

Medicaid Rebates: CMS Releases The Long-Anticipated Proposed AMP Rule

The Patient Protection and Affordable Care Act, as amended (PPACA), made major changes in the methodology for determining Medicaid rebates that pose operational challenges and compliance risks for manufacturers. Effective October 1, 2010, PPACA changed the definition of the Average Manufacturer Price (AMP), which is a key driver of pharmaceutical manufacturers' rebate liability. Effective December 15, 2010, the Centers for Medicare and Medicaid Services (CMS) withdrew most of the pre-PPACA AMP regulations, but directed manufacturers to comply with PPACA.¹ Since then, manufacturers have been calculating AMPs in a "regulatory vacuum," making reasonable assumptions in areas where the statute is ambiguous or silent. On January 27, 2012, CMS released a proposed rule to interpret and implement the new statutory provisions on AMP.² In addition to defining AMP, the new rule proposes changes to CMS' Best Price regulations, and adds new provisions on the calculation of Medicaid rebates and Medicaid drug reimbursement amounts. After providing a brief background, this advisory summarizes the key changes proposed in the rule relating to: (a) calculation of AMP for standard drugs; (b) calculation of AMP for so-called "5i" drugs; (c) determination of Best Price; (d) identification of so-called "new formulations" and calculation of the unit rebate amount (URA) for such drugs; and (e) issues relating to Medicaid reimbursement. CMS will accept comments on this proposed rule through April 2, 2012. Given the number of important issues addressed and the proposals that CMS has made, it will be important for pharmaceutical companies to submit comments on the proposed rule.

I. Background: the Emergence of the Two AMPs

Effective October 1, 2010, Congress created two alternative AMPs. One AMP is calculated for inhalation, infusion, instilled, implanted, or injectable drugs that are "not generally dispensed through a retail community pharmacy" (the 5i AMP). The other AMP (the Standard AMP) is calculated for all other covered outpatient drugs.

¹ See 75 Fed. Reg. 69591, 69591-69597 (Nov. 15, 2010).

² CMS-2345-P, Medicaid Program; Covered Outpatient Drugs, available at http://www.ofr.gov/OFRUpload/OFRData/2012-02014_PI.pdf.

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Healthcare Reform Chart

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Under PPACA, AMP is generally defined as the manufacturer’s average price (1) to “retail community pharmacies” (defined more narrowly than CMS had defined the “retail pharmacy class of trade”); and (2) to “wholesalers” (generally defined more narrowly than previously) for drugs distributed to “retail community pharmacies,” subject to a list of transactions that are excluded from or included in AMP. PPACA defines these terms as follows:

- “Retail community pharmacy” means “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. Such term does not include a pharmacy that dispenses prescription medications to patients 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.”³
- “Wholesaler” means “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.”⁴

The statute’s language on 5i drugs (added in August 2010) was designed to fix a problem PPACA created: under its more narrow AMP definition, physician-administered drugs generally sold outside retail pharmacy channels might well have no AMP-eligible sales, thus making it impossible to calculate an AMP and a rebate amount. The new 5i language modified the part of the AMP definition that otherwise excluded from AMP payments from (or discounts

or rebates to) various entities such as Pharmacy Benefit Managers (PBMs), insurers, hospitals, clinics, and mail order pharmacies. Specifically, the amended statute provides:

The [AMP] . . . shall exclude—payments received from, and rebates or discounts provided to, pharmacy benefit managers, managed care organizations, health maintenance organizations, insurers, hospitals, clinics, mail order pharmacies, long term care providers, manufacturers, or any other entity that does not conduct business as a wholesaler or a retail community pharmacy, unless the drug is an inhalation, infusion, instilled, implanted, or injectable drug that is not generally dispensed through a retail community pharmacy.⁵

Thus, the key statutory language on the two AMPs can be summarized briefly as follows:

- The Standard AMP and the 5i AMP both include direct and indirect sales to retail community pharmacies; and
- The Standard AMP excludes, but the 5i AMP does not exclude, transactions with PBMs, insurers, hospitals, clinics, mail order pharmacies, etc.

In the following sections, we list some of the key AMP questions left open during the regulatory vacuum period and explain how CMS has proposed to address them in its proposed rule.

II. Proposed Definitions

The proposed rule adopts the definitions of retail community pharmacy and wholesaler as set out in PPACA. Additionally, the proposed rule offers a number of key definitions that, if adopted, would significantly influence how key provisions of the rule would be applied. These definitions are discussed below.

Bona Fide Service Fee. The proposed rule would exclude bona fide service fees from AMP and Best Price, and would define the term “bona fide service fee” for purposes of both AMP and Best Price as “a fee paid by a manufacturer to wholesalers or retail community pharmacies; that

³ Social Security Act (SSA) § 1927(k)(10).

⁴ SSA § 1927(k)(11).

⁵ SSA § 1927(k)(1)(B)(i)(IV) (emphasis added).

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).⁶ Please see pages 6-7 and 12-13 of this document for a discussion of this definition as applied to AMP and Best Price, respectively.

Bundled Sales. The proposed rule would revise CMS' current regulatory definition of "bundled sale," as follows:

Bundled sale means an arrangement regardless of physical packaging under which the rebate, discount, or other price concession is conditioned upon the purchase of the same drug, drugs of different types (that is, at the nine-digit National Drug Code (NDC) level) or another product or some other performance requirement (for example, the achievement of market share, inclusion or tier placement on a formulary), or where the resulting discounts or other price concessions are greater than those which would have been available had the bundled drugs been purchased separately or outside the bundled arrangement. ~~For bundled sales,~~ (1) The discounts in a bundled sale, including, but not limited to those discounts resulting from a contingent arrangement, are allocated proportionally to the total dollar value of the units of all drug sold under the bundled arrangement. (2) For bundled sales where multiple drugs are discounted, the aggregate value of all the discounts in the bundled arrangement shall be proportionally allocated across all the drugs in the bundle.⁷

The preamble to the proposed rule characterizes the revised provision (1) of the definition as a "clarifying statement."⁸ To the extent that this proposal could be read to mean that non-contingent parts of a bundled discount arrangement must also be allocated, this proposal would represent a significant change in the prior rule, rather than a clarifying statement.

Covered Outpatient Drug. Manufacturers must pay Medicaid rebates on their "covered outpatient drugs," otherwise States generally will not receive Federal Medicaid matching payments for use of those drugs.⁹ CMS' proposed definition of "covered outpatient drug" generally tracks the statutory definition, with some exceptions. For example, the statute excludes from the definition of "covered outpatient drug" a drug that is provided incident to certain services where a payment bundling the drug and services "may be made." In contrast, the regulation would exclude a drug provided incident to services only if a bundled payment "is made."¹⁰ The proposed regulatory definition also adds the following exceptions to the definition of covered outpatient drug, which do not appear in the text of the rebate statute: "Any drug product that is not listed electronically with the FDA"; "Any drug product for which a manufacturer has not submitted to CMS evidence to demonstrate that the drug product satisfies the criteria of paragraph (1) [related to the categories of FDA approvals necessary to be a covered outpatient drug]"; and (3) "Over-the-counter [(OTC)] products that are not drugs."¹¹ CMS asserts in the preamble to the proposed rule that these changes "align[] with a proposal in the fiscal year (FY) 2012 President's Budget to require drugs to be properly listed electronically with the FDA as a requirement to be covered under Medicaid," and would permit CMS "to verify State and manufacturer submissions by referencing the FDA's electronic drug listing information."¹² Also, CMS' proposed definition of "covered outpatient drug"

⁶ Proposed rule at 163 (proposed 42 C.F.R. § 447.502).

⁷ Proposed rule at 163-164 (proposed 42 C.F.R. § 447.502).

⁸ Proposed rule at 16.

⁹ SSA § 1927(a).

¹⁰ Proposed rule at 166 (proposed 42 C.F.R. § 447.502) (emphasis added).

¹¹ Id.

