Medicaid Program; Covered Outpatient Drugs; Proposed Rule (CMS-2345-P)

NHIA Summary

The Centers for Medicare & Medicaid Services (CMS) on February 2, 2012 published in the Federal Register a proposed rule entitled “Medicaid Program; Covered Outpatient Drugs.” Comments on the proposed rule must be submitted to CMS by April 2, 2012.

The proposed rule implements several provisions of the Patient Protection and Affordable Care Act of 2010 and the Health Care and Education Reconciliation Act of 2010 (collectively referred to as “ACA”) related to Medicaid payments for covered outpatient drugs. Specifically, CMS proposes revisions to the:

- Definition and calculation of average manufacturer price (AMP);
- Definition and calculation of “best price;”
- Federal upper reimbursement limit for drugs; and
- Medicaid drug rebate program.

CMS estimates that the rule would result in approximately $17.7 billion in savings for Federal fiscal years (FFYs) 2010 through 2014 - $13.7 billion in Federal savings and $4.0 billion in State savings. CMS anticipates that the rule would cost managed care organizations (MCOs), drug manufacturers and States a total of $81.4 million for FFYs 2010 through 2014, which it attributes to “administrative and infrastructure expenses necessary to implement the required systems changes.” CMS estimates that the vast majority of these costs ($80.91 million) would be due to the new requirements for manufacturers.

Covered Outpatient Drugs

CMS proposes to adopt the statutory definition of “covered outpatient drug,” and generally defines the term as a prescription drug that is medically necessary, approved as safe and effective by FDA, was commercially sold in the United States before the enactment of the Drug Amendments of 1962 (or which is identical, similar or related to such drugs) and which are not “new drugs.” The term would also include certain prescription biologic products and insulin. CMS specifies that “covered outpatient drugs” would not include drugs, biologic products or insulin provided in the same setting as part of or incident to the following: inpatient services, outpatient hospital services, physician services, laboratory and x-ray services, nursing facility services, services provided by an intermediate care facility for the mentally retarded, hospice services, renal dialysis services, and certain dental services. In addition, a “covered outpatient drug” would be required to have a national drug code (NDC) number and be listed electronically with the FDA. Manufacturers would be
required to report to CMS the number of an approved FDA application for a product or otherwise show that the product meets the statutory definition of a covered outpatient drug.

**Definition of Average Manufacturer Price**

Congress in Section 2503(a)(2) of the ACA revised the definition of AMP to mean “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.” CMS proposes to codify the new definition of AMP and to: (1) define “retail community pharmacy,” “wholesalers” and other terms used in the determination of AMP, (2) specify the entities to be included in and excluded from AMP, and (3) include in the determination of the AMP infusion, inhalation, instilled, implanted, or injectable drugs (which CMS collectively refers to as “5i drugs”) that are not generally dispensed through a retail community pharmacy.

A manufacturer that holds the NDA of an authorized generic drug (primary manufacturer) would be required to include in its calculation of AMP its sales of authorized generic drugs directly to a wholesaler. In addition, the primary manufacturer would be required to include in its calculation of AMP its sales of authorized generic drugs that have been sold or licensed to a secondary manufacturer (a manufacturer that does not hold the NDA but is authorized by the primary manufacturer to sell the drug), including transfer prices and fees paid by the secondary manufacturer to the primary manufacturer when the secondary manufacturer acts as a wholesaler.

**Definition of Retail Community Pharmacy and Wholesalers**

CMS proposes to define “retail community pharmacy” as “an independent pharmacy, a chain pharmacy, a supermarket pharmacy, and 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.”

Wholesalers would be defined as “a drug wholesaler that is engaged in wholesale distribution of prescription drugs to retail community pharmacies, including but not limited to manufacturers, repackers, distributors, own-label distributors, private-label distributors, jobbers, brokers, warehouses (including manufacturer’s and distributor’s warehouses, chain drug warehouses, and wholesale drug warehouses), independent wholesale drug traders, and retail community pharmacies that conduct wholesale distributions.”

CMS interprets the statutory definition of AMP to suggest that home infusion pharmacies, specialty pharmacies, and home healthcare agencies could be included in the determination of AMP because they conduct business as wholesalers or retail community pharmacies. CMS notes that certain oral covered outpatient drugs are dispensed exclusively through specialty and home infusion pharmacies. CMS concludes that if these entities were to be excluded from AMP calculations, an AMP would not be available for these oral covered outpatient drugs and manufacturers would not be able to calculate rebates for these products. This contradicts the statutory provisions requiring
rebates for such drugs. As a result, CMS proposes to “include in the determination of AMP payments received from and rebates or discounts provided to an entity that conducts business as a wholesaler or retail community pharmacy, such as specialty and home infusion pharmacies, and home healthcare providers, since these entities dispense medications to segments of the general public at retail prices.”

