Department of Health & Human Services

OFFICE OF INSPECTOR GENERAL

REPLACING AVERAGE WHOLESALE PRICE: MEDICAID DRUG PAYMENT POLICY

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EXECUTIVE SUMMARY

OBJECTIVES

1. To determine how States will set reimbursement for Medicaid prescription drugs after First DataBank stops publishing average wholesale prices (AWP) in September 2011.
2. To determine the role that States would prefer the Centers for Medicare & Medicaid Services (CMS) to play in developing Medicaid reimbursement methodologies for prescription drugs.

BACKGROUND

Federal regulations require, with certain exceptions, that Medicaid reimbursement amounts for prescription drugs not exceed (in the aggregate) the lower of (1) the estimated acquisition cost plus a dispensing fee or (2) the provider's usual and customary charge to the public for the drug. CMS allows States flexibility in determining the estimated acquisition cost. In the first quarter of 2011, 45 States estimated the acquisition cost based on AWP; 37 of these States obtained AWP data from the pricing compendium published by First DataBank. However, Office of Inspector General reports have consistently found that the fundamentally flawed nature of AWP-based reimbursement has caused Medicaid to pay too much for certain drugs.

Following the filing of a lawsuit, First DataBank decided to stop publishing AWPs no later than September 26, 2011. This presents States with an opportunity to implement new reimbursement methodologies that more closely approximate pharmacy acquisition costs. States have a variety of other pricing options, such as obtaining AWP from a different source or replacing AWP with average sales price, average manufacturer price, average acquisition cost, or wholesale acquisition cost (WAC).

In January 2011, we surveyed all 50 States and the District of Columbia (hereinafter referred to as States) and received responses from each. We asked States whether they intend to change their reimbursement methodologies once AWPs are no longer published by First DataBank. We then asked the States to describe any plans to replace AWP, the timeframe for implementation, and the actions necessary for implementation. We also asked States to describe the role they would prefer CMS to play in developing Medicaid reimbursement methodologies and whether States would prefer that CMS develop a single national benchmark.

We interviewed CMS staff in February 2011 to determine whether the agency had provided guidance to all States regarding recent AWP issues. We also asked CMS to describe any guidance it is planning to provide States about this topic.

FINDINGS

Twenty States had not developed any definitive plans for prescription drug reimbursement after First DataBank stops publishing AWPs. Of the 45 States with AWP-based reimbursement methodologies in the first quarter of 2011, 20 had not made any definitive plans regarding reimbursement for Medicaid prescription drugs after September 2011 (all 20 had obtained AWPs from First DataBank in the first quarter of 2011). Eight of the twenty States had not decided whether they will continue to use AWP (from another source) or instead select another benchmark. Among the remaining 12 States, 6 intend to discontinue using AWP but had not yet taken any steps to select a new benchmark, 3 intend to continue using AWP but had not selected the publishing source for AWP data, and 3 are considering whether to use AWP from another source or to replace AWP with WAC.

Fifteen States have relatively well-developed plans to move away from AWP-based reimbursement. Of the 45 States, 15 have relatively well-developed plans to implement new reimbursement methodologies that replace AWP with another benchmark. Among these 15 States, 3 plan to replace AWP with average acquisition cost and 12 plan to replace AWP with WAC.

Ten States will continue using AWP to set reimbursement, at least in the short term. Of the 45 States, 10 plan to continue using the AWP after September 2011. This number includes 4 of the 37 States that currently obtain AWPs from First DataBank and now plan to obtain AWP data from another source (Medi-Span and/or Micromedex). The other six States that will continue using AWP were already getting the data from one of these other sources.

Forty-four States would like CMS to develop a national benchmark to set Medicaid reimbursement for prescription drugs. Most States (44 of 51) would prefer that CMS develop a single national benchmark to set Medicaid reimbursement rates. Twenty-four States specified that they want a benchmark based on pharmacy acquisition costs.

According to CMS staff, the agency has not yet provided uniform guidance about options for Medicaid reimbursement after AWPs are no longer available from First DataBank, but is taking steps to address this issue and plans to provide guidance to States. CMS stated that although the agency does not mandate that a specific formula or methodology be used for reimbursement, it plans to conduct a nationwide survey to collect retail community pharmacy prices for drugs (including acquisition costs) and intends to discuss the results and other options for States in future guidance and/or in proposed rulemaking.

RECOMMENDATION

First DataBank will stop publishing AWPs no later than September 26, 2011, forcing many States to reevaluate how they will pay for prescription drugs. It will also present States with the opportunity to move to new reimbursement methodologies that could better reflect pharmacy acquisition costs. However, many States are not fully prepared to implement new reimbursement methodologies at this time. As a result, these States will need to develop, obtain CMS approval for, and implement new reimbursement methodologies in an extremely limited timeframe. In addition, a number of States will either begin or continue to base reimbursement on WAC, a manufacturer-reported benchmark that, like AWP, is not based on actual sales transactions.

