker Lindsay M. Borgeson Michelle Capezza Karen L. Cavalli Aime Dempsey Kenneth W. DiGia Charles C. Dunham, IV Jerrod I. Ehrlich Gregory H. Epstein Hanna Fox James S. Frank Arthur J. Fried John F. Gleason Robert D. Goldstein Robert S. Groban, Jr. Gretchen Harders Bethany J. Hills Carly Eisenberg Hoinacki Jennifer M. Horowitz Kenneth J. Kelly Joseph J. Kempf, Jr. Basil H. Kim Stephanie G. Lerman Leonard Lipsky Purvi Badiani Maniar Wendy G. Marcarì Eileen D. Millett Shilpa Prem Jackie Selby Victoria M. Sloan Steven M. Swirsky Benjamin T. Tso David E. Weiss Alison M. Wolf* Benjamin M. Zegarelli	NEWARK John D. Barry Christina Burke Joan A. Disler James P. Flynn Diana M. Fratto Gary W. Herschman Laurajane B. Kastner Daniel R. Levy Theodora McCormick Maxine Neuhauser Anjana D. Patel Victoria Vaskov Sheridan Erica F. Sibley Scheherazade A. Wasty Jack Wenik Sheila A. Woolson	WASHINGTON, DC Alan J. Arville Robert F. Atlas* Kirsten M. Backstrom Clifford E. Barnes James A. Boiani George B. Breen Lee Calligaro Tanya V. Cramer Anjali N.C. Downs Jason E. Christ Steven B. Epstein John W. Eriksen Wandaly E. Fernández Daniel C. Fundakowski Brandon C. Ge Stuart M. Gerson Daniel G. Gottlieb M. Brian Hall, IV Philo D. Hall Douglas A. Hastings Jonathan K. Hoerner Robert J. Hudock Richard H. Hughes IV William G. Kopit Amy F. Lerman Wenxi Li* Christopher M. Locke Katherine R. Lofft Mark E. Lutes Teresa A. Mason David E. Matyas Colin G. McCulloch Frank C. Morris, Jr. Leslie V. Norwalk René Y. Quashie	Jonah D. Retzinger Serra J. Schlanger Bonnie I. Scott Deepa B. Selvam Lynn Shapiro Snyder Adam C. Solander James S. Tam* David B. Tatge Daly D.E. Temchine Bradley Merrill Thompson Carrie Valiant Patricia M. Wagner Robert E. Wanerman Meghan F. Weinberg Constance A. Wilkinson Kathleen M. Williams Lesley R. Yeung <i>*Not Admitted to the Practice of Law</i>
BOSTON Emily E. Bajcsi Barry A. Guryan				
CHICAGO Bradley S. Davidsen Amy K. Dow Mark A. Mosby Kevin J. Ryan				
HOUSTON Mark S. Armstrong		PRINCETON Anthony Argiropoulos Thomas Kane Andrew Kaplan Jeffrey G. Kramer		
LOS ANGELES Adam C. Abrahms Ted A. Gehring Paul A. Gomez J. Susan Graham		SAN DIEGO Kim Tyrrell-Knott		
		STAMFORD Ted Kennedy, Jr. David S. Poppick		