*Entities Included In and Excluded from the AMP*

CMS proposes to include in the determination of AMP the following sales, discounts, rebates, payments, nominal price sales, and other transactions:

- Sales to wholesalers for drugs dispensed to retail community pharmacies.
- Sales to other manufacturers who act as wholesalers for drugs distributed to retail community pharmacies.
- Sales, discounts, rebates (other than rebates under the Medicaid drug rebate program or otherwise specified in regulation), payments or other financial transactions that are received by, paid by, or passed through to retail community pharmacies. CMS indicates that although it is uncertain to what extent the manufacturer knows that such transactions occur, the manufacturer must include such discounts where it has evidence or documentation demonstrating that such discounts have been passed through to the pharmacy.
- Sales, discounts, rebates (other than rebates under the Medicaid drug rebate program or otherwise specified in regulation), payments, or other financial transactions that are received by, paid by, or passed through to entities conducting business as wholesalers or retail community pharmacies, including specialty pharmacies, home infusion pharmacies, and home healthcare agencies.

CMS proposes that AMP include “cash discounts except prompt pay discounts extended to wholesalers, free goods that are contingent on any purchase requirement, volume discounts, chargebacks that can be identified with adequate documentation, incentives, administrative fees, service fees, distribution fees, and any other rebates, discounts or other financial transactions, other than rebates under section 1927 of the Act, which reduce the price received by the manufacturer for drugs distributed to retail community pharmacies.”

CMS proposes to exclude from the determination of AMP the following sales, discounts, rebates and payments:

- Prices to other Federal programs, including the Indian Health Services (IHS), the Department of Veterans Affairs (DVA), a State home receiving funds from the Department of Veterans’ Affairs (under 38 U.S.C. § 1741), the Department of Defense (DoD), the Public Health Service (PHS), 340B covered entities (including inpatient prices charged to certain hospitals), prices charged under the Federal Supply Schedule (FSS) of the General Services Administration (GSA); any depot prices (including TRICARE) and single award contract prices of any agency of the Federal government.
• Sales outside the United States (including the 50 States, District of Columbia and the territories).

• Direct or indirect sales to hospitals, where the drug is used in either the inpatient setting or the outpatient pharmacy for outpatient hospital use.

• Sales to health maintenance organizations (HMOs) and MCOs, including HMO/MCO operated pharmacies.

• 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.

• Sales to mail order pharmacies.

• Sales to clinics and outpatient facilities, such as surgical centers, ambulatory care centers, dialysis centers, and mental health centers.

• Sales to government pharmacies.

• Sales to charitable and not-for-profit pharmacies.

• Sales, associated rebates and other price concessions paid directly to insurers.

• 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 pharmacy, such as inventory management fees, product stocking allowances, fees associated with administrative agreements and patient care programs (including bona fide service fees paid to Group Purchasing Organizations).

• Customary prompt pay discounts extended to wholesalers.

• Reimbursement by the manufacturer for recalled, damaged, expired, or otherwise unsalable returned goods, such as reimbursement for the cost of goods and any reimbursement of costs associated with return goods handling and processing, reverse logistics, and drug destruction.

• Associated discounts, rebates, or other price concessions provided under the Medicare Covered Gap Discount Program.

• Sales to pharmacy benefit managers (PBMs), including their mail order pharmacy’s purchases.

• Rebates under the national rebate agreement or a CMS-authorized State supplemental rebate agreement paid to State Medicaid Agencies.
• Sales to hospices (inpatient and outpatient).
• Sales to prisons.
• Direct sales to physicians.
• Direct sales to patients.
• Free goods, not contingent upon any purchase requirement.
• Manufacturer coupons to a consumer redeemed by the manufacturer or any entity acting on behalf of a manufacturer. The full value of the coupon must be passed to the consumer and the entity acting on the manufacturer’s behalf may not receive any price concession.
• Manufacturer vouchers.
• Prices negotiated under manufacturer-sponsored drug discount card programs.
• Goods provided free of charge under manufacturer-sponsored patient refund/rebate programs, manufacturer copayment assistance programs, or patient assistance programs.
Infusion, Inhalation, Instilled, Implanted, or Injectable Drugs

CMS proposes that manufacturers be responsible for identifying covered outpatient infusion, inhalation, instilled, implanted, or injectable drugs that are not generally dispensed through a retail community pharmacy (which CMS collectively refers to as “5i drugs”) on a monthly and quarterly basis. Manufacturers would be required to identify 5i drugs using routes of administration identified on a list CMS created from the FDA Structured Product Labeling, Route of Administration data standards. The drugs would be considered “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. CMS is specifically soliciting comments on the 90 percent threshold for determining whether a 5i drug is “not generally dispensed through a retail community pharmacy.”

