Medicaid Program: Covered Outpatient Drugs, Final Rule with Comment Period Summary

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I. Introduction

On January 21, 2016, the Centers for Medicare & Medicaid Services (CMS) released the final rule implementing the prescription drug rebate provisions enacted as part of the health care reform law, the Affordable Care Act (ACA).[1] The rule finalizes a notice of proposed rulemaking (NPRM) first published in the Federal Register on February 2, 2012.[2] In all, the agency reports that it received over 400 comments on the proposed rule from a broad spectrum of stakeholders. The final rule will become effective on April 1, 2016; however, to the extent that the rule implements provisions of the statute that were effective prior to that date, those provisions are, and have been, in effect since January 1, 2010. For certain specified issues in the rule, there is a 60 day comment period beginning Feb. 1, 2016.

This document summarizes the major provisions of the final rule. Where relevant, it notes how the final rule deviates from policies that were proposed in the NPRM issued in February, 2012. It will also note any provisions that may be effective on a date other than the general implementation date of January 1, 2010 (for example, CMS gives transition periods for some provisions). The regulations will be codified at 42 C.F.R. § 447.500 *et. seq*.

II. Specific Provisions of the Final Rule

A. Definitions

1. "5I" DRUGS

Although CMS has chosen not to finalize a definition of this term, it notes that the designation of drugs that are inhaled, infused, instilled, implanted or injected are commonly referred to as "5i" drugs and CMS uses that nomenclature throughout the rule.

2. BONA-FIDE SERVICE FEES

CMS generally finalized its definition of "bona fide service fee." A fee meets the definition, and is therefore excluded from the calculation of AMP, if it: (1) is paid by the manufacturer to an entity; (2) that represents fair market value for a bona-fide, itemized service; (3) is actually performed on behalf of the manufacturer that the manufacturer would have otherwise performed in the absence of the service arrangement; and (4) that is not passed on, in whole or in part, to a client or customer of the entity, regardless of whether it takes title to the drug.

Under the final rule, CMS modified its proposed definition to clarify that a service fee can count as "bona fide" if it is paid to an "entity:" that is, other than a wholesaler or a retail pharmacy. Thus, the definition of bona fide service fee is the same for AMP as it is for best price. CMS also aligns its policy on bona-fide service fees with the ASP definition of that term regarding manufacturer assumptions that a service fee is not passed on to a client or customer of the entity purchasing the drug.

3. COVERED OUTPATIENT DRUG

CMS clarifies, in response to a question, that a radiopharmaceutical can be a covered outpatient drug and rejects an argument that, just because a radiopharmaceutical is typically prescribed as a diagnostic, it should not be considered a covered outpatient drug.

CMS also deleted its proposal that a covered outpatient drug be electronically listed with the FDA.

Under the statute, a drug is excluded from the definition of a covered outpatient drug if it is billed as a bundled service and provided as part of or incident to services such as, for example, inpatient hospital services, physician services, renal dialysis services, outpatient hospital services. For the exclusion to apply, separate payment cannot be made for the drug.

The proposed rule addresses this exclusion in the context of renal dialysis services that may be paid partially under Medicare (under the dialysis PPS bundle) and Medicaid (which may pay separately for a dialysis drug provided to a dual-eligible enrollee). The agency clarifies that drugs subject to the dialysis bundle are not subject to Medicaid rebates.

The agency also clarifies that states are responsible for determining whether or not a particular drug has been paid separately; manufacturers do not have this responsibility.

CMS adopts a policy regarding the definition of innovator multiple source drug that will require some manufacturers that had been treating some products as noninnovator multiple source to change that categorization. CMS addresses several comments on this issue. CMS notes that patent protection or market exclusivity is **not** the determinant of whether or not a drug is single source. CMS gives manufacturers four quarters to adjust to this change.

4. CUSTOMARY PROMPT PAY DISCOUNT

CMS finalizes its definition of this term as a discount off of the purchase price of a drug routinely offered by the manufacturer to a wholesaler of the drug for prompt payment of a purchased drug within a specified time frame and consistent with customary business practices.

5. LINE EXTENSION DRUG

CMS notes that it received numerous comments objecting to the agency's proposed broad definition of line extension drug that would implement the provisions of the ACA imposing the CPI penalty on a new formulation of a single source drug or an innovator multiple source drug that is an oral solid dosage form. The agency notes that it is not, at this time, finalizing its proposed definition, but that it is requesting additional comments on the definition of line extension drug as the agency "may consider addressing this in future rulemaking."

(See further discussion in Section E of this summary below.)

6. STATE AND UNITED STATES

CMS has finalized its proposal to extend the Medicaid drug rebate program to the Territories of the United States. However, the agency is delaying implementation of the policy for one year.

B. Determination of Average Manufacturer Price (AMP)

CMS begins by noting that, in the absence of clear guidance as to whether a sale of a drug should be included in the calculation of the AMP of the drug, manufacturers must make/are permitted to make reasonable assumptions regarding the inclusion of the sale in AMP. Generally, CMS proposed two approaches to determining AMP: "presumed inclusion" (presume, in the absence of documentation to the contrary, that prices paid to manufacturers are for sale to retail pharmacies) and the "buildup" methodology (only include in AMP calculation prices when there is adequate, verifiable documentation that the drug was actually distributed to a community pharmacy). CMS rejects the buildup approach in the final rule.