¹² Proposed rule at 21.

does not address the provision of the statutory definition of this term related to OTC products: “If a State [Medicaid] plan ... includes coverage of prescribed drugs as described in section 1905(a)(12) and permits coverage of [OTC] ... if they are prescribed by a physician (or other person authorized to prescribe under State law), such a drug shall be regarded as a covered outpatient drug.”¹³ The proposed rule defines an OTC drug as “a drug that is appropriate for use without the supervision of a health care professional such as a physician, and which can be purchased by a consumer without a prescription.”¹⁴

Exclusively Pediatric/Clotting Factors. The Medicaid rebate statute, as amended by PPACA, provides that, for innovator drugs that are “approved by [FDA] exclusively for pediatric indications” or “a clotting factor for which a separate furnishing payment is made under [SSA] section 1842(o)(5) and which is included on a list of such factors specified and updated regularly by the Secretary,” a lower percentage of AMP (17.1%) should be used in calculating the Medicaid Unit Rebate Amount (URA) than generally applies for innovator drugs (23.1%).¹⁵ CMS proposes regulatory text that would define “pediatric indication” narrowly to mean “a specifically stated indication for use by the pediatric age group, meaning from birth through 16 years of age, or a subset of this group, as specified in the ‘Indications and Usage’ section of the FDA approved labeling.”¹⁶ With regard to whether a product is exclusively pediatric, CMS explains in the preamble that “[d]rugs that are not approved and labeled exclusively for pediatric use, that merely reference use in children in any part of the labeling, or that receive a supplemental indication for pediatric use, will not qualify for the minimum rebate of 17.1 percent of AMP.”¹⁷ CMS proposes a definition of “clotting factor” that is the same as appears in the statute, but with the following changes: “a hemophilia clotting factor for which a separate furnishing payment is made under section 1842(o) (5) of the Act and which is included on a list of such factors

specified and updated regularly by the Secretary CMS and posted on the CMS web site.”¹⁸

Manufacturer. Under the rebate statute, the manufacturer of a covered outpatient drug that signs a Medicaid Rebate Agreement with the government must report pricing data (including AMP and Best Price), and pay rebates on, its covered outpatient drugs. The proposed rule generally would define “manufacturer” the same as CMS’ current regulations define the term, but with the following change: “For drugs subject to private labeling arrangements, the term ‘manufacturer’ will also include the entity ~~that does not possess legal title to the NDC under whose own label or trade name the product will be distributed.~~”¹⁹

S/N/I Drugs. Medicaid rebate and pharmacy reimbursement calculations vary depending upon the “classification” of the drug. CMS proposes to define “single source drug” with the following changes from the current CMS regulatory definition: “Single source drug means a covered outpatient drug that is produced or distributed under an ~~original~~ NDA approved by the FDA and has an approved NDA number issued by the FDA, including a drug product marketed by any cross-licensed producers or distributors operating under the NDA. It also includes a covered outpatient drug approved under a biological license application (BLA), product license approval (PLA), establishment license approval (ELA), or antibiotic drug approval (ADA). For purposes of the MDR program, an original NDA is equivalent to an NDA filed by the manufacturer for approval under section 505 of the FDCA for purposes of approval by the FDA for safety and effectiveness.”²⁰ (CMS does not explain its goal with these changes, but they do appear related to a preamble statement in the DRA final rule, which equated the term “original NDA” with “NDA.”²¹) CMS proposes similar changes to the current regulatory definition of innovator multiple source drug, e.g., “a multiple source drug ~~that was originally~~ marketed under an ~~original~~ new drug application” CMS proposes to define

13 SSA § 1927(k)(4).

14 Proposed rule at 170 (proposed 42 C.F.R. § 447.502).

15 SSA § 1927(c)(1)(B)(iii)(II).

16 Proposed rule at 170 (proposed 42 C.F.R. § 447.502).

17 Proposed rule at 31.

18 Proposed rule at 164 (proposed 42 C.F.R. § 447.502).

19 Proposed rule at 168 (proposed 42 C.F.R. § 447.502).

20 Proposed rule at 171 (proposed 42 C.F.R. § 447.502).

21 72 Fed. Reg. 39142, 39163 (Jul. 17, 2007) (“[T]he FDA does not make a distinction between an NDA and an original NDA; therefore, we view these terms as having the same meaning.”).

noninnovator multiple source the same as it is defined in current regulations, but would add the following provisions to the definition: “(4) Any drug that has not gone through an FDA approval process, but otherwise meet the definition of covered outpatient drug; or (5) Any noninnovator drug that is not therapeutically equivalent. (6) If any of the drug products listed in this definition of a noninnovator multiple source drug subsequently receives a new NDA or ANDA approval from the FDA, the manufacturer must change the reporting of the product’s drug category to correlate with the new product application type and furnish the appropriate information.”²² If finalized, these changes would include in the definition of “innovator multiple source drugs” drugs that are not multiple source drugs, *i.e.*, that are not therapeutically equivalent, pharmaceutically equivalent, and bioequivalent. Finally, CMS proposes to define the term multiple source drug, a term not currently defined by CMS’ regulations, in a manner that tracks the statutory definition closely.

State and United States. Currently, CMS’ Medicaid rebate regulations define the term “State” as the fifty States and the District of Columbia.²³ CMS proposes to expand this definition to include “the territories (the Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands and America Samoa).”²⁴ CMS acknowledges that this change would both expand AMP -- by including in AMP sales to retail community pharmacies located in the territories -- and the Medicaid drug utilization on which manufacturers pay rebates. CMS asserts, “[W]e believe it is in the best interests of the Medicaid program to include the territories in the definition of States so that they may achieve the savings that drug rebates provide”²⁵ However, CMS “acknowledge[s] that there may be concerns with the territories participating in the MDR program,” and therefore requests comments on this issue.²⁶ CMS also proposes defining “United States” as the fifty States, the District of Columbia, and the territories.²⁷

22 Proposed rule at 169 (proposed 42 C.F.R. § 447.502).

23 42 C.F.R. 447.502.

24 Proposed rule at 171 (proposed 42 C.F.R. § 447.502).

25 Proposed rule at 34.

26 *Id.*

27 Proposed rule at 171 (proposed 42 C.F.R. § 447.502).

III. Standard (Non 5i) AMP Calculations

A. “Default” Rule for Sales to Wholesalers

Prior to PPACA, now-withdrawn CMS regulations provided that sales to wholesalers were included in AMP, unless there was “adequate documentation” that the drugs were “subsequently resold to any ... excluded entit[y]”²⁸ -- in other words, the “default” rule was that sales to wholesalers were included in AMP when the end-user was unknown.

In the proposed rule, CMS refers to this default rule as the “presumed inclusion policy.” After discussing the various arguments for and against such a policy, CMS states: “[W]e have concerns that a presumed inclusion policy would lead to the inclusion of sales by a manufacturer to entities not contemplated in the statutory definition. Accordingly, for purposes of this proposed rule, we are proposing that manufacturers must calculate AMP based on sales: (1) To wholesalers for drugs distributed to retail community pharmacies, or (2) to retail community pharmacies.”²⁹ Thus, CMS proposes to reject the default rule and (apparently) to require that manufacturers obtain data on the end-user for all sales to wholesalers. CMS seeks comments on this issue and also requests information “concerning distribution data, specifically data concerning wholesaler sales to the retail community pharmacies so that we can further consider this policy decision.”³⁰

B. Sales to Specialty Pharmacies

The definition of “retail community pharmacy” (quoted above) does not specifically mention specialty pharmacies, but it does exclude pharmacies that dispense “primarily through the mail,” which suggests that (at least in most cases) sales to specialty pharmacies would be excluded from Standard AMP.