In addition to the sales and associated discounts, rebates, payments, or other financial transactions generally included in the determination of AMP, CMS proposes that the AMP for 5i drugs include the following:

- Sales to physicians.
- Sales to PBMs where the PBM is not acting as an insurer, including its mail order pharmacy purchases.
- Sales to HMOs, including MCOs.
- Sales, discounts, or rebates paid directly to insurers (except for rebates under the Medicaid drug rebate program)
- Sales to hospitals.
- Sales to clinics and outpatient facilities.
- Sales to mail order pharmacies.
- 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.
- Sales to hospices.
- Sales to other manufacturers who conduct business as a wholesaler or retail community pharmacy.

Best Price

The best price for a single source drug or innovator multiple source drug of a manufacturer is “the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, [HMO], nonprofit entity, or governmental entity in the United States in any pricing
structure… in the same quarter for which the AMP is computed.” CMS proposes to revise the prices exempt from “best price” to make the “best price” determination consistent with the AMP calculation. Therefore, the list of prices excluded from best price would be revised and expanded to include the following:

- Prices charged to IHS, DVA, a State home receiving funds from the Department of Veterans’ Affairs (under 38 U.S.C.§ 1741), DoD, PHS, 340B covered entities (including inpatient prices charged to certain hospitals), the FSS of the GSA, and any depot prices (including TRICARE) and single award contract prices of any agency of the Federal government.

- Any prices provided to a designated State Pharmacy Assistance Program (SPAP).

- Any prices charged which are negotiated by a prescription drug plan under Medicare Part D, by any MA-PD plan for covered Part D drugs, or by a Qualified Retiree Prescription Drug Plan for drugs for individuals entitled to Medicare Part A or enrolled in Medicare Part B, or any discounts provided by manufacturers under the Medicare coverage gap discount program.

- Rebates under the national rebate agreement or a CMS-authorized supplemental rebate agreement paid to State Medicaid Agencies.

- Prices negotiated under manufacturer-sponsored drug discount card programs.

- Manufacturer coupons to a consumer redeemed by a consumer or an entity acting on behalf of the manufacturer; but only if the full value of the coupon is passed on to the consumer and entity does not receive any price concession.

- Goods provided free of charge under manufacturer-sponsored patient refund/rebate programs, manufacturer copayment assistance programs or patient assistance programs.

- Manufacturer vouchers.

- Free goods, not contingent upon any purchase requirement.

- Reimbursement by the manufacturer for recalled, damaged, expired, or otherwise unsalable returned goods.

- Nominal prices charged to certain entities.

- 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.

- 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.
• Sales outside the United States.

Best price would be net of cash discounts, free goods that are contingent on any purchase requirement, volume discounts, customary prompt pay discounts, chargebacks, returns, incentives, promotional fees, administrative fees, 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.

It is unclear whether a primary manufacturer would be required to include the best price of an authorized generic drug in its computation for a single source drug during a rebate period. CMS’ proposed regulations specify 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.” However, in the preamble, CMS indicates that it is revising the best price regulations to specify “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.” Therefore, we may want to seek clarity on this point from CMS.

**Changes to the Medicaid Drug Rebate Program**

CMS proposes to codify several provisions of the ACA by (1) revising the formulas used to calculate the rebate amounts for single source drugs and innovator multiple source drugs, line extension drugs and noninnovator multiple source drugs; (2) requiring manufacturers to pay drug rebates for drugs dispensed to individuals enrolled in MCOs; and (3) requiring States to remit to the Federal government savings due to the increases in rebate percentages.