States overwhelmingly would prefer that CMS, to address the uncertainty surrounding drug reimbursement decisions, develop a national benchmark to set reimbursement. A national benchmark that reflects actual pharmacy acquisition costs would eliminate States' reliance on the inflated published prices that cause Medicaid and its beneficiaries to pay too much for certain drugs. Therefore, we recommend that CMS:

Develop a national benchmark that accurately estimates acquisition cost and encourage States to consider it when determining Medicaid reimbursement for prescription drugs.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS concurred with our recommendation. CMS stated that it is contracting with a vendor to develop a survey of retail prices and acquisition cost information. CMS expects to develop an estimate of

average acquisition cost using the data from this survey. CMS also stated that it intends to include external stakeholders in this process to ensure that there is transparency in the average acquisition cost determination and that the methodology is implemented appropriately. We did not make any changes to the report based on CMS's comments.

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BACKGROUND

Numerous reports by the Office of Inspector General (OIG) have found that the fundamentally flawed nature of AWP-based reimbursement has caused Medicaid to pay too much for certain drugs. OIG has recommended that CMS work with States and Congress to base payments on a figure that more accurately reflects pharmacy acquisition cost.[1]

However, as of the first quarter of 2011, 45 States still used AWP as a primary benchmark when setting Medicaid reimbursement amounts; 37 of these States obtained AWP data from the publishing company First DataBank. Following the filing of a lawsuit, First DataBank decided to stop publishing AWPs no later than September 26, 2011.[2] This has forced many States to reevaluate how they will pay for prescription drugs after that date and presents States with the opportunity to move to new reimbursement methodologies that better reflect pharmacy acquisition costs.

[1] For example, see *Comparison of Medicaid Federal Upper Limit Amounts to Average Manufacturer Prices* (OEI-03-05-00110), June 2005; *Variation in State Medicaid Drug Prices* (OEI-05-02-00681), September 2004; *Cost Containment of Medicaid HIV/AIDS Drug Expenditures* (OEI-05-99-00611), July 2001; or *Medicaid Pharmacy – Additional Analyses of the Actual Acquisition Cost of Prescription Drug Products* (A-06-02-00041), September 2002.

[2] First DataBank, *Drug Pricing Policy*. Accessed at http://www.firstdatabank.com on November 22, 2010. First DataBank will continue to publish other pricing data, such as wholesale acquisition cost (WAC).

Medicaid Reimbursement for Prescription Drugs

The Medicaid program, established under Title XIX of the Social Security Act (the Act), is administered by States and financed using State and Federal funds. Medicaid pays for medical and health-related assistance for certain vulnerable and needy individuals and families. All 50 States and the District of Columbia (hereinafter referred to as States) provide coverage for prescription drugs under Medicaid. In 2009, Medicaid expenditures for prescription drugs totaled $26 billion.[3]

Medicaid beneficiaries typically receive covered drugs through pharmacies, which are reimbursed by State Medicaid agencies. Federal regulations require, with certain exceptions, that State Medicaid reimbursement for a covered outpatient drug not exceed (in the aggregate) the lower of (1) the estimated acquisition cost plus a dispensing fee or (2) the provider's usual and customary charge to the public for the drug.[4] Estimated acquisition cost refers to the State's best estimate of the price generally and currently paid by providers for the drug.[5] CMS allows States flexibility in determining the estimated acquisition cost. Estimating pharmacy acquisition cost has historically presented a challenge for States because they lack access to pricing data that are based on actual drug sales.

AWP and WAC. States typically estimate the acquisition cost for a drug based on published prices, such as AWP and WAC.[6] Most States have historically used the pricing compendium published by First DataBank to obtain AWP and WAC data. First DataBank relies on manufacturers (or other third parties) to report or otherwise make available the values for AWP and WAC.[7, 8]

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[3] This was the most recent year for which complete expenditure data were available.

[4] 42 CFR § 447.512.

[5] 42 CFR § 447.502.

[6] For certain generic drugs, States may also set reimbursement through the Federal upper limit and/or the State maximum allowable cost programs.

[7] Although most brand-name drugs have a WAC, many generic drugs do not.

[8] The term "manufacturers" refers to manufacturers, repackagers, private labelers, and other suppliers. First DataBank, *Drug Pricing Policy*. Accessed at http://www.firstdatabank.com on November 22, 2010.

Neither AWP nor WAC is based necessarily on actual sales transactions. AWP is not defined in law or regulation and fails to account for prompt pay or other discounts, rebates, and reductions.[9] Section 1847A(c)(6)(B) of the Act defines WAC as the manufacturer's list price for the drug to wholesalers or direct purchasers, not including prompt pay or other discounts, rebates, or reductions, for the most recent month for which information is available.