The proposed rule, however, would include in Standard AMP the following:

Sales, discounts, rebates ..., payments, or other transactions that are received by, paid by, or passed through to entities that conduct business as wholesalers or retail community

28 Withdrawn 42 C.F.R. 447.504(g)(1).

29 Proposed rule at 49 (emphasis added).

30 Proposed rule at 49.

pharmacies, which includes but is not limited to specialty pharmacies, home infusion pharmacies, and home healthcare providers.³¹

The CMS discussion leading up to this proposal suggests that sales to specialty pharmacies (and home infusion pharmacies and home healthcare providers) would be included in Standard AMP because otherwise AMPs could not be calculated for certain drugs (including oral drugs not subject to the special 5i calculation).³² But the proposed rule would include these sales in AMPs for all drugs (not just drugs where these sales must be counted or an AMP could not be calculated). CMS does not define the term “entities that conduct business as wholesalers or retail community pharmacies” (except to say that the phrase includes specialty pharmacies, home infusion pharmacies, and home health providers, and to say that they “conduct business as a retail community pharmacy inasmuch as they dispense medications to the general public at retail prices and are licensed by the State as a pharmacy”).³³ While these entities may serve a “specific part” of the general public with a certain medical condition, CMS adds, nevertheless they sell drugs in the “retail marketplace” and the drugs are available to “any member of the general public who has one of these medical conditions.”³⁴ CMS does not explicitly address whether sales and discounts to specialty or home infusion pharmacies are still included in Standard AMP even if the pharmacy dispenses “primarily through the mail,” and thus would not qualify as a “retail community pharmacy.”

C. Definition of Bona Fide Service Fees

PPACA provides that “in general” AMP excludes:

bona fide service fees paid by manufacturers to wholesalers or retail community pharmacies, including (but not limited to) distribution service fees, inventory management fees, product stocking allowances, and fees associated with administrative services

agreements and patient care programs (such as medication compliance programs and patient education programs).³⁵

Before PPACA, the regulations excluded from AMP (and Best Price) bona fide service fees, defined as:

[F]ees paid by a manufacturer to an entity; that represent 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 are 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.³⁶

CMS’ November 2010 Final Rule withdrawing most AMP regulations did not formally withdraw this definition of “bona fide service fees” -- but it did provide that (until new regulations are issued) manufacturers should use this definition only for Best Price purposes, not AMP purposes.³⁷

The proposed rule would define bona fide service fees as follows:

a fee paid by a manufacturer to wholesalers or retail community pharmacies; 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).³⁸

31 Proposed rule at 173 (proposed 42 C.F.R. § 447.504(b)(4)) (emphasis added).

32 Proposed rule at 44-45, 50.

33 Proposed rule at 51 (emphasis added).

34 Id.

35 SSA § 1927(k)(1)(B)(i)(II) (emphasis added).

36 42 C.F.R. § 447.502.

37 75 Fed. Reg. at 69593.

38 Proposed rule at 163 (proposed 42 C.F.R. § 447.502).

Therefore, CMS is proposing that the fees named specifically in the statute must satisfy the general requirements of this definition in order to qualify as bona fide service fees. In this regard, CMS explains that:

We are not proposing to further define the type of fees used as examples in the [statutory] definition of bona fide service fees because we believe that these terms can be read in concert with the current definition of bona fide service fee. As noted previously, they provide specific examples of what could qualify as a bona fide service fee. We note however that retroactive price adjustments, sometimes also known as price appreciation credits, do not meet the definition of a bona fide service fee as they do not reflect any service or offset of a bona fide service performed on behalf of the manufacturer.³⁹

In addition, we note that in order “to avoid potential fraud concerns,” CMS does not define “fair market value” in the proposed rule.⁴⁰ Instead, CMS states that “manufacturers should appropriately determine fair market value and make reasonable assumptions consistent with adequate documentation that will support their payment for these services at fair market rates sufficient that an outside party can determine the basis for the fair market value determination.”⁴¹ CMS claims that such a requirement “is consistent with the 2007 AMP Final Rule (72 FR 39184) and the ASP reporting rule (71 FR 69667).”⁴² However, to the extent that this proposal could be read to mean that manufacturers are required to obtain a fair market value assessment to support a bona fide service fee determination, this proposal would represent a significant change from CMS’s prior guidance on this issue.

CMS also makes the following observations concerning GPO fees:

To the extent that ... fees to GPOs meet the definition of “bona fide service fee”, we propose that such fees

should be excluded from the determination of AMP and are not considered price concessions. However, ... where these fees are passed on in whole or in part to a wholesaler or retail community pharmacy, the fees would not qualify as bona fide service fees. To the extent this occurs, such fees cannot be considered bona fide service fees and, in accordance with section 1927(k)(l)(B)(ii) of the [Social Security] Act, should be included in AMP.⁴³

D. Authorized Generics

PPACA slightly modified the statutory provision on authorized generics and AMP, so that it now reads as follows:

In the case of a manufacturer that approves, allows, or otherwise permits any drug of the manufacturer to be sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act, [AMP] shall be inclusive of the average price paid for such drug by wholesalers for drugs distributed to the retail community pharmacies.⁴⁴

The current regulation on authorized generics (which was not withdrawn) provides that the manufacturer holding title to the NDA should include authorized generic sales in AMP “only when such drugs are being sold by the manufacturer holding title to the NDA directly to a wholesaler.”⁴⁵ Consistent with this regulation, CMS guidance suggests that the AMP for a branded drug includes sales of an authorized generic version from the primary manufacturer to the secondary manufacturer, if the secondary manufacturer is a wholesaler. And PPACA’s “wholesaler” definition (quoted above) explicitly includes manufacturers.

The new proposed rule provides that:

The primary manufacturer must include in its calculation of AMP [for the brand drug] its sales of authorized generic drugs that have been sold or licensed to a secondary manufacturer, acting as a wholesaler, or

³⁹ Proposed rule at 57 (emphasis added).

⁴⁰ Proposed rule at 56.

⁴¹ Proposed rule at 56-57.

⁴² Proposed rule at 57.

⁴³ Proposed rule at 57-58 (emphasis added).

⁴⁴ SSA § 1927(k)(1)(C).

⁴⁵ 42 C.F.R. § 447.506(b).

when the primary manufacturer holding the NDA sells directly to a wholesaler.⁴⁶

CMS does not explain specifically when a manufacturer is “acting as a wholesaler,” but a “wholesaler” would be defined broadly as follows:

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.⁴⁷

As discussed earlier, CMS is proposing not to adopt the old default rule on sales to wholesalers (where sales to wholesalers are included in AMP if the end-user is unknown). Instead, CMS proposes to require that manufacturers obtain data on the end-user for all units sold to wholesalers. If CMS ultimately adopts that approach, then CMS would likely modify the authorized generics provision accordingly. This would mean that the primary manufacturer would be required to include in the AMP of the branded version of the drug any authorized generic units sold to a secondary manufacturer acting as a wholesaler, or directly to a wholesaler, when the authorized generics are ultimately resold to a retail community pharmacy. This approach (if adopted) would require the primary manufacturer to obtain data identifying the end-users of the authorized generic in order to calculate the AMP for the branded drug.

E. Discounts Fully Passed on to Patients (e.g., Coupons, Vouchers)

The statute now includes in Standard AMP “financial transactions ... received by ... retail community

pharmacies.”⁴⁸ This raises the question of whether a discount that is given to a retail community pharmacy with the understanding that it must be fully passed through to the patient would be “received” by the pharmacy and thus included in Standard AMP.

The proposed rule does not specifically address the “received by” issue, but it would generally exclude patient coupons, vouchers, and similar programs as long as the retail community pharmacy does not receive “any discount, rebate, or price concessions” in connection with the program in question. CMS proposed this approach for: (1) coupons; (2) vouchers; (3) manufacturer-sponsored drug discount card programs; (4) manufacturer-sponsored patient refund/rebate programs; and (5) copayment and patient assistance programs.⁴⁹ CMS does not define the circumstances in which it would consider “a discount, rebate or price concession” to be retained by a retail community pharmacy. As required by the statute, the proposed rule also would exclude Part D coverage gap discounts from AMP.