CMS also did not finalize its proposal to include in AMP sales to specialty pharmacies, home infusion pharmacies, and home health agencies. Under the final rule, sales to these entities would only be included to the extent they actually operate as retail pharmacies.

CMS finalized its proposal to exclude from AMP bona-fide service fees paid by manufacturers to wholesalers or retail community pharmacies. Similarly, prompt pay discounts extended to wholesalers are also exempt from AMP. See definitions section for a definition of bona-fide service fees.

Regarding the issue of PBM sales and price concessions:

- CMS clarifies in the final rule that, because manufacturers do not typically "sell" to PBMs, the effect on AMP of transactions between manufacturers and PBMs is determined by reference to rebates, discounts and price concessions made to PBMs.

In the proposed rule, CMS addressed the impact of manufacturer discounts or benefits to patients (such as manufacturer coupons, voucher programs, drug discount programs, refund/rebate programs and patient assistance programs) on AMP. In general, the NPRM proposed that all five categories be excluded when calculating AMP. These discounts are only excluded, however, to the extent that the full value of the discount/coupon is passed on to the customer and the pharmacy (or any other agent or entity) does not receive any price concession.

- In the final rule, CMS generally adopts the proposed policy with modifications. It groups patient assistance programs together with vouchers. In addition, as with free goods, the discount or benefit must not be contingent on any other purchase requirement.

The rule also addresses state pharmacy assistance programs (SPAPs) in the context of AMP. CMS clarifies that rebates paid to SPAPs are excluded from the calculation of AMP.

CMS also addresses the treatment of "5i" drugs in the final rule.

- First, CMS did not adopt its proposal to use the FDA "Routes of Administration" list to identify 5i drugs. Rather, manufacturers must make reasonable assumptions in determining whether a drug is a 5i drug, and CMS does mandate a particular method of making these assumptions.
- Second, CMS has not adopted its proposal to use a 90% threshold in determining whether or not a 5i drug is not "generally dispensed" to retail pharmacies. Instead, CMS will establish the threshold at 70%. That is, a 5i drug would be considered "not generally dispensed" to retail pharmacies if the manufacturer determined that 70% or more of its sales (based on units of the drug at the NDC-9 level, not dollars) are to entities other than retail community pharmacies. The determination is to be made on a monthly basis.

CMS clarifies that the quarterly AMP calculation is the weighted average of the AMP calculation in the three months in the quarter.

C. Determination of Best Price

CMS finalized its proposal to conform the regulatory text for "best price" to the statutory text. In particular, best price will include prices and any associated discounts or price concessions that adjust prices either directly or indirectly and that are granted to best price-eligible entities. The agency notes that it is considering how value-based purchasing arrangements in the pharmaceutical marketplace may affect best price and states that it may be issuing further guidance on this issue.

Under the rule, direct patient sales are excluded from best price. Also excluded from the best price calculation are manufacturer-sponsored programs that provide free goods, including vouchers and patient assistance programs (so long as the programs are not contingent on any other purchase requirement; the full value or benefit of the program is passed on to the patient; and the pharmacy does not receive any price concession).

Any prices, rebates or discounts provided to SPAPs are exempt from best price under the final rule.

The final rule clarifies that **any** prices charged to 340B covered entities are exempt from best price. Commenters expressed confusion and opposition to the proposed rule, which states that **340B prices** were exempt from best price, the implication being that a price below the 340B price would affect best price. CMS notes that its finalized policy includes discounts on orphan drugs offered to the newly-expanded list of covered entities.

The final rule also addresses the implications of authorized generics on AMP and best price. In general, if the sale of an authorized generic from a primary manufacturer to a secondary manufacturer is an AMP or best price eligible sale (which would be the case when the secondary manufacturer is acting as a wholesaler), the transfer price is included in the primary manufacturer's calculation of AMP and best price for the drug. If the secondary manufacturer is not acting as a wholesaler, the price is not so included.

D. Nominal Price Sales

CMS finalized its proposal to add non-profit organizations exempt from tax under section 501(c)(3) of the Internal Revenue Code and providing health clinic services, as well as organizations providing family planning services, to the list of entities that can receive drugs at nominal pricing without affecting the best price of the manufacturer. CMS notes that although it has authority to expand the list of entities that can receive nominal pricing, it has chosen not to do so.

E. Rebates

1. LINE EXTENSIONS

The final regulation implements the ACA-mandated increase in the rebate percentages.

The Preamble to the final rule describes the NPRM's proposed policy on new formulations (line extensions) of existing drugs and summarizes the comments received. As noted above, CMS has decided not to finalize the proposed policy on line extensions and notes that it may address the policy in the future. In the interim period, manufacturers must rely on the statutory definition of line extension, and are permitted to use reasonable assumptions as to whether or not a particular formulation of a drug is a "new formulation" and therefore subject to the alternative rebate calculation.