In accordance with the ACA, CMS proposes to revise the definition of “multiple source drug” to be a covered outpatient drug for which there is at least one other drug product sold or marked in the United States that is therapeutically equivalent, pharmaceutically equivalent and bioequivalent. Accordingly, CMS proposes that at least two therapeutically equivalent formulations must be included in the FDA’s Orange Book for a drug to be defined as a “multiple source drug.”
Rebates for Single Source Drugs and Innovator Multiple Source Drugs

The ACA increased the minimum rebate percentages for single source drugs and innovator multiple source drugs from 15.1 percent to generally 23.1 percent. For certain types of clotting factors or drugs approved by the FDA exclusively for pediatric indications, the rebate percentage would be 17.1 percent. Accordingly, CMS proposes that the amount of basic rebate for each dosage form and strength of a single source drug or an innovator multiple source drug would be equal to the product of the total number of units of each dosage form and strength paid for under the State plan in the rebate period and the greater of (1) the difference between the AMP and best price for the dosage form and strength of the drug; or (2) the AMP multiplied by 23.1 percent or, where applicable, 17.1 percent.

The rebate amount for each dosage form and strength of a single source drug or an innovator multiple source drug would be increased by an additional rebate amount equal to the product of (1) the total number of units of such dosage form and strength paid for under the State plan in the rebate period and (2) the amount by which the AMP for the dosage form and strength of the drug for the period exceeds the adjusted base date AMP for such dosage form and strength. The total rebate amount for single source drugs and innovator multiple source drugs would be equal to the basic rebate amount plus the additional rebate amount. However, the total rebate would be limited to 100 percent of the AMP of the drug.

Rebates for Line Extensions of Single Source Drugs and Innovator Multiple Source Drugs

CMS proposes to define line extension 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 listed drug, such as a new ester, a new salt, or other noncovalent derivative; a new formulation of a previously approved drug; a new combination of two or more drugs; or a new indication for an already marketed drug.” CMS proposes using the FDA’s list of Chemical Types listed in FDA Drugs in FDA’s database to identify the line extension drug. Line extension drugs would include Chemical Type 2 (new ester, a new salt, or other noncovalent derivative), Chemical Type 3 (new formulation), Chemical Type 4 (new combination) and Chemical Type 6 (new indication). Chemical Type 1 (new molecular entity) represents the initial brand name listed drug.

In accordance with the ACA, the rebate amount for line extension drugs would be the greater of (1) the amount computed for the single source or innovator multiple source drug, as described above, or (2) the product of the AMP of the line extension drug, the highest additional rebate (calculated as a percentage of the AMP) for any strength of the original single source or innovator multiple source drug, and 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. The total rebate amount would be limited to 100 percent of AMP for line extension drugs.
Rebates for Noninnovator Multiple Source Drugs

The ACA increases the minimum rebate percentage for noninnovator multiple source drugs from 11 to 13 percent. The rebate amount for each dosage form and strength of a noninnovator multiple source drugs would be equal to the product of (1) the total number of units of each dosage form and strength for which payment was made under the State plan for the rebate period and (2) the AMP for the dosage form and strength for the rebate period multiplied by 13 percent.

Rebates for Drugs Dispensed Through Medicaid Managed Care Organizations

In accordance with the ACA, CMS proposes that manufacturers participating in the Medicaid drug rebate program should pay rebates for covered outpatient drugs dispensed to individuals enrolled in Medicaid MCOs if the MCO is responsible for the coverage of the drugs. Manufacturers would be exempt from this requirement if the covered outpatient drugs are dispensed by HMOs, including Medicaid MCOs, and are subject to discounts under the 340B program. Medicaid MCOs that are responsible for providing covered outpatient drugs to Medicaid beneficiaries would be required to submit quarterly reports to the State that contain specific information about drug utilization.

Federal Offset of Rebates

For single source drugs and innovator multiple source drugs (other than blood clotting factors and drugs approved by the FDA exclusively for pediatric indications), if the AMP minus best price is less than or equal to the AMP times 15.1 percent, then the offset amount would be 8 percent of the AMP (23.1 percent of AMP minus 15.1 percent of AMP). If the AMP minus best price is greater than the AMP times 15.1 percent but less than 23.1 percent, the offset amount would be the difference between the AMP times 23.1 percent and the AMP minus best price. If the AMP minus best price is equal to or greater than the AMP times 23.1 percent, there would not be an offset amount.

For single source drugs and innovator multiple source drugs that are subject to a rebate percentage of 17.1 percent of the AMP (certain types of clotting factors or drugs approved by the FDA exclusively for pediatric indications), if the AMP minus best prices is less than or equal to the AMP times 15.1 percent, the offset amount would be 2 percent of the AMP. If the AMP minus best price is greater than the AMP times 15.1 percent but less than the AMP times 17.1 percent, then the offset amount would be the difference between the AMP times 17.1 percent and the AMP minus best price. If the AMP minus best price is equal to or greater than the AMP times 17.1 percent, there would not be an offset amount.