F. Other Standard AMP Inclusions/Exclusions

AMP “Catchall” Provision. PPACA provides that “notwithstanding clause [1927(k)(1)(B)](i) [listing AMP exclusions], any other discounts, rebates, payments, or other financial transactions that are received by, paid by, or passed through to, retail community pharmacies shall be included in [AMP].”⁵⁰ In the proposed rule, CMS does not make clear whether it views this “catchall” provision as, for example: (1) including in AMP transactions that are otherwise explicitly excluded by the statute (i.e., including these transactions “notwithstanding” the statutory exclusions); or (2) including in AMP transactions “other” than those explicitly excluded from AMP by statute. CMS’ proposed AMP regulation would provide:

Except for those sales, nominal price sales, rebates, discounts and other financial transactions identified in paragraph (c) of this section [the AMP exclusions

46 Proposed rule at 181 (proposed 42 C.F.R. § 447.506(b)) (emphasis added).

47 Proposed rule at 171 (proposed 42 C.F.R. § 447.502) (emphasis added).

48 SSA § 1927(K)(1)(B)(ii).

49 Proposed rule at 61-63.

50 SSA § 1927(k)(1)(B)(ii) (emphasis added).

specified by the proposed regulation], AMP... includes ... Sales, discounts, rebates (other than rebates under section 1927 of the Act or as otherwise specified in regulations), payments, or other financial transactions that are received by, paid by, or passed through to retail community pharmacies.⁵¹

CMS' preamble discussion of this topic suggests that it might be focused here on sweeping into AMP payments by third parties (i.e., parties other than the manufacturer) to retail community pharmacies, at least if the manufacturer somehow knows its payment to the third party was passed through to the pharmacy.⁵²

Returns. As amended by PPACA, the statute excludes from AMP "reimbursement 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."⁵³ The DRA Final Rule provided an exclusion -- now withdrawn -- from AMP for goods returned "in good faith." CMS now proposes regulatory language that would exclude from AMP "[r]eimbursement by the manufacturer 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 but only to the extent that such payment covers only those costs."⁵⁴ In the preamble to the proposed rule, CMS notes that the exclusion for returns "is applicable only to the extent that payment for these returned goods

covers the cost of returns and does not otherwise serve as payment to the pharmacy as a price concession."⁵⁵ CMS also proposes "to exclude the value of returned goods themselves from the determination of AMP when returned in good faith,"⁵⁶ but that concept does not appear in the proposed regulatory text. CMS requests comment on what constitutes an "unsalable" product, and whether it should define relevant terms in the exception for returns.

TRRx Rebates. Under Section 703 of the National Defense Authorization Act for Fiscal Year 2008, the TRICARE Retail Pharmacy Program (TRRx), an outpatient prescription drug benefit offered by the Department of Defense (DoD), "shall be treated as an element of the [DoD] for purposes of the procurement of drugs by Federal agencies under section 8126 of title 38 to the extent necessary to ensure that pharmaceuticals paid for by the [DoD] are subject to the pricing standards in such section 8126."⁵⁷ In light of this provision, and CMS' interpretation that "prices to Federal programs " must be excluded from AMP, CMS proposes "that [TRRx] prices should be treated as price to the DoD and therefore excluded from the calculation of AMP."⁵⁸ CMS does not specify whether a "price to the DoD" in this context means only the rebate paid to the DoD on TRRx utilization or the initial sale to the wholesaler of a drug dispensed to a TRRx beneficiary. In general, however, CMS explains that "the sales to wholesalers for drugs distributed to retail community pharmacies and retail community pharmacies would be included in AMP calculations, regardless of how the drug is ultimately reimbursed when provided to the beneficiary,"⁵⁹ which suggests that TRRx sales and units should not be subtracted from the AMP numerator and denominator. This issue may require clarification as part of the rulemaking process.

51 Proposed rule at 173 (proposed 42 C.F.R. § 447.504(b)) (emphasis added).

52 See, e.g., Proposed rule at 55 ("[W]e propose to exclude from the determination of AMP payments received from, and any rebates, discounts, or payments that are provided directly to insurers that are not passed through to retail community pharmacies.") (emphasis added).

53 SSA § 1927(k)(1)(B)(i)(III).

54 Proposed rule at 175 (proposed 42 C.F.R. § 447.504(c)(16)) (emphasis added).

55 Proposed rule at 58.

56 Id.

57 P.L. No. 110-181.

58 Proposed rule at 52.

59 Proposed rule at 56.

IV. 5i AMP Issues

A. Identifying 5i Drugs "Not Generally Dispensed" by Retail Community Pharmacies

As noted above, special AMP-calculation rules apply to "an inhalation, infusion, instilled, implanted, or injectable drug" that is "not generally dispensed through a retail community pharmacy."⁶⁰ Whether a 5i drug is subject to these special rules thus depends on how the "not generally dispensed through a retail community pharmacy" language is construed.

The proposed rule offers some clarification. Proposed 42 C.F.R. § 447.507 provides:

A manufacturer must identify each covered outpatient drug that is a 5i drug that is not generally dispensed through a retail community pharmacy.

(a) Identification of a 5i drug. A manufacturer must use the list of FDA's Routes of Administration posted on the CMS Web site to identify each covered outpatient drug that qualifies as a 5i drug.

(b) Not generally dispensed through a retail community pharmacy. A manufacturer must determine if the 5i drug is not generally dispensed through a retail community pharmacy based on the percentage of sales to entities other than retail community pharmacies.

(1) A 5i drug is not generally dispensed through a retail community pharmacy if 90 percent or more of the sales of the 5i drug, during the reporting period, were to entities other than retail community pharmacies or wholesalers for drugs distributed to retail community pharmacies.

(2) A manufacturer is responsible for determining whether a 5i drug is not generally dispensed through a retail community pharmacy on a monthly and quarterly basis.⁶¹

According to the proposed rule, manufacturers would need to apply this test to all their 5i drugs for every monthly and

⁶⁰ SSA § 1927(k)(1)(B)(i)(IV).

⁶¹ Proposed rule at 182 (proposed 42 C.F.R. § 447.507).

quarterly AMP calculation — creating a new significant burden. CMS' proposal does not address: (1) whether the invoice date or credit memo date should be used in selecting sales data for applying the proposed 90 percent test; (2) which lagged price concession (LPC) data should be used in performing the LPC rolling average for products that switch between "generally dispensed" and "not generally dispensed" status from month to month; or (3) how should quarterly AMP be calculated for products that switch between "generally dispensed" and "not generally dispensed" status from month to month within the quarter?

B. Calculating 5i AMP

The key statutory provisions governing the sales to include in and exclude from 5i AMP provide:

In general ... "[A]verage manufacturer price" means ... the average price paid to the manufacturer for the drug in the United States by — (i) wholesalers for drugs distributed to retail community pharmacies; and (ii) retail community pharmacies that purchase drugs directly from the manufacturer.⁶²

The [AMP] for a covered outpatient drug shall exclude— payments received from, and rebates or discounts provided to, pharmacy benefit managers, managed care organizations, health maintenance organizations, insurers, hospitals, clinics, mail order pharmacies, long term care providers, manufacturers, or any other entity that does not conduct business as a wholesaler or a retail community pharmacy, unless the drug is an inhalation, infusion, instilled, implanted, or injectable drug that is not generally dispensed through a retail community pharmacy.⁶³

In new 42 C.F.R. §447.504(d), the proposed rule would provide that sales and associated discounts, rebates, payments or other transactions to all customers that are included in the standard AMP calculation "as specified in paragraph [42 C.F.R. § 447.504](b)" also would be included in 5i AMP. Additionally, associated discounts, rebates,

⁶² SSA § 1927(k)(1)(A)(emphasis added).