Based on information from CMS's Web site, at the end of 2010 all but a few States either used AWPs discounted by a certain percentage (5 to 50 percent) to determine estimated acquisition costs for most covered drugs or used AWP in combination with other available pricing data (e.g., WAC).[10]

Dispensing fees. In addition to reimbursing pharmacies for the cost of the drug, States are required to determine a "reasonable" dispensing fee.[11] This fee represents the charge for the professional services provided by the pharmacist when dispensing a prescription (including overhead expenses and profit).[12] In the fourth quarter of 2010, State dispensing fees paid to pharmacies ranged from $1.00 to $14.01 per prescription.[13]

AWP Lawsuit Involving First DataBank and McKesson

Typically, a drug manufacturer sells a drug to a wholesaler, which then sells it to a pharmacy.[14] The price wholesalers charge pharmacies for the drug is generally based on WAC. As previously mentioned, WAC is the undiscounted list price that manufacturers report to publishing companies, such as First DataBank, which use these data to produce

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[9] First DataBank, *Drug Pricing Policy*. Accessed at http://www.firstdatabank.com on November 22, 2010.

[10] CMS, *Medicaid Prescription Reimbursement Information by State – Quarter Ending December 2010*. Accessed at http://www.cms.gov on February 22, 2011.

[11] 42 CFR § 447.512.

[12] Health Resources and Services Administration, *Pharmacy Affairs & 340B Drug Pricing Program*. Accessed at http://www.hrsa.gov on April 26, 2011.

[13] CMS, *Medicaid Prescription Reimbursement Information by State – Quarter Ending December 2010*. Accessed at http://www.cms.gov on February 22, 2011. This range excludes fees for IV therapy and compounded prescriptions.

[14] Prescription Access Litigation (PAL), *Current Lawsuits: First DataBank McKesson Medi-Span*. Accessed at http://www.prescriptionaccess.org on October 26, 2010.

pricing compendia. Pharmacies are reimbursed for most drugs covered under Medicaid based on the State's estimated acquisition cost formula (e.g., based on AWP), plus the dispensing fee.[15] Pharmacies can profit from the difference between what they pay to the wholesaler for the drug and what Medicaid reimburses for the drug (commonly referred to as the spread).[16]

In June 2005 and February 2006, members of PAL[17] filed a lawsuit alleging that First DataBank and a wholesaler, McKesson, engaged in a scheme to increase the spread of certain prescription drugs by reporting higher AWPs.[18] This case was eventually settled, and First DataBank announced it would discontinue publishing AWPs no later than September 26, 2011.[19]

Other Pricing Options for States

Since the announcement of First DataBank's settlement, many stakeholders (e.g., purchasers, pharmacies, providers) have speculated about the various other pricing benchmarks that could be used as the basis for Medicaid reimbursement. These include, but are not limited to, WAC, average acquisition cost (AAC), average manufacturer price (AMP), and average sales price (ASP). There is little industry consensus as to which, if any, of these benchmarks will be used by States. Some stakeholders believe that an AWP replacement may not even be necessary, at least not in the short term,[20] as States will have

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[15] 42 CFR § 447.512.

[16] PAL, *Current Lawsuits: First DataBank McKesson Medi-Span.* Accessed at http://www.prescriptionaccess.org on October 26, 2010.

[17] According to its Web site, PAL is a national coalition of more than 130 organizations whose stated purpose is to challenge illegal drug pricing tactics and to work to make prescription drug prices more affordable for consumers through class action litigation and public education. Accessed at http://www.prescriptionaccess.org on November 9, 2010.

[18] PAL, *Current Lawsuits: First DataBank McKesson Medi-Span.* Accessed at http://www.prescriptionaccess.org on October 26, 2010.

[19] First DataBank, *Drug Pricing Policy*. Accessed at http://www.firstdatabank.com on November 22, 2010.

[20] Journal of Managed Care Pharmacy, *What Is the Price Benchmark to Replace Average Wholesale Price (AWP)?* Accessed at www.amcp.org on October 22, 2010. Atlantic Information Services, Inc., Health Business Daily, *Competing Stakeholders Disagree Over the Future of AWP Drug Pricing Benchmark and Possible Replacements.* Accessed at www.aishealth.com on October 26, 2010.

access to AWPs in pricing compendia published by other companies, such as Medi-Span.

WAC. Although First DataBank will cease publication of AWPs, it will continue to publish other pricing information, such as WACs (pricing compendia published by other companies will also include WACs). In a June 2010 white paper, the American Medicaid Pharmacy Administrators Association and the National Association of State Medicaid Directors (AMPAA–NASMD) recommended that States use WAC along with a well-designed maximum allowable cost program[21] as an interim alternative for AWP until a better option is developed.[22] According to AMPAA–NASMD, WAC should be only a temporary solution because it is practically impossible to audit, does not account for discounts and therefore does not reflect actual prices, and could be subject to inflation.

