Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

STATES' USE OF NEW DRUG PRICING DATA IN THE MEDICAID PROGRAM

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Inspector General

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Office of Inspector General

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OBJECTIVE

To provide an early assessment of whether States are considering using new pricing data for Medicaid prescription drug reimbursement.

BACKGROUND

All States and the District of Columbia offer prescription drug coverage under Medicaid. In 2005, Federal and State expenditures for prescription drugs in the Medicaid program reached $41 billion.

Pursuant to the Deficit Reduction Act of 2005 (DRA), the Centers for Medicare & Medicaid Services (CMS) is providing States with sales-based drug pricing information that was previously not available for their use. Recent studies have found that published prices, such as average wholesale price and wholesale acquisition cost used by States to estimate drug acquisition costs, are higher than prices based on actual sales transactions. In July 2006, CMS began sending States average manufacturer price (AMP) data monthly. CMS will also provide retail sales price (RSP) data to States starting in early 2007. However, the DRA does not require States to use AMP or RSP data to revise their current Medicaid drug reimbursement formulas. Pursuant to the DRA, CMS must promulgate a regulation that clarifies AMP requirements by July 1, 2007.[1]

To assess whether States are considering using new pricing data for Medicaid prescription drug reimbursement, we surveyed Medicaid pharmacy directors in all 50 States and the District of Columbia. We asked States whether they are planning to use AMP and/or RSP data for Medicaid drug reimbursement. We also asked States to describe any factors that are influencing their decisions and indicate what additional information they would like to receive before deciding whether to use the new drug pricing data. Forty-seven States completed the survey.

FINDINGS

Most States have not decided whether to use AMP data for Medicaid drug reimbursement. Thirty-nine of forty-seven States have not decided whether to use AMP data for Medicaid drug reimbursement. Of the remaining eight States, four are planning to use AMP data for

[1] Deficit Reduction Act of 2005, section 6001(c)(3)(B).

Medicaid drug reimbursement but have not yet implemented changes. Another three States do not plan to use AMP data. One State indicated that it is using AMP data to help determine maximum allowable costs (MAC) for most drug products under its MAC program.

States raised concerns about the AMP data received from CMS. States described inconsistencies between the AMP amounts provided by CMS and the typical unit definition of the associated drug products. In addition, some States reported that several drug products in CMS's data file did not have associated AMPs, that there were both unusually high and low values (outliers) in the data, or that the AMP data seemed unrelated to pharmacy acquisition costs. States also questioned whether the vendors that already provide them with drug pricing information for claims processing would have access to AMP data.

States that are undecided about using the AMP would like assurances from CMS that the AMP data are accurate and valid. States are anticipating CMS's final regulations to clearly explain how the AMP will be defined and calculated, including how the AMP would take into account price differences among different pharmacy types within the retail pharmacy class of trade.

Few States have decided whether to use RSP data for Medicaid drug reimbursement. Of the 47 States, 1 indicated that it plans to use RSP data and 3 indicated that they do not. The remaining 43 States have not decided whether to use RSP data.

States had many of the same concerns regarding RSP data that they had with AMP data and want assurances that RSP data will be valid and accurate. States also want to know how RSP data will be determined and defined, how RSP data will be collected, what geographic areas the RSP data will represent, and how RSP data will compare to other pricing data.

RECOMMENDATIONS

Pursuant to the DRA, CMS must promulgate regulations clarifying the requirements for the AMP. In a May 2006 report, mandated by the DRA, the Office of Inspector General made recommendations to CMS regarding the clarification of AMP definitions and the issuance of guidance to the States regarding the AMP-related reimbursement provisions of the DRA.

In this study, we conducted an early assessment of whether States are considering using new pricing data for Medicaid prescription drug reimbursement. Overall, many States have not decided whether they will use either AMP or RSP data for Medicaid drug reimbursement. States reported that AMP and RSP data must be accurate, reliable, and accessible if they are to use these data in their Medicaid prescription drug programs.

To ensure this, CMS should:

Explicitly detail AMP's definition and calculation, including the definition of retail pharmacy class of trade, when promulgating final regulations regarding the AMP. Consistent with our previous recommendations, States' concerns about how the AMP will take into account different types of pharmacies reinforce the need for CMS to clarify requirements in regard to the definition of retail pharmacy class of trade.

Furnish States with interim guidance and/or information regarding AMP data. We continue to recommend that CMS issue guidance to States that addresses AMP-related reimbursement provisions of the DRA. More specifically, based on the concerns raised by States in this review, we recommend that CMS provide States with the unit definition for drug products in AMP files distributed to States. In addition, before the final regulations are published, CMS should work with States to address their concerns regarding whether and how data would be provided to their vendors for incorporation into their pricing and claims processing systems.