⁶³ SSA § 1927(k)(1)(B)(i)(IV) (emphasis added).

payments or other financial transactions to the following enumerated customers would be included in 5i AMP:

- (1) Sales to physicians.
- (2) Sales to pharmacy benefit managers where the PBM is not acting as an insurer, including its mail order pharmacy purchases.
- (3) Sales to health maintenance organizations (HMOs), including managed care organizations (MCOs).
- (4) Sales, discounts, or rebates paid directly to insurers (except for [Medicaid] rebates ...).
- (5) Sales to hospitals.
- (6) Sales to clinics and outpatient facilities (for example, surgical centers, ambulatory care centers, dialysis centers, mental health centers).
- (7) Sales to mail order pharmacies.
- (8) Sales to long-term care providers, including nursing facility pharmacies, nursing home pharmacies, long-term care facilities, contract pharmacies for the nursing facility where these sales can be identified with adequate documentation, and other entities where the drugs are dispensed through a nursing facility pharmacy, such as assisted living facilities.
- (9) Sales to hospices.
- (10) Sales to other manufacturers who conduct business as a wholesaler or retail community pharmacy.⁶⁴

The proposed rule does not clearly address how to treat classes of trade that are expressly excluded from “AMP” at 42 C.F.R. § 447.504(c), but not specifically included in 5i AMP by 42 C.F.R. § 447.504(d). (The proposed rule provides: “AMP for 5i . . . drugs . . . shall include sales and associated discounts, rebates, payments or other financial transactions to all entities as specified in paragraph [42 C.F.R. § 447.504](b) of this section, as well as the following sales and associated discounts, rebates, payments or

other transactions [specified in 42 C.F.R. § 447.504(d)].”⁶⁵) These classes of trade include sales to government pharmacies, sales to 340B covered entities, sales to not-for-profit pharmacies, and sales to charitable pharmacies. We believe CMS likely intends to exclude sales (and price concessions) to these classes of trade from 5i AMP. CMS also creates ambiguity in the proposed definition of 5i AMP because some classes of trade excluded from “AMP” at 42 C.F.R. § 447.504(c) do not match exactly with corresponding proposed 5i AMP inclusions at 42 C.F.R. § 447.504(d). For example, 42 C.F.R. § 447.504(c) excludes “Direct sales to physicians,” while 42 C.F.R. § 447.504(d) includes in 5i AMP “Sales to physicians.” CMS also does not explain the difference (if any) between the following classes of trade, both of which are included 5i AMP: “Sales to other manufacturers who act as wholesalers for drugs distributed to [RCPs]” and “Sales to other manufacturers who conduct business as a wholesaler or [RCP].”⁶⁶

Please see the appendix to this document for a list of classes of trade and transactions and proposed inclusions in and exclusions from standard and 5i AMP.

V. Smoothing Methodology for Both Standard and 5i AMP

The proposed rule also seeks to implement SSA § 1927(e) (5), which requires CMS to adopt a smoothing process for AMP that is similar to the smoothing process used in determining the Average Sales Price (ASP) for Medicare Part B drugs. Accordingly, CMS proposes a “12-month rolling percentage” methodology for estimating the value of LPCs in the calculation of monthly AMP.⁶⁷ Consistent with prior CMS guidance in rebate release number 83, manufacturers would be required to calculate the “total lagged price concessions” for the previous 12-month period and to convert that dollar amount into a percentage of total sales to AMP-eligible customers over the same 12-month period. That percentage would then be multiplied by the

⁶⁴ Proposed rule at 176-77 (proposed 42 C.F.R. § 447.504(d)).

⁶⁵ Proposed rule at 176 (proposed 42 C.F.R. § 447.504(d)).

⁶⁶ Proposed rule at 173 and 177 (proposed 42 C.F.R. §§ 447.504(b)(2), 447.504(d)(10)).

⁶⁷ Proposed rule at 191 (proposed 42 C.F.R. § 447.510(d)(2)).

current month's "total sales" to estimate the LPCs for the month.⁶⁸ Manufacturers may wish to seek confirmation that the "total lagged price concessions" for the previous 12-month period and the current month's "total sales" only include AMP-includable price concessions and sales.

VI. Best Price Issues

A. Prices Charged to 340B Covered Entities

PPACA amended the 340B statute to exempt manufacturers from the requirement to offer 340B ceiling prices on orphan drugs sold to certain new categories of 340B covered entities, including certain cancer hospitals, critical access hospitals, rural referral centers, and sole community hospitals.⁶⁹ Manufacturers may choose, however, to provide 340B ceiling prices on orphan drugs sold to these new categories of covered entities, raising the issue of whether such voluntarily-extended prices may be excluded from Best Price.

The 340B Best Price exclusion in the Medicaid rebate statute provides that "Best Price" excludes "any prices charged on or after October 1, 1992 to ... a covered entity described in subsection (a)(5)(B) [of the Medicaid rebate statute] (including inpatient prices charged to [disproportionate share hospitals (DSHs) participating in 340B])."⁷⁰ Under the proposed rule, however, Best Price would exclude "[p]rices charged under the 340B drug pricing program to a covered entity described in subsection (a)(5)(B) [of the Medicaid rebate statute]" and "[a]ny inpatient prices charged to [DSH hospitals participating in the 340B program]."⁷¹

The regulations do not further define what it means for a price to be charged "under the 340B drug pricing program," but the preamble suggests that CMS may consider a variety of voluntary prices (beyond those to entities covered by the orphan drug exclusion) to fall "outside" of the 340B program. CMS states that "there may be circumstances in

which covered entities purchase drugs outside of the 340B program, such as instances when drugs are purchased for inpatient use, drugs that have both inpatient and outpatient uses, and when a covered entity purchases drugs outside the 340B program to dispense to its Medicaid patients."⁷²

CMS specifically "invite[s] comments regarding other circumstances in which covered entities purchase drugs outside of the 340B program." In addition to the Best Price treatment of voluntary 340B prices on orphan drugs sold to entities covered by the orphan drug exclusion, manufacturers may also wish to comment on: (1) the Best Price treatment of voluntary 340B prices on inpatient drugs sold to covered entities other than DSH hospitals; (2) the Best Price treatment of voluntary sub-ceiling prices on covered outpatient drugs sold to covered entities; and (3) whether failure to exclude such prices from Best Price would be consistent with the Medicaid rebate statute provision that Best Price excludes "any prices charged on or after October 1, 1992 to ... a covered entity."

B. Bona Fide Service Fees

The proposed rule would replace the current Best Price exemption for "bona fide service fees" with an exception that mirrors the bona fide service fee language that CMS proposed in the AMP context. The proposed rule would exempt from Best Price "bona fide service fees paid by manufacturers to wholesalers, retail community pharmacies, or any other entity that conducts business as a wholesaler or a retail community pharmacy, including but not limited to inventory management fees, product stocking allowances, and fees associated with administrative agreements and patient care programs (such as medication compliance programs and patient education programs), including bona fide service fees paid to Group Purchasing Organizations."⁷³ CMS also proposes to delete the "except bona fide service fees" language currently in the "[f]urther clarification of best price" provision in 42 C.F.R. § 447.505(e)(1).⁷⁴

68 Proposed rule at 105-06.

69 42 U.S.C. § 256b(e). The Medicare and Medicaid Extenders Act of 2010 removed children's hospitals from the scope of the orphan drug exemption. P.L. No. 111-309, § 204.

70 SSA § 1927(c)(1)(C)(i)(I) (emphasis added).

71 Proposed rule at 179 (proposed 42 C.F.R. § 447.505(c)(2)) (emphasis added).

72 Proposed rule at 75.

73 Proposed rule at 180 (proposed 42 C.F.R. § 447.505(c)(16)).

74 CMS proposes to amend the provision as follows: "Best price ~~is~~ shall be net of cash discounts, free goods that are contingent on any purchase requirement, volume discounts, customary prompt

On its face, this proposed language would allow only fees to wholesalers, retail community pharmacies, and GPOs to be excluded from Best Price as bona fide service fees. Service fees to PBMs, health plans, and other customers would not be eligible for exclusion as bona fide service fees. CMS does not provide any explanation in the preamble for this change, nor does it explain how, practically speaking, manufacturers are to include in their Best Price calculations those service fees that would otherwise be bona fide service fees except that they are to customers other than wholesalers, retail community pharmacies, or GPOs. Manufacturers may therefore wish to comment on CMS's proposal to import the bona fide service definition from the AMP context (which relates to only sales to retail community pharmacies and sales to wholesalers for distribution to retail community pharmacies) to the Best Price context (which includes a much larger universe of sales). In this regard, it is worth noting that PPACA expressly added a definition of bona fide service fee for AMP purposes, but did not include any provision on the treatment of bona fide services in the Best Price context.