AAC. Two States (Alabama and Oregon) recently switched from an AWP-based reimbursement method to an AAC-based method. The first State to do so, Alabama, received CMS approval to implement a new methodology that uses AAC as the reimbursement benchmark for brand-name and generic drugs effective September 22, 2010.[23] To determine AAC, Alabama (through a contractor) requests that randomly selected pharmacies submit 1 month's worth of invoices semiannually. The State reviews these invoices and other applicable information to calculate AAC. CMS also approved Alabama's request to increase the dispensing fee from $5.40 to $10.64 per prescription. Alabama's Web site states that its AAC plan will establish a transparent, timely, and accurate pharmacy reimbursement system.

Effective January 1, 2011, CMS approved Oregon's State Plan Amendment to replace AWP with AAC in setting payment for Medicaid

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[21] States may develop maximum allowable cost programs to establish maximum reimbursement amounts for equivalent groups of multiple-source generic drugs.

[22] AMPAA–NASMD, *Post AWP Pharmacy Pricing and Reimbursement*. Accessed at http://hsd.aphsa.org on October 26, 2010.

[23] Alabama Medicaid Agency, *AAC Program Implementation*. Accessed at http://www.medicaid.state.al.us on October 25, 2010. In cases in which no AAC is available, reimbursement will be based on WAC plus 9.2 percent.

prescription drugs.[24] Similar to Alabama's new methodology, Oregon (through a contractor) will establish AAC by conducting rolling surveys of enrolled pharmacies to verify the actual invoice amount paid for a drug. Oregon is using a tiered per-prescription dispensing fee instead of a flat rate.

AMP. Section 1927(k)(1) of the Act, as amended by section 2503 of the Patient Protection and Affordable Care Act (ACA), P.L. 111-148, defines AMP as the average price paid to a manufacturer by wholesalers for drugs distributed to retail community pharmacies and by retail community pharmacies that purchase drugs directly from the manufacturer, with certain exclusions.

Manufacturers that enter into a Medicaid rebate agreement must report AMPs to CMS monthly and quarterly.[25] AMPs provided monthly are used to establish Federal upper limit amounts,[26] and AMPs provided quarterly are used primarily to calculate the rebate amounts owed to States under the Medicaid drug rebate program.[27]

The Deficit Reduction Act of 2005 (DRA), P.L. 109-171, required CMS to make AMP data available to all State Medicaid agencies.[28] This would have enabled States to use monthly AMP data when setting Medicaid reimbursement rates for prescription drugs. However, section 2503 of the ACA modified this requirement in a way that limits the AMP information available to States for reimbursement or other purposes.[29]

ASP. ASP is defined as a manufacturer's sales of a drug to all purchasers in the United States in a calendar quarter divided by the total number of drug units sold by the manufacturer in that same

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[24] Oregon Medicaid Agency, *State Plan Amendment,* Transmittal # 10-13. Accessed at http://www.oregon.gov on January 19, 2011.

[25] Section 1927(b)(3) of the Act.

[26] Section 2503(a)(1)(B) of ACA.

[27] Section 1927(c)(1)(A) of the Act.

[28] Section 6001 of the DRA required that CMS provide States with AMP data. Although the DRA did not require States to use AMP data in determining reimbursement, the dissemination of AMP data would have provided States with a new source for establishing estimated acquisition cost.

[29] The ACA requires CMS to publish weighted AMPs for certain multiple-source drugs, instead of publishing AMPs for all drugs.

quarter, net of any discounts.[30] Certain sales are exempt from the calculation of ASP, including sales at a nominal charge. Manufacturers report ASP data to CMS quarterly, with submissions due 30 days after the close of the quarter.[31]

As of January 2005, CMS replaced AWP with ASP as the basis for determining reimbursement for most drugs covered under Medicare Part B.[32] Manufacturers report ASPs to CMS only for certain drugs covered under Part B, which represent a limited subset of prescription drugs covered under Medicaid. The Medicare Part B payment amounts for these drugs are generally 106 percent of ASP.[33]

Previous OIG Work on AWP

OIG has produced a significant amount of work demonstrating that the AWPs States use to estimate acquisition costs often overstate the prices retail pharmacies pay to purchase drugs. This has resulted in inflated reimbursement rates and has led to excessive Medicaid expenditures for prescription drugs.[34] Prior OIG reports concluded that the reliance on manufacturer-reported AWPs as a basis for drug reimbursement is fundamentally flawed and that AWPs exceed other pricing points.[35] OIG has also repeatedly recommended that CMS work with Congress to set Medicaid drug reimbursement amounts that more closely approximate pharmacy acquisition costs.[36] CMS concurred with these recommendations and stated that OIG's reports make clear that current

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[30] Section 1847A(c) of the Act, as added by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), P.L. 108-173.

[31] Section 1927(b)(3) of the Act.