Explicitly detail RSP's definition, calculation, and method of collection when distributing RSP data to States. CMS should detail whether and how it will take into account differences in prices among pharmacy types and within various geographical areas when determining RSPs.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS generally agreed with our recommendations and has taken several steps toward addressing them. CMS published a proposed regulation on December 22, 2006, addressing the definition, calculation, and method of collection for the AMP and reported that it will also address these issues when it promulgates the final regulations. CMS also provided guidance to State Medicaid directors on December 15, 2006; however, the guidance does not address the States' concerns regarding whether

and how the new pricing data could be provided to their vendors for incorporation into their pricing and claims processing systems. We continue to recommend that CMS provide this information to States as they consider the use of the new drug prices. CMS stated that unit definitions for AMPs are available on its Web site; however, we recommend incorporating this information in the AMP data file to make the file a more effective and efficient tool for States.

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INTRODUCTION

OBJECTIVE

To provide an early assessment of whether States are considering using new pricing data for Medicaid prescription drug reimbursement.

BACKGROUND

Pursuant to the Deficit Reduction Act of 2005 (DRA), the Centers for Medicare & Medicaid Services (CMS) is providing States with sales-based drug pricing information that was previously not available for their use. Recent studies have found that published prices, such as average wholesale price and wholesale acquisition cost used by States to estimate drug acquisition costs, are higher than prices based on actual sales transactions. In July 2006, CMS began sending States average manufacturer price (AMP) data monthly. CMS will also provide retail sales price (RSP) data to States starting in early 2007. There is the potential that States could reduce Medicaid drug expenditures by incorporating the new drug pricing data into their reimbursement formulas. This study provides an early look at whether States are considering using the new pricing data and it identifies potential barriers to States' use of the new drug pricing data for Medicaid drug reimbursement.

State Drug Reimbursement Methodologies

All States and the District of Columbia offer prescription drug coverage under the Medicaid program (throughout the report, the District of Columbia will be referred to as a State). Medicaid prescription drugs are generally dispensed to beneficiaries through pharmacies that are then reimbursed for the drugs by State Medicaid agencies. In 2005, Federal and State expenditures for prescription drugs in the Medicaid program reached $41 billion.[2]

Federal regulations require, with certain exceptions, that States reimburse Medicaid prescription drugs in the aggregate at rates that do not exceed the lower of (1) the estimated acquisition cost plus reasonable dispensing fees, or (2) the provider's usual and customary

[2] Calculated using national summary data for 2005. Available online at http://www.cms.hhs.gov/MedicaidDrugRebateProgram/SDUD/list.asp. Accessed on October 30, 2006.

charge to the public for the drug.[3] The regulations define estimated acquisition cost to be the State's "best estimate" of the price generally and currently paid by providers for the drug.[4] States have flexibility in determining what will constitute an estimated acquisition cost for their Medicaid program. Most States currently use the average wholesale price (AWP) discounted by a specified percentage to determine estimated acquisition cost. Fewer States use wholesale acquisition cost (WAC) plus a markup percentage.[5] The AWP and the WAC are drug prices that are published in compendia produced by private companies.

There are several cost containment programs in place that impact Medicaid drug spending. For example, the Federal Upper Limit (FUL) program was established to ensure that the Government is a prudent purchaser of Medicaid prescription drugs.[6] Under the FUL program, at the time of our review, reimbursement for drugs that have at least three therapeutically equivalent drugs available was capped so that each drug is reimbursed at 150 percent of the published price for the lowest cost equivalent drug.[7] States are required to meet the FUL requirements only in the aggregate. Therefore, a State can pay more than the FUL amount for certain products as long as it pays less than the FUL amount for other products. States may also establish Maximum Allowable Cost (MAC) programs that stipulate maximum drug prices for Medicaid reimbursement. Compared to the FUL program, States generally have more latitude in determining which drugs to include in their MAC programs and at what prices to set MACs. As of fiscal year 2006, 32 States reported having MAC programs in place to help contain their Medicaid drug costs.[8]

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[3] 42 CFR § 447.331(b). In December 2006, CMS issued a proposed regulation that removes 42 CFR § 447.331 but includes the substance of that section in a new section designated as 42 CFR § 447.512.

[4] 42 CFR § 447.301. In the December 2006 proposed regulation, this definition is included in a new section designated as 42 CFR § 447.502.

[5] "Medicaid Prescription Reimbursement Information by State – Quarter Ending September 2006." Available online at http://www.cms.hhs.gov/MedicaidDrugRebateProgram/Downloads/RxReimbursementRateSeptember2006Qtr.pdf. Accessed October 16, 2006.

[6] State Medicaid Manual, section 6305.1.

[7] Section 1927(e)(4) of the Social Security Act and 42 CFR § 447.332.

[8] "Low Medicaid Spending Growth Amid Rebounding State Revenues," The Kaiser Commission on Medicaid and the Uninsured. Available online at http://www.kff.org/medicaid/upload/7569.pdf. Accessed October 10, 2006.

The dispensing fees that States pay in addition to estimated