C. Authorized Generics

The proposed rule would revise the existing regulations on the Best Price treatment of authorized generics at 42 U.S.C. § 447.506(c) to provide that:

A primary manufacturer holding the NDA must include the best price of an authorized generic drug in its computation of best price for an innovator multiple source drug during a rebate period to any manufacturer, wholesaler, retailer, provider, HMO, non-profit entity, or governmental entity in the United States only when such drugs are being sold by the manufacturer holding the NDA.⁷⁵

pay discounts, chargebacks, returns, incentives, promotional fees, administrative fees, service fees, ~~(except bona fide service fees)~~, distribution fees, and any other discounts or price reductions and rebates, other than rebates under section 1927 of the Act, which reduce the price available from the manufacturer." Proposed rule at 181 (proposed 42 C.F.R. § 447.505(d)).

⁷⁵ Proposed rule at 181-82 (proposed 42 C.F.R. § 447.506(c)) (emphasis added).

Notably, this provision does not include a requirement to include the Best Price of an authorized generic in the computation of Best Price for a *single source* drug. This omission may have been inadvertent, because the preamble describes this provision as stating that "a primary manufacturer holding the NDA must include the best price of an authorized generic drug in its computation of best price for a single source or innovator multiple source drug...".⁷⁶ Manufacturers may wish to seek clarification regarding this point.

The proposed rule would also add a new 42 U.S.C. § 447.506(d), which would clarify that "[t]he secondary manufacturer of an authorized generic drug must provide a rebate based on its sales of authorized generics, and must calculate AMP and best price, consistent with the requirements specified in § 447.504 and § 447.505 of this subpart."⁷⁷ This provision does not appear materially to change the existing requirements governing the calculation of Best Price for authorized generics.

D. Nominal Price

The proposed rule would add two new categories of entities for which sales at nominal price are excluded from Best Price. The first category includes an entity that: (1) is an exempt organization as defined by section 501(c)(3) of the Internal Revenue Code; and exempt from tax under 501(a) of the Internal Revenue Code, or is State-owned or operated; and (2) provides that same type of services to the same type of populations as a 340B covered entity but does not receive grant funding under the Public Health Service Act.⁷⁸ The second category would include an entity that is a public or nonprofit entity or an entity based at an institution of higher learning, whose primary purpose is to provide health care services to students of that institution or that provides services as described under section 1001(a) of the Public Health Service Act, 42 U.S.C. § 300.⁷⁹ These provisions would codify changes to the nominal price

⁷⁶ Proposed rule at 77 (emphasis added).

⁷⁷ Proposed rule at 181-82 (proposed 42 C.F.R. § 447.506(d)).

⁷⁸ Proposed rule at 183 (proposed 42 C.F.R. § 447.508(a)(5)).

⁷⁹ Proposed rule at 183 (proposed 42 C.F.R. § 447.508(a)(4)).

definition imposed, retroactive to January 1, 2007, as part of the Stimulus Bill that President Obama signed early in 2009.⁸⁰

E. Other New Best Price Exemptions

The proposed rule would add several new Best Price exclusions that CMS notes are intended to provide consistency between the AMP and Best Price regulations. Specifically, the proposed rule would exclude from Best Price: (1) manufacturer vouchers; (2) manufacturer-sponsored patient refund/rebate programs; (3) sales outside the United States (as redefined to include the territories); (4) discounts provided under the Medicare Coverage Gap Discount Program.⁸¹ CMS also proposes to add a Best Price exclusion for returned goods that mirrors the AMP exclusion — *i.e.*, Best Price would exclude “[r]eimbursement by the manufacturer 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 but only to the extent that such payment covers only those costs.”⁸² These exemptions are discussed further (in the AMP context) in Sections II and III above.

CMS also proposes to revise the current Best Price exclusion for certain PBM transactions by replacing the term “price concessions” with “financial transactions,” such that Best Price would exclude “PBM rebates, discounts, or other financial transactions except their mail order pharmacy’s purchases or where such rebates, discounts, or other financial transactions are designed to adjust prices at the retail or provider level.”⁸³ CMS does not provide any explanation for this change.

VII. Line Extensions and Alternative URA Calculation

A. Definition of Line Extension

PPACA defines a “line extension” as “a new formulation of the drug, such as an extended release formulation.” CMS now proposes to define a line extension in its regulations much more broadly as “a single source or innovator multiple source drug that is an oral solid dosage form that has been approved by the FDA as a change to the initial brand name listed drug in that it represents a new version of the previously approved 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.”⁸⁴

CMS also asserts that “[t]hese modifications to the initial brand name listed drug are often approved under section 505(b)(2) of the FFDCA. ... Examples of drugs that have been approved under the 505(b)(2) application include drugs with a new formulation, dosing regimen, change in active ingredient (such as a different salt or ester, combination product) and/or new drug indication. ... We have included these changes within our definition of line extension drugs.”⁸⁵ The preamble suggests that, “regardless of whether the drug is approved under an NDA or a supplemental NDA, if the change to the drug is assigned to one of the above changes, it will be considered a line extension.”⁸⁶ CMS also does not plan to exclude single source or innovator multiple source drugs that receive 3-year exclusivity, pediatric exclusivity, or 7-year orphan drug exclusivity from the definition of line extension drug,⁸⁷ nor does it propose to exclude reformulations of existing products that incorporate abuse deterrent technologies from the definition of line extension drugs.⁸⁸

⁸⁰ Pub. Law. No. 111-8, § 221 (2009).

⁸¹ Proposed Rule at 179-80 (proposed 42 C.F.R. § 447.505(c)); see also proposed rule at 74-76.

⁸² Proposed rule at 180 (proposed 42 C.F.R. § 447.505(c)(14)) (emphasis added).

⁸³ Proposed rule at 180 (proposed 42 C.F.R. § 447.505(c)(17)) (emphasis added).

⁸⁴ Proposed rule at 167 (proposed 42 C.F.R. § 447.502).

⁸⁵ *Id.*

⁸⁶ Proposed rule at 25.

⁸⁷ Proposed rule at 88-89.

⁸⁸ Proposed rule at 82-83.

CMS also proposes to use the FDA's list of Chemical Types to identify the line extension drug as well as the initial brand name listed drug of the line extension drug:

- (A) The FDA's list of Chemical Types, listed in FDA Drugs in FDA's database, is used to identify the line extension drug and the initial brand name listed drug.
- (B) Chemical Type 2, new ester, new sale, or other noncovalent derivate; Chemical Type 3, new formulation; Chemical Type 4, new combination; and Chemical Type 6, new indication are determined to be line extension drugs.
- (C) Chemical Type 1, new molecular entity, represents the initial brand name listed drug.⁸⁹

CMS then proposes to create a master list that will match the active ingredient information in FDA's Drugs@FDA database with the NDC numbers for the initial brand name listed drug and the line extension drug. Following the initial three quarterly updates to this master list, which would be performed by CMS, manufacturers would be responsible for identifying and reporting to CMS which of their NDCs is the initial brand name listed drug and which is the line extension drug.⁹⁰

CMS also proposes that a "new strength of the initial brand name listed drug would not qualify as a line extension," because otherwise "it would be difficult to identify the first strength of the initial brand name listed drug because multiple strengths are often launched simultaneously and CMS would not be able to track back to the first strength of the initial brand name listed drug."⁹¹

CMS' proposals in this area raise a host of issues for manufacturers on which they may wish to comment, including, CMS's broad proposed definition of line extension and CMS's decision not to exclude drugs receiving various types of exclusivity. Additionally, manufacturers may wish to seek clarification on whether drugs approved under section 505(b)(2) are by definition line extensions, or whether

CMS has merely referenced 505(b)(2) approved drugs as examples of drugs that would often be line extensions under its proposed definition of the term.