[32] Sections 303(b) and 305(a) of the MMA.

[33] Section 1847A(b)(1) of the Act.

[34] For example, see *Medicaid's Use of Revised Average Wholesale Prices* (OEI-03-01-00010), September 2001.

[35] For example, see *Medicaid Drug Price Comparisons: Average Manufacturer Price to Published Prices* (OEI-05-05-00240), June 2005; *Medicaid Drug Price Comparison: Average Sales Price to Average Wholesale Price* (OEI-03-05-00200), June 2005; or *Medicaid's Use of Revised Average Wholesale Prices* (OEI-03-01-00010), September 2001.

[36] For example, see *Comparison of Medicaid Federal Upper Limit Amounts to Average Manufacturer Prices* (OEI-03-05-00110), June 2005; *Variation in State Medicaid Drug Prices* (OEI-05-02-00681), September 2004; *Cost Containment of Medicaid HIV/AIDS Drug Expenditures* (OEI-05-99-00611), July 2001; or *Medicaid Pharmacy – Additional Analyses of the Actual Acquisition Cost of Prescription Drug Products* (A-06-02-00041), September 2002.

Medicaid payment rules result in overpayments for drugs and emphasize the need for reform. Although systemwide reforms were explored in 2004 and 2005 through congressional hearings[37] and proposed in the President's 2006 budget, many States continue to use AWP as their primary method for setting reimbursement.

Ongoing Work Involving AWP

OIG is conducting an audit that will collect pharmacy invoice data for selected drugs. The purpose of the audit is to determine pharmacies' actual acquisition costs and then to compare them to other benchmarks, such as AWPs, WACs, and AMPs. The audit will provide pricing data that can help States assess the various benchmarks that could be used when establishing Medicaid reimbursement methodologies for prescription drugs.

METHODOLOGY

Data Collection

In January 2011, we emailed online surveys to pharmacy program administrators at the 51 State Medicaid agencies and received complete responses from all.[38] We also interviewed CMS staff in February 2011.

Medicaid reimbursement survey. In the survey, we asked States to describe their reimbursement methodologies for Medicaid prescription drugs in the first quarter of 2011. We also asked States to report the sources of the data used to determine reimbursement during that quarter (e.g., First DataBank).

To assess the effect of First DataBank's ceasing publication of AWPs, we first asked States that use AWP as the basis for reimbursement whether they intended to continue using it. If States intended to continue using AWP, we asked what publishing company they would obtain these data from and whether they intend to use AWP in the long term. If the States did not intend to continue using AWP, we asked that they describe the changes they had made or anticipate making to their

[37] For example, see *Medicaid Prescription Drug Reimbursement: Why the Government Pays Too Much*, House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, 108th Congress (2004).

[38] This includes the 50 States and the District of Columbia.

reimbursement methodologies. These States were asked to provide the benchmark they intend to use to estimate acquisition cost, the actions necessary for implementation, and the expected date of implementation.

We also asked all States to describe the role they would prefer CMS to play in developing Medicaid reimbursement methodologies and whether States would prefer that CMS develop a single national benchmark.

Interview with CMS. We asked staff from CMS's Center for Medicaid, Children's Health Insurance Programs and Survey & Certification (CMCS)[39] whether the agency has provided guidance to all States in regard to First DataBank's ceasing publication of AWPs. If so, we asked that they provide us with copies of this guidance and the date it was released. In addition, we asked whether individual States had contacted CMS with concerns about this topic. We asked whether CMS intends to provide guidance to all States about AWP issues and Medicaid reimbursement and, if so, to describe it.

Data Analysis

States' reimbursement methodologies. We reviewed States' responses to the surveys and determined that 45 States had AWP-based reimbursement methodologies in the first quarter of 2011 (either alone or in combination with other pricing points, such as WAC) and 37 of these States obtained AWP information from First DataBank in that quarter. Of the six States that did not use AWP as a basis for reimbursement, four usually used WAC (Rhode Island, Massachusetts, North Carolina, and Ohio) and two had recently switched from AWP to AAC (Alabama and Oregon).

For the 45 States that reported using AWP-based reimbursement methodologies in the first quarter of 2011, we analyzed descriptions about any changes to their methodologies in relation to First DataBank and AWP. We determined the number of States that (1) were unsure about their plans to replace AWP, (2) intended to replace AWP with other benchmarks, or (3) intended to continue using AWP. We further analyzed the effect First DataBank's ceasing publication of AWPs may

[39] CMCS performs many functions such as assisting States with improving the quality of their Medicaid operations, and identifying and proposing modifications to Medicaid program measures, regulations, laws, and policies.

have on reimbursement methodologies by calculating the number of States within each of the three groups that had obtained AWPs from First DataBank in the first quarter of 2011.

If a State was unsure about its plans to continue using AWP, we reviewed its responses to other survey questions to gain a better perspective of how the State would likely proceed. For example, we reviewed answers about whether a new source for AWP had been considered and whether the State had begun to develop plans for a new methodology.