That said, the agency does clarify or modify some of its proposed policies regarding line extensions. In the case of a line extension marketed by a different manufacturer, CMS says that it has decided to limit the line extension provision to make clear that a drug by one manufacturer will not be treated as a line extension of a drug by a different manufacturer, unless there is a corporate relationship between the two manufacturers.

The final rule also clarifies that a new strength of the same formulation of the initial brand name drug is not a line extension of the initial brand name drug.

CMS clarifies the effective date of the line extension provisions as applying to drugs paid for by states after December 31, 2009. Requirements set forth in the final rule are prospective only.

2. MEDICAID MANAGED CARE ORGANIZATIONS

The final rule also addresses the ACA changes regarding drugs dispensed through Medicaid managed care organizations (MCOs). There is some discussion in the final rule about how these provisions interact with the 340B program when Medicaid managed care organizations pay for drugs dispensed to enrollees who fill prescriptions at 340B covered entities, but CMS says that states have the obligation to ensure that Medicaid rebates are not paid on 340B drugs. "States have flexibility to use a variety of methods to prevent duplicate discounts." CMS has not finalized its proposal to require MCOs to report to states on drugs dispensed to 340B covered entity patients.

F. Submission of AMP

CMS has elected not to finalize its proposal regarding imposition of civil monetary penalties automatically on manufacturers who fail to file quarterly AMP reports within 30 days of the close of the quarter, and clarifies that it is the Office of Inspector General that determines whether or not to impose penalties. The agency also lists certain instances in which a manufacturer may restate AMP outside of the 12-quarter correction period.

CMS, however, finalized its proposal from the NPRM, to allow manufacturers to restate base date AMP to reflect changes made by the ACA.

G. Obligations of States

The final rule codifies, in regulatory text, the requirement of states to provide data to manufacturers on drugs dispensed in the prior quarter within 60 days of the close of the quarter. CMS rejected commenters' suggestions to absolve manufacturers from liability from rebates if states did not provide all required information within 60 days. Some commenters noted that some states had still, six years after enactment of the ACA, not provided information to manufacturers on drugs dispensed to Medicaid MCO enrollees (that are currently subject to rebates). In response to this comment, CMS merely re-iterated the 60-day requirement.

CMS encourages states to provide a means to identify a drug that is paid for under the 340B program so as to avoid submitting a rebate claim for that drug. The agency encourages states to include a provision to this effect in managed care organization contracts.

H. Upper Payment Limits for Drugs

CMS finalized its proposal to allow states to pay for Medicaid covered outpatient drugs at the actual acquisition cost (as opposed to the estimated acquisition cost). The agency rejected the use of estimated acquisition costs because this data is based on published compendia pricing that showed list prices and did not take into account discounts, chargebacks, rebates, and other price concessions. CMS also notes,

in response to a comment, that a state can maintain a maximum allowable cost (MAC) system to set pharmacy prices.

CMS also reiterates, in the final rule, that dispensing fees to pharmacists must conform with § 1902(a)(30)(A) (payments must be consistent with efficiency, economy, and quality of care and sufficient to enlist sufficient providers).

With respect to multiple source drugs, CMS explains the federal upper limit (FUL) methodology that it is applying pursuant to the ACA. The FUL is an aggregate upper limit of 175% of the weighted average of the monthly AMPs of a drug with at least three therapeutically and pharmaceutically equivalent products. The final rule modifies the proposed rule in the sense that for some drugs (where acquisition costs are higher than the FUL), CMS will use a higher multiplier to determine the FUL. In addition, CMS notes that it will not include 5i drugs in the FUL calculation.

CMS also finalized policies relating to state adoption of state plan amendments (SPAs) regarding pharmacy reimbursement. In general, CMS notes that states must submit a SPA when altering pharmacy reimbursement methodologies. The agency also notes, repeatedly, that concerns regarding pharmacy reimbursement must be raised with the state.

Some commenters objected to the use of AMP as a basis for pharmacy reimbursement, but CMS intends to permit that option to states.

Some commenters also objected to the practice of states mandating "Medicaid carve-out" for drugs dispensed to patients of 340B covered entities (i.e., states require that these drugs qualify for the Medicaid rebate and therefore not 340B pricing). CMS rejects the request to prohibit these arrangements, saying that it is up to states how to administer their Medicaid programs.

CMS specifically rejects requests to develop mechanisms to ensure against duplicate discounts for drugs dispensed to patients of 340B covered entities.

III. Conclusion

As noted above, CMS will codify the rules at 42 C.F.R. § 447.500 *et. seq.* The final rule will become effective on April 1, 2016, 60 days after its publication in the Federal Register.

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1. Pub. L. No. 111-148 and Pub. L. No. 111-152. CMS, Medicaid Program; Covered Outpatient Drugs, Final Rule with Comment Period (CMS-2345-FC), Display Copy available here (to be published in the Federal Register on Feb. 1, 2016.)
2. 77 Fed. Reg. 5318 (Feb. 2, 2012).

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