The offset amount for line extension drugs would be the difference between the unit rebate amount (URA) calculated based on the single source or innovator multiple source drug and the URA calculated for the line extension drug based on the highest additional rebate.

For noninnovator multiple source drugs, the offset amount would be equal to 2 percent of the AMP (the difference between 13 percent of the AMP and 11 percent of the AMP).

Reporting Requirements
CMS proposes several changes to the reporting requirements for manufacturers. CMS proposes to allow manufacturers to recalculate the base date AMP based on the new calculation of AMP. Manufacturers would be able to choose to recalculate base date AMP on a product-by-product basis.

Manufacturers would be required to submit to CMS a monthly AMP as well as the total number of units used to calculate the monthly AMP for each covered outpatient drug within 30 days after the ends of the last day of each prior month. Similarly, manufacturers would be required to submit quarterly reports that contain information on AMP, best price, customary prompt pay discounts, and nominal prices to CMS by the thirtieth day after the end of a rebate period. CMS proposes that a manufacturer that fails to submit its quarterly AMP or its monthly AMP and total number of units used to calculate the monthly AMP in a timely manner be subject to a civil monetary penalty of $10,000 per day per drug. CMS is soliciting comments on providing regulatory guidance on suspension and termination for manufacturers that do not report monthly or quarterly AMP data on a timely basis or are out of compliance with the rebate requirements.

CMS proposes that manufacturers calculate monthly AMP as net sales divided by total units sold (excluding goods or other items excluded in the statute or regulations). The monthly AMP would be calculated based on the weighted average of prices for all the manufacturer’s package sizes of each covered outpatient drug sold by the manufacturer during a month. In addition, manufacturers would be required to use a 12-month rolling percentage to estimate the value of lagged price concessions. In general, manufacturers would be required to report to CMS revisions to monthly AMP within 36 months. Similarly, manufacturers have 12-quarters to report changes to the AMP, best price, customary prompt pay discounts, and nominal prices included in their quarterly submissions.

CMS proposes to make exceptions to the 36 month/12-quarter rule filing limitation for changes to monthly or quarterly submissions that: (1) result from a change in drug category or market date; (2) are initial submissions for products; (3) are due to a manufacturer being terminated from the Medicaid drug rebate program for failing to submit pricing data; (4) are due to technical corrections, which are not based on changes in sales transactions or pricing adjustments from such transactions; and (5) address specific underpayments to States, or potential liability regarding those underpayments, as required by CMS or court order, or pursuant to an internal investigation, or an OIG or DOJ investigation. CMS proposes an exception to the time limits for revisions to monthly and quarterly AMPs when the revision solely results from data related to lagged price concessions. In addition, CMS proposes to allow manufacturers to report revisions outside of the 12-quarter limit for changes to quarterly AMP based on the approval of CMS for good cause.

Federal Upper Reimbursement Limit

In accordance with the ACA, CMS proposes that a Federal upper limit (FUL) be established for each multiple source drug available for purchase by retail community pharmacies on a nationwide basis that the FDA has rated three or more products therapeutically and pharmaceutically equivalent. The FUL would be calculated using only therapeutically and pharmaceutically equivalent drugs. CMS proposes that the an agency’s payment for multiple source drugs be limited to a professional dispensing fee established by the state agency plus an amount established by CMS that is equal to 175 percent of the weighted average of the most recently reported monthly AMP.
For drugs other than multiple source drugs for which a FUL has been established or for a brand name drug that a physician certifies as medically necessary for a particular beneficiary, payment would be limited to the lower of: (1) the actual acquisition cost plus a professional dispensing fee or (2) providers’ usual and customary charges to the general public. CMS proposes to define “actual acquisition cost” as “the agency’s determination of the pharmacy providers’ actual prices paid to acquire drug products marketed or sold by specific manufacturers.” In the preamble, CMS suggests that this definition would be satisfied if payment is based on an average of the actual acquisition costs from a number of representative pharmacies. States could develop reimbursement methods consistent with this regulatory definition for their Medicaid pharmacy reimbursement.

The FUL for prescribed drugs would apply to payment for drugs provided as part of SNF services, intermediate care facility services and under prepaid capitation arrangements.

* * * * *

Prepared by NHIA legal counsel Polsinelli Shughart PC