If the State did not intend to continue using AWP, we reviewed State responses to determine the benchmark that would be used to replace AWP, the reasons for selecting the new benchmark, and when the new methodology might be implemented.

For States that intend to continue using an AWP-based reimbursement methodology, we determined whether they had selected a publishing company to use in obtaining AWP, and if so, which source was selected. We also determined whether the States intend to use AWP in the long term.

CMS's role in AWP issues. We reviewed responses from CMS staff to determine whether the agency has provided guidance (or intends to provide guidance) to all States in regard to AWP issues. We also determined whether individual States had contacted CMS with questions about the future of Medicaid reimbursement after AWPs are no longer available from First DataBank. In conjunction with the CMS interview, we reviewed States' responses about the role they would like CMS to play in regard to this topic. We calculated the number of States that would prefer CMS to develop one national benchmark to set Medicaid reimbursement.

Limitations

Our findings are based on self-reported survey responses of State Medicaid agencies. We did not verify their accuracy. Responses were current as of February 2011; therefore, how States intend to pay for prescription drugs may have changed after that date.

Standards

This study was conducted in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

Twenty States had not developed any definitive plans for prescription drug reimbursement after First DataBank stops publishing AWPs

Twenty of the forty-five States that used AWP to set reimbursement for Medicaid prescription drugs in the first quarter of 2011 had not made any definitive plans regarding reimbursement for Medicaid prescription drugs after September 2011. These 20 States were among the 37 that obtained AWPs from First DataBank in the first quarter of 2011. As a result, in an extremely short timespan, all 20 States will need to either contract with a new publishing company to obtain AWP data or implement new reimbursement methodologies that do not rely on AWPs.

Eight of the twenty States were unsure about nearly every aspect of their post-September 2011 reimbursement plans. These eight States had not decided whether they will continue to use AWP (from another source) or instead select another benchmark. The remaining 12 States were able to provide some detail about their reimbursement plans. Six States intend to discontinue using AWP but had not yet taken any steps to select a new benchmark, three States intend to continue using AWP but had not selected the publishing source for AWP data,[40] and three States are considering plans to either use AWP from another source or replace AWP with WAC.

Fifteen States have relatively well-developed plans to move away from AWP-based reimbursement

In total, 15 of the 45 States that used AWP in determining reimbursement for Medicaid prescription drugs in the first quarter of 2011 have relatively well-developed plans to implement new methodologies that replace AWP with another benchmark.[41] Thirteen of these fifteen States were among the 37 that used AWP data from First DataBank in the first quarter of 2011. In addition, two States that had

[40] One of these States noted that it is using AWP as a contingency plan until it can incorporate CMS-published prices, such as AMP or actual acquisition cost.

[41] We considered a State to have a relatively well-developed plan if it could provide details about how drugs would be reimbursed after First DataBank stops publishing AWPs (e.g., the benchmark that would be used to replace AWP).

obtained AWP from a source other than First DataBank in the first quarter of 2011 still intend to replace AWP.

Three of the fifteen States plan to replace AWP with acquisition cost

Three States are developing new reimbursement methodologies that use acquisition cost obtained through pharmacy surveys.[42, 43] Two of these States had used First DataBank and the third State had used Medi-Span to obtain AWPs in the first quarter of 2011. Of the States using First DataBank, one has collected the pharmacy data needed to calculate AAC and hopes to use these data in calculating Medicaid reimbursement in the third quarter of 2011; the other State has proposed legislative changes and intends to complete a pharmacy acquisition cost survey. The State that obtained AWP from Medi-Span has drafted a preliminary reimbursement plan to use AAC.

Twelve of the fifteen States plan to replace AWP with WAC

Twelve States intend to use WAC to determine Medicaid reimbursement amounts after AWPs are no longer available from First DataBank.[44] The factors these States considered when selecting WAC as the new benchmark included its budget neutrality and availability. All but one of these States had obtained AWPs from First DataBank in the first quarter of 2011.

Three of the 12 States already included WAC as a reimbursement option (in addition to AWP) prior to the first quarter of 2011.[45] These three States intend to eliminate the AWP option from their methodologies once First DataBank stops AWP publication and instead use WAC exclusively. Among the remaining nine States, three did not have a set date for implementing the new WAC-based methodologies

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[42] In addition to these three States, Alabama and Oregon implemented reimbursement methodologies that replaced AWP with AAC in September 2010 and January 2011, respectively.

[43] Based on online reports, one of these States no longer intends to implement an AAC-based reimbursement method. Accessed at http://www.drugchannels.net on April 13, 2011.

[44] This is in addition to the four States (Rhode Island, Massachusetts, North Carolina, and Ohio) that did not have AWP-based reimbursement methodologies in the first quarter of 2011 and were using WAC exclusively.

