Congress Changes Definition of Medicaid Average Manufacturer Price…Again

Just months after healthcare reform[1] overhauled the Medicaid rebate statute's definition of Average Manufacturer Price (AMP),[2] on August 10, 2011, President Obama signed into law HR1586, which makes further changes in AMP. Specifically, the new law changes the AMP definition for certain inhalation, infusion, instilled, implanted, and injectable drugs (the so-called five "I" drugs). These changes, like the changes to the definition of AMP enacted this past March by the healthcare reform law, will take effect October 1, 2010.

I. The Revised AMP Definition

In short, the March 2010 healthcare reforms redefined AMP as a manufacturer's average price to "wholesalers for drugs distributed to retail community pharmacies" and to "retail community pharmacies that purchase directly from the manufacturer," subject to certain "exclusions."[3] This week's amendment revised one of these exclusions. To help the reader understand how these changes fit together, below we present the AMP definition that will take effect October 1, 2010, with this week's changes in bold text:

(A) In general.—Subject to subparagraph (B), the term "average manufacturer price" means, with respect to a covered outpatient drug of a manufacturer for a rebate period, 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.

1 In March 2010, the Patient Protection and Affordable Care Act (PPACA), P.L. 111-148, and the Health Care and Education Reconciliation Act of 2010 (the Reconciliation Act), P.L. 111-152, amended the definition of AMP and made numerous other important changes to the healthcare system of interest to the pharmaceutical and medical device industries. For further detail, please see our advisory, "UPDATE: Healthcare Reform: A Pocket Guide for Pharmaceutical and Device Manufacturers," *available at:* http://www.arnoldporter.com/public_document.cfm?id=15548&key=24I0.

2 AMPs are used to calculate the rebates paid by drug manufacturers on Medicaid utilization and drug discounts under the 340B Program, and will be used to calculate Federal Medicaid upper limits on pharmacy reimbursement.

3 Social Security Act (SSA) § 1927(k)(1) (42 U.S.C. § 1396r-8(k)(1)).

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Healthcare Reform Chart

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(B) EXCLUSION OF CUSTOMARY PROMPT PAY DISCOUNTS AND OTHER PAYMENTS.—

(i) IN GENERAL.—The average manufacturer price for a covered outpatient drug shall exclude—

(I) customary prompt pay discounts extended to wholesalers;

(II) 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);

(III) 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;

(IV) payments received from, and rebates or discounts provided to, pharmacy benefit managers [PBMs], managed care organizations [MCOs], health maintenance organizations [HMOs], insurers, hospitals, clinics, mail order pharmacies, long term care [LTC] 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; and**

(V) discounts provided by manufacturers under [Social Security Act (SSA)] section 1860D-14A [the Medicare Part D coverage gap discount program].

(ii) INCLUSION OF OTHER DISCOUNTS AND PAYMENTS.—Notwithstanding clause (i), 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 the average manufacturer price for a covered outpatient drug.[4]

This week's revision to the AMP definition was likely prompted by concern that under the narrow definition of AMP in the healthcare reform law, many drugs (particularly those commonly administered in physicians' offices, hospitals, and clinics) could have no AMP eligible sales (or would have AMPs that could be distorted by low levels of AMP-eligible sales).[5] Although this week's statutory amendment may remedy this issue, it raise new questions.

II. Interpreting the New AMP Definition

Under the new AMP definition, it appears that the AMP for five "I" drugs that generally are not dispensed by retail community pharmacies will:

(1) Include any direct or indirect sales to retail community pharmacies;[6]

4 SSA § 1927(k)(1)(A),(B) (42 U.S.C. § 1396r-8(k)(1)(A),(B)).

5 The healthcare reform law generally defined AMP as a manufacturer's average price to "wholesalers for drugs distributed to retail community pharmacies" and to "retail community pharmacies that purchase directly from the manufacturer," subject to specified exclusions and inclusions. A retail community pharmacy is defined narrowly as "an independent pharmacy, a chain pharmacy, a supermarket pharmacy, or a mass merchandiser pharmacy that is licensed as a pharmacy by the State and that dispenses medications to the general public at retail prices. 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." SSA § 1927(k)(10) (42 U.S.C. § 1396r-8(k)(10)). A wholesaler is an entity "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." SSA § 1927(k)(11) (42 U.S.C. § 1396r-8(k)(11)).

6 This category also would include sales to wholesalers where the product is resold to unknown entities, if the Centers for Medicare and Medicaid Services (CMS) keeps the current "default rule" that governs this situation. Under the current default, sales to wholesalers

(2) Exclude customary prompt pay discounts to wholesalers, bona fide service fees, and reimbursement by manufacturers for unsalable returned goods;

(3) Include payments received from (i.e., sales revenues from), and rebates or other discounts provided to, PBMs, MCOs, HMOs, insurers, hospitals, clinics, mail order pharmacies, LTC providers, or anyone else (including doctors) that is not a wholesaler or a retail community pharmacy (meaning that for these drugs AMP would at least include **direct** sales to hospitals, clinics, LTC providers, and other purchasers that are not wholesalers or retail community pharmacies—more on indirect sales to these purchasers, and on discounts to PBMs and insurers follows below);

(4) Exclude coverage gap discount program payments; and

(5) Include any other types of payments, not mentioned above, that the manufacturer makes to retail community pharmacies.