B. Definition of Oral Solid Dosage Form

The proposed regulatory definition of line extension includes only "a single source or innovator multiple source /drug that is an oral solid dosage form" Therefore, for the purpose of the alternative URA calculation discussed below, CMS proposes that both the initial brand name drug and the line extension drug must be an oral solid dosage form.⁹² CMS in turn proposes to define an "oral solid dosage form" as "capsules, tablets, or similar drug products intended for oral use as defined in accordance with the FDA regulation at 21 CFR 206.3 that defines solid oral dosage form."⁹³ In the preamble, FDA provides a table of oral solid dosage forms to provide manufacturers with guidance to assist them in determining which drugs should be considered oral solid dosage forms.⁹⁴

C. Alternative URA Calculation

PPACA established a separate formula for calculating the rebate amount for a drug that is "a line extension of a single source drug or an innovator multiple source drug that is a oral solid dosage form."⁹⁵ For such a line extension drug, the statute provides that the URA will be the amount calculated under section 1927 of the Act or, if greater, the product of: (i) the AMP of the line extension of a single source drug or an innovator multiple source drug that is an oral solid dosage form; and (ii) the highest additional rebate (calculated as a percentage of AMP) for any strength of the original single source drug or innovator multiple source drug. In the proposed rule, CMS refers to these two URA options as the "Standard URA" and the "Alternative URA."

CMS proposes regulatory language that closely follows the statutory language governing the URA calculation for line extensions:

89 Proposed rule at 186 (proposed 42 C.F.R. § 447.509(a)(4)(C)(iii)); see also proposed rule at 82-86.
 90 Proposed rule at 87-88.
 91 Proposed rule at 88.

92 Proposed rule at 81-82.
 93 Proposed rule at 169 (proposed 42 C.F.R. § 447.502).
 94 Proposed rule at 29-30.
 95 SSA § 1927(c)(2)(C).

In the case of a drug that is a line extension of a single source drug or an innovator multiple source drug that is an oral solid dosage form, the rebate obligation is the amount computed under paragraphs(a)(1) through (a)(3) of this section for such new drug or, if greater, the product of all of the following: (A) The AMP of the line extension of a single source drug or an innovator multiple source drug that is an oral solid dosage form[;] (B) The highest additional rebate (calculated as a percentage of AMP) under this section for any strength of the original single source drug or innovator multiple source drug[and ;] (C) The total number of units of each dosage form and strength of the line extension product paid for under the State plan in the rebate period (as reported by the State).⁹⁶

CMS provides an example of this calculation at pages 91-94 of the proposed rule. CMS proposes that it will calculate the URA for line extension drugs and will provide this amount to States, but also suggests manufacturers must calculate URA themselves as well.⁹⁷ In addition, CMS proposes that the URA cap of 100% of AMP will apply to the URA calculation for line extension drugs.⁹⁸ CMS also proposes that, when the initial brand name listed drug has been terminated, manufacturers should not be responsible for calculating the Alternative URA.⁹⁹ However, CMS suggests that in circumstances where different manufacturers produce the initial brand name listed drug and its line extension, the manufacturers should share data to allow the calculation of the Alternative URA: “[M]anufacturers are responsible for ensuring that all necessary product and pricing data, whether such information is for the initial brand name listed drug or the line extension drug, are exchanged between the manufacturer of the initial brand name listed drug and the manufacturer of the line extension drug to accurately calculate the URA for the line extension drug and provide rebates in accordance with the statute.”¹⁰⁰

96 Proposed rule at 185 (proposed 42 C.F.R. § 447.509(a)(4)).
 97 Proposed rule at 91.
 98 Proposed rule at 91 (citing 42 C.F.R. § 447.509(a)(5)).
 99 Proposed rule at 90.
 100 Proposed rule at 90-91.

VIII. Restatements

CMS proposes to revise its current regulations that require manufacturers to report to CMS any revisions to AMP, Best Price, customary prompt pay discounts, or nominal prices for a period not to exceed 12-quarters from the quarter in which the data were due.¹⁰¹ The proposed rule also would create exceptions to the 12-quarter rule filing limitation currently in place for such restatements. Specifically, the proposed rule provides:

[A]ny request from manufacturers submitted to CMS to revise the monthly and quarterly AMP, best price, customary prompt pay discounts, or nominal prices that are outside of the 12-quarter filing deadline will be considered, only if it falls within one of the following categories:

- The change is a result of the drug category change or a market date change.
- The change is an initial submission for a product.
- The change is due to termination of a manufacturer from the MDR Program for failure to submit pricing data and must submit pricing data to reenter the program.
- The change is due to a technical correction (such as a keying error), that is, not based on any changes in sales transactions or pricing adjustments from such transactions.
- The change is to address specific underpayments to States, or potential liability regarding those underpayments, as required by CMS, applicable law or regulations, or an OIG or DOJ investigation.¹⁰²

For pricing revisions that fall within these criteria, CMS is considering whether to impose a timeframe as to how far back they should allow manufacturers to revise pricing metrics. For example, if an error extends back to the beginning of the Medicaid rebate program in 1991, should CMS allow the manufacturer to restate AMP or Best Price going back more than 20 years? CMS also proposes that,

101 Proposed rule at 101.
 102 *Id.*

if a restatement request is submitted for monthly AMP and AMP units, then the manufacturer must also revise quarterly AMP and vice versa.¹⁰³

CMS also proposes a so-called “good cause” option for manufacturers who wish to submit restatement requests outside of the 12-quarter time limit. Proposed 42 C.F.R. § 447.510(b)(2) provides:

A manufacturer may report revisions to AMP, best price, customary prompt pay discounts, or nominal prices for a period in excess of 12 quarters from the quarter in which the data were due based on the approval of CMS for good cause.”¹⁰⁴

CMS notes in the proposed rule preamble that “[b]ased on questions from manufacturers often as a result of False Claims Act concerns, we have considered allowing manufacturers to submit recalculations of AMP and Best Price outside of the twelve quarter time limit due to good cause.¹⁰⁵ This good cause option would allow a manufacturer to revise its “methodology for calculating AMP and best price,” and “to address underpayments and potential liability regarding those underpayments” that may extend outside of the 12-quarter recalculation period.¹⁰⁶ CMS is also considering a “good cause” option for extending the time limit for filing a recalculation request.

IX. Base Date AMP issues

In the 2007 DRA Final Rule, CMS gave manufacturers the option to report a revised base date AMP to CMS within the first four full calendar quarters following the publication date of the final rule. The proposed rule would offer manufacturers a similar option. The proposed rule provides:

We propose giving manufacturers the option to report a recalculated base date AMP based on the Affordable Care Act. We propose to allow manufacturers the option to decide whether they will recalculate and

report to CMS an Affordable Care Act base date AMP in light of the revised definition of AMP or continue to use their existing base AMP. We propose to give manufacturers this option because we are aware that some manufacturers may not have the actual data needed to recalculate their base date AMP or may find the administrative burden to be more costly than the savings gained.¹⁰⁷

Thus, manufacturers would be permitted to recalculate base date AMPs in light of the revised AMP definition at 42 C.F.R. § 447.504, within the first four full calendar quarters following publication of the final rule. This calculation would be optional, and could be performed on a drug-by-drug basis, but could only be performed “us[ing] actual and verifiable pricing records.”¹⁰⁸

X. Reimbursement Issues

A. Actual Acquisition Cost

In general, States currently reimburse for covered outpatient drugs based, in part, on the estimated acquisition cost (EAC) of the drugs.¹⁰⁹ In order “for States to have a more accurate reference price to base reimbursement for prescription drugs,” CMS now proposes to replace EAC with “actual acquisition cost” (AAC).¹¹⁰ AAC would be defined as “the agency’s determination of the actual prices paid by pharmacy providers to acquire drug products marketed or sold by specific manufacturers.”¹¹¹ CMS believes that “using the AAC in determining the drug ingredient component of the reimbursement formula will be more reflective of actual prices paid, as opposed to unreliable published compendia pricing.”¹¹² To support proposed changes in reimbursement using AAC, “[s]tates must provide adequate data, including, but not limited to, a State or national survey or retail pharmacy providers or other reliable data which reflects the pharmacy’s actual or average acquisition cost

¹⁰³ Proposed rule at 102.