[45] Two of the States had added the WAC option in December 2010; the remaining State has included WAC and AWP in its reimbursement plan since 2003.

and six provided tentative dates that ranged from July 2011 to "late" 2011.

Ten States will continue using AWP to set reimbursement, at least in the short term

Ten of the forty-five States that used AWP to set reimbursement for Medicaid prescription drugs in the first quarter of 2011 plan to continue using the benchmark after September 2011. Among these 10 States, 4 had obtained AWPs from First DataBank in the first quarter of 2011 and now plan to obtain AWP data from another source (Medi-Span and/or Micromedex). The other six States were already getting the data from one of these other sources.

However, only 1 of the 10 States was certain it would use AWP to calculate reimbursement in the long term.[46] The remaining nine States were either unsure whether they would use AWP as a long-term method (six States) or reported that they would use AWP as an interim plan until a new benchmark was selected (three States).

Forty-four States would like CMS to develop a national benchmark to set Medicaid reimbursement for prescription drugs

Most States (44 of 51) wanted CMS to develop a single national benchmark to set Medicaid reimbursement rates. Almost half of States (24) specified that they wanted a benchmark based on pharmacy acquisition costs (the majority of the remaining States did not specify a preferred benchmark). One State mentioned that CMS would have less of a challenge obtaining access to acquisition cost data than would individual States. In addition, if CMS obtained acquisition cost data, that would relieve States of the need for and expense of conducting an acquisition cost survey on their own. Certain States also mentioned that the acquisition cost benchmark should be updated frequently and consider regional (urban or rural) differences and pharmacy-type differences (e.g., chain, independent, specialty).

Among the seven States that did not want CMS to develop a national benchmark, the majority (four) had plans to continue using AWP (two had obtained AWPs from First DataBank and two from Medi-Span in the first quarter of 2011). Of the remaining States, one had already

[46] We did not provide States with a definition for what constitutes a long-term plan.

switched from AWP to an AAC-based reimbursement method, one intended to switch to a WAC-based reimbursement method, and one did not have definitive reimbursement plans after First DataBank stops publishing AWPs.

CMS is taking steps to address the AWP issue and plans to provide guidance in the future

Our interview with CMS staff in February 2011 indicated that the agency had not yet provided uniform guidance to all States about options for Medicaid reimbursement after AWPs are no longer available from First DataBank. However, CMS intends to provide guidance about this topic in the future. CMS stated that although the agency does not mandate that a specific formula or methodology be used for reimbursement, it plans to conduct a nationwide survey to collect retail community pharmacy prices for drugs[47] (including acquisition costs) and intends to discuss the results and other options for States in future guidance and/or proposed rulemaking. In addition, when individual States contacted CMS about whether it plans to provide a new reference price that reflects pharmacy acquisition costs, CMS responded that it will make the data derived from this survey publicly available.[48] When complete, these data would provide States with an additional benchmark option that reflects actual cost.

[47] As described in section 6001(e) of the DRA.

[48] CMS, Statement of Work, *Survey of Retail Prices; Payment and Utilization Rates; and Performance Rankings.* Accessed at http://www.fbo.gov on February 22, 2011.

RECOMMENDATION

To ensure that Medicaid pays appropriately for prescription drugs, any reimbursement methodology must be based on benchmarks that are accurate and reliable estimates of pharmacy acquisition costs. As of the first quarter of 2011, the majority of States used AWP data obtained from First DataBank as the primary benchmark. Several OIG reports have shown that the inflated nature of AWPs causes Medicaid to pay too much for certain drugs, and as a result, we recommended that CMS work with States and Congress to base payments on a benchmark that more accurately reflects pharmacy acquisition costs. Regardless, many States continue to use AWPs to set drug reimbursement amounts.

First DataBank will stop publishing AWPs no later than September 26, 2011. This has forced many States to reevaluate how they will pay for prescription drugs after that date and presents States with the opportunity to move to new reimbursement methodologies that would better reflect pharmacy acquisition costs. However, many States are not fully prepared to implement new reimbursement methodologies at this time. As a result, they will need to develop, obtain CMS approval for, and implement new reimbursement methodologies in an extremely limited timeframe. In addition, a number of States will either begin or continue to base reimbursement on WAC, a manufacturer-reported benchmark that, like AWP, is not based on actual sales transactions.