III. Open Issues

A. What Does "Not Generally Dispensed" by Retail Community Pharmacies Mean?

The new language just added to the AMP definition only applies to five "I" drugs that are **"not generally dispensed" by retail community pharmacies**. It is not clear how the Centers for Medicare and Medicaid Services (CMS), the agency that administers the Medicaid drug rebate program, will interpret the "not generally dispensed" standard, but potentially CMS could take a fairly strict view of "not generally dispensed," (e.g., CMS might require that at least 90 percent of the drug's sales be made to entities other than retail community pharmacies). If the "not generally dispensed" standard were more lenient (e.g., if CMS required at least 51 percent of the drug's sales be made to entities other than retail community pharmacies) then more five "I" drugs would be subject to the new calculation; this could sweep in many drugs with appreciable sales to retail community pharmacies and potentially affect their Medicaid reimbursement rates.[7]

B. Are Indirect Sales to Hospitals, Physicians, etc. Included in the New AMP Calculation?

The AMP for five "I" drugs not generally dispensed through retail community pharmacies must include "payments received from, and rebates or discounts provided to [PBMs, MCOs, HMOs], insurers, hospitals, clinics, mail order pharmacies, [LTC] providers, manufacturers, or any other entity that does not conduct business as a wholesaler or a retail community pharmacy." Therefore, a **direct** sale to a hospital or doctor of these five "I" drugs likely will be included in the drug's AMP. Also, chargebacks paid to wholesalers for drugs distributed to these customers would likely be included in AMP (as "discounts provided to" these customers).

Although CMS will probably permit manufacturers to include in AMP sales to wholesalers of five "I" drugs that are resold to physicians, hospitals, etc., the possibility of CMS instead excluding these sales cannot be ruled out, because the new provision's plain language suggests that sales to wholesalers of drugs resold to these customers would be excluded from AMP. Clause (A) of the AMP definition does not include in AMP sales of drugs to wholesalers that are resold to entities other than retail community pharmacies, nor does the "unless the drug is [five 'I']" language in clause (B)(i)(IV), which includes in AMP only named entities that are not wholesalers and a catchall for "any other entity that does not conduct business as a wholesaler."

are included in AMP unless "adequate documentation" shows that the product was resold to an AMP-excluded entity. See 42 C.F.R. § 447.504(g)(1).

7 Currently, CMS must establish Federal Upper Limits (FULs) to cap Medicaid programs' pharmacy reimbursements for certain multi-source drugs. SSA § 1927(e)(4) (42 U.S.C. § 1396r-8(e)(4)). (Federal matching funds are generally unavailable to a State Medicaid program to the extent that the program's aggregate payments to pharmacies for these drugs exceed the FUL plus reasonable dispensing fees.) The Deficit Reduction Act of 2005 (DRA) set the FUL at 250 percent of the lowest AMP in a group of two or more multi-source drugs, although ongoing litigation over CMS' rule implementing the DRA's FUL provisions still blocks them from taking effect. Under PPACA, FULs will be "no less than 175 percent of the weighted average (determined on the basis of utilization) of the most recently reported monthly [AMPs] for pharmaceutically and therapeutically equivalent multiple source drug products that are available for purchase by retail commercial pharmacies on a nationwide basis," and will only apply to products with three or more multiple source drugs. SSA § 1927(e)(5) (42 U.S.C. § 1396r-8(e)(5)). The FUL changes take effect October 1, 2010.

C. Do Rebates to PBMs, Insurers, etc. Need to Be Included in the Five "I" AMP?

Congress enacted the new AMP definition for five "I" drugs not generally dispensed though retail community pharmacies so that AMPs could be calculated, and rebates paid, for those drugs. But the provision on its face includes rebates to entities such as PBMs, HMOs, and insurers, and thus goes beyond including the minimum classes of trade necessary to accomplish this purpose. If a drug falls within the five "I" provision, it is an open question whether manufacturers will be required to include sales or discounts to all of the entities listed in clause (B)(i)(IV) in its AMP, or whether CMS instead will permit (or perhaps even try to require) manufacturers to omit those classes of trade that appear unnecessary to calculating an AMP that reflects providers' acquisition costs for these drugs (e.g., rebates to PBMs and insurers).

IV. Conclusion

This week's AMP definition change will take effect on October 1, 2010. Because key issues—such as how to identify drugs not "generally" dispensed by retail community pharmacies, and how to perform the alternative AMP calculation for these drugs—are not clear, we expect that CMS will issue guidance clarifying the new law. In the absence of CMS guidance, a manufacturer is permitted to calculate AMP using "reasonable assumptions" that are documented and "consistent with the general requirements and the intent of the [Social Security] Act, Federal regulations, and its customary business practices."[8] We encourage drug manufacturers to evaluate these new statutory provisions; seek CMS guidance where necessary; consider any systems or operational changes that may be required to implement the new law; and develop and document reasonable assumptions as necessary.

We hope you found this advisory useful. If you have additional questions, please contact your Arnold & Porter attorney or:

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8 72 Fed. Reg. 39142, 39164 (Jul. 17, 2007).