¹⁰⁴ Proposed rule at 190 (proposed 42 C.F.R. § 447.510(b)(2)).

¹⁰⁵ Proposed Rule at 103.

¹⁰⁶ *Id.*

¹⁰⁷ Proposed rule at 104.

¹⁰⁸ Proposed rule at 191 (proposed 42 C.F.R. § 447.510(c)(4)(iii)).

¹⁰⁹ 42 C.F.R. § 447.502.

¹¹⁰ Proposed rule at 13.

¹¹¹ Proposed rule at 163 (proposed 42 C.F.R. § 447.502).

¹¹² Proposed rule at 110.

as a base to support any proposed change in ingredient reimbursement.¹¹³ CMS seeks comments on the practicality and design of such surveys, and how closely States must conform to the survey results in the reimbursement rates they propose.¹¹⁴

CMS does not propose specific methodologies for how AAC should apply in the case of reimbursement for covered outpatient drugs purchased under federal drug programs other than Medicaid, such as the 340B program and Federal Supply Schedule program. However, CMS proposes that States without specific methodologies for such reimbursement develop methodologies consistent with the proposed shift from EAC to AAC, and further proposes that each State Medicaid plan must describe the agency's payment methodology for drugs dispensed by a 340B covered entity or by a contract pharmacy under contract with a participating covered entity.¹¹⁵

B. Federal Upper Limits

PPACA revised SSA § 1927(e) to change the requirement for a Federal Upper Limit (FUL) for reimbursement of multiple source drugs (for which the definition was modified). To implement the statutory change, CMS proposes that the FUL be established for each multiple source drug for which the FDA has rated three or more products therapeutically and pharmaceutically equivalent.¹¹⁶ For purposes of applying this proposal, CMS considers drug products to be therapeutically equivalent if they are identified as A-rated in the current edition of FDA's Orange Book.¹¹⁷

CMS also proposes that FULs should be calculated at 175% of the weighted average of the most recently reported monthly AMPs for pharmaceutically and therapeutically equivalent multiple source drug products.¹¹⁸ CMS proposes to determine the weighted average based on the manufacturer-submitted utilization of the most recently reported monthly

AMPs for all therapeutically equivalent innovator (I) and non-innovator (N) multiple source drug products that are available for purchase by retail community pharmacies on a nationwide basis. Single source (S) drugs will not be included in the FUL calculation, in accordance with the statute.¹¹⁹ CMS does not propose a specific methodology to smooth FULs in the proposed rule, but specifically invites comments on this issue.¹²⁰

XI. Burden Analysis

Finally, as matter for consideration in the comment process, we note that CMS appears to have underestimated the level of burden on drug manufacturers associated with implementation of the proposed rule. CMS has identified the following additional requirements, and associated projected costs, for manufacturers:

- Changes to AMP and Best Price definitions: 240 hours per manufacturer, 144,000 total hours, and \$8,640,000 in costs.¹²¹
- Reporting of the FDA application number or the covered outpatient drug status of each drug: one time total of 3,000 hours and a one-time total cost of \$180,000.¹²²
- Identifying 5i drugs: 1,500 hours and a one-time cost of \$90,000.¹²³
- Determining 90% threshold for 5i drugs on a monthly and quarterly basis: 320 hours annually per manufacturer, or 192,000 hours total. A cost of \$11,520,000.¹²⁴
- Calculating Alternative URA for new formulations: 20 hours per quarter per manufacturer, or 48,000 total hours annually and a total estimated cost of \$2,880,000.¹²⁵

Manufacturers should consider commenting on CMS's burden estimates, both in terms of hours and costs.

¹¹³ Proposed rule at 198 (proposed 42 C.F.R. § 447.518(d)).

¹¹⁴ Proposed rule at 126.

¹¹⁵ Proposed rule at 198 (proposed 42 C.F.R. § 447.518(a)).

¹¹⁶ Proposed rule at 196 (proposed 42 C.F.R. § 447.514(a)).

¹¹⁷ Proposed rule at 112.

¹¹⁸ Proposed rule at 196 (proposed 42 C.F.R. § 447.514(b)).

¹¹⁹ Proposed rule at 115.

¹²⁰ Proposed rule at 122-125.

¹²¹ Proposed rule at 133.

¹²² Proposed rule at 134.

¹²³ Proposed rule at 135.

¹²⁴ *Id.*

¹²⁵ Proposed rule at 136.

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Appendix - Proposed AMP Classes of Trade / Transactions

Sales / Transactions	Include in Standard AMP?	Include in 5i AMP?
Direct sales to retail community pharmacies (RCPs)	Yes	Yes
Sales to wholesalers for drugs distributed to retail community pharmacies (RCPs)	Yes	Yes
Sales to other manufacturers who act as wholesalers for drugs distributed to [RCPs]	Yes	Yes
Sales to other manufacturers who conduct business as a wholesaler or [RCP]	Yes**	Yes
Sales, price concessions (other than Medicaid rebates or “as otherwise specified in regulations”), payments or other financial transactions that are “received by, paid by, or passed through to” RCPs	Yes	Yes
Sales, price concessions (other than Medicaid rebates or “as otherwise specified in regulations”), payments or other financial transactions that are “received by, paid by, or passed through to” entities that conduct business as wholesalers or RCPs	Yes	Yes
Sales, price concessions (other than Medicaid rebates), payments or other financial transactions made directly or indirectly to specialty pharmacies, home infusion pharmacies, and home healthcare providers	Yes	Yes
“Any prices” to the IHS, VA, certain State veterans homes, DoD, PHS, or a 340B covered entity; FSS sales; depot prices (including TRICARE), single award contract prices	No	No**
Sales outside the United States (i.e. outside the 50 states and the territories)	No	No**
Hospital sales* (inpatient or outpatient***)	No	Yes
Sales to HMOs (including MCOs), including to HMO / MCO operated pharmacies*	No	Yes
Sales to long-term care (LTC) providers (including nursing facility pharmacies, nursing home pharmacies, LTC pharmacies, assisted living facilities, contract pharmacies)	No	Yes
Sales to mail order pharmacies	No	Yes
Sales to clinics and other outpatient facilities (e.g., surgical centers, ambulatory care centers, dialysis centers, and mental health centers)	No	Yes
Sales to government pharmacies (e.g., Federal, State, county, municipal)	No	No**
Sales to charitable and not-for-profit pharmacies	No	No**
Sales, discounts, rebates to insurers (other than “rebates under section 1927 and this subpart”)*	No	Yes
Qualifying bona fide service fees, “including bona fide service fees paid to [GPOs]”	No	No**
Customary prompt pay discounts to wholesalers	No	No**
Returns meeting standards of the proposed rule	No	No**
Discounts under the Part D coverage gap discount program	No	No**
Sales to PBMs, including their mail order pharmacy’s purchases*	No	Yes

Rebates under a national Medicaid rebate agreement or CMS-authorized Medicaid supplemental rebates	No	No**
Sales to hospices*	No	Yes
Sales to prisons	No	No**
Sales to physicians*	No	Yes
Sales to patients*	No	Yes
Free goods, not contingent on a purchase requirement	No	No**
Qualifying manufacturer coupons	No	No**
Qualifying manufacturer vouchers	No	No**
Prices negotiated under qualifying manufacturer-sponsored drug discount cards	No	No**
Goods provided free of charge under qualifying manufacturer-sponsored patient refund/rebate programs	No	No**
Goods provided free of charge under qualifying manufacturer copayment assistance and patient assistance programs	No	No**

* Paraphrasing was necessary because some categories excluded from Standard AMP at 42 C.F.R. 447.504(c) do not match exactly with the proposed 5i AMP inclusions at 42 C.F.R. 447.504(d).

** Although the proposed rule is not entirely clear on this point, we believe this is what likely CMS intends.

*** Proposed rule at 53 (“[S]ales to hospitals ... where the drug is used in either the inpatient setting or the outpatient pharmacy for outpatient hospital use are excluded from the determination of [Standard] AMP.”).