States overwhelmingly would prefer that CMS, to address the uncertainty surrounding drug reimbursement decisions, develop a national benchmark to set reimbursement. A national benchmark that reflects actual pharmacy acquisition costs would eliminate States' reliance on the inflated published prices that cause Medicaid and its beneficiaries to pay too much for certain drugs. A CMS-developed national benchmark may also be more efficient and cost-effective than having 51 State Medicaid agencies individually collecting acquisition cost data from pharmacies. Therefore, we recommend that CMS:

Develop a national benchmark that accurately estimates acquisition cost and encourage States to consider it when determining Medicaid reimbursement for prescription drugs

A CMS contractor plans to administer a survey to collect monthly pharmacy pricing data, including acquisition costs. Using the data gathered in this survey, CMS should develop a national benchmark that reflects pharmacy acquisition costs (by the fourth quarter of 2011, if

possible), giving States an additional option to use in setting Medicaid reimbursement for prescription drugs. Among other things, this benchmark should account for differences in the types and the geographical locations of pharmacies. After the national benchmark is provided to States, CMS should update it frequently to reflect price changes in the market. In addition, with the implementation of any new methodology based on this benchmark, CMS should ask States to review their dispensing fees to ensure that payment levels for pharmacies are fair and appropriate.

Although we recognize that CMS currently does not mandate the method States use to set reimbursement rates, we believe CMS should encourage all States to adopt the national benchmark. According to our survey, States are looking to CMS for guidance in setting a benchmark and would welcome one based on actual pharmacy acquisition costs. This benchmark would have the potential to streamline Medicaid reimbursement systems; provide a transparent basis for payment; and, if applied appropriately, significantly reduce Medicaid payment amounts for prescription drugs.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS concurred with our recommendation. CMS stated that it is contracting with a vendor to develop a survey of retail prices and acquisition cost information. CMS expects the survey will provide the ingredient costs of all covered outpatient drugs purchased by retail community pharmacies, including independent community pharmacies, chain pharmacies, and specialty pharmacies. CMS expects to use these data to develop an estimate of AAC. CMS also stated that it intends to include external stakeholders in this process to ensure that there is transparency with the AAC determination and that the methodology is implemented appropriately.

We did not make any changes to the report based on CMS's comments. For the full text of CMS's comments, see Appendix A.

APPENDIX ~ A

Agency Comments

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: JUN 0 8 2011

TO: Daniel R. Levinson
Inspector General

FROM: Donald M. Berwick, M.D. /S/
Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: "Replacing Average Wholesale Price: Medicaid Drug Payment Policy," (OEI-03-11-00060)

Thank you for the opportunity to review and comment on the OIG Draft Report entitled "Replacing Average Wholesale Price: Medicaid Drug Payment Policy" (OEI-03-11-00060). The OIG surveyed all 50 States and the District of Columbia to determine how States will set reimbursement for Medicaid prescription drugs after First DataBank stops publishing average wholesale prices (AWP) in September 2011, and to determine the role that States would prefer the Centers for Medicare & Medicaid Services (CMS) to play in developing Medicaid reimbursement methodologies for prescription drugs.

The OIG found that of the 45 States with an AWP-based reimbursement methodology in the first quarter of 2011, 20 States had not developed any definitive plans for prescription drug reimbursement after First DataBank stops publishing AWPs. The OIG also reported that 15 States have relatively well-developed plans to move away from AWP-based reimbursement. Finally, the OIG reported that there were 10 States that stated they would continue using AWP to set reimbursement after First DataBank ceases to publish these rates. Four of the 10 States were receiving AWP from First DataBank, and have now made plans to obtain AWP data from another source (Medi-Span and/or Micromedex).

In addition, the OIG learned that 44 States would like CMS to develop a national benchmark to use in setting Medicaid reimbursement for prescription drugs.

OIG Recommendation

CMS should develop a national benchmark that accurately estimates acquisition cost and encourage States to consider it when determining Medicaid reimbursement for prescription drugs.

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CMS Response

The CMS concurs regarding the need for a national benchmark, which could be considered by States to accurately determine payment rates for Medicaid covered-outpatient drugs. CMS is currently in the process of contracting with a vendor to develop a survey of retail survey prices and acquisition cost information.

We expect that this survey will provide for the ingredient costs of all covered outpatient drugs purchased by retail community pharmacies, which we expect will include purchase prices derived from independent community pharmacies, chain pharmacies, and specialty pharmacies. We also expect that the prices will be updated on at least a monthly basis. We expect to develop an average acquisition cost (AAC) using the data developed in this survey.

The CMS intends to include external stakeholders, including the OIG, to ensure that the methodology is implemented appropriately and to assure that there is transparency and input on the AAC determination process.

The CMS would again like to thank the OIG for their efforts in reviewing the States' plans for payment methodology for prescription drugs after AWP ceases to be published by First DataBank, and for determining the role that States prefer CMS to play in developing a national benchmark for Medicaid prescription drug reimbursement. We look forward to working with the OIG on this and other issues in the future.

ACKNOWLEDGMENTS

This report was prepared under the direction of Robert A. Vito, Regional Inspector General for Evaluation and Inspections in the Philadelphia regional office, and David E. Tawes, Director of the Medicare and Medicaid Prescription Drug Unit.

Stephanie Yeager served as the team leader for this study. Central office staff who contributed include Kevin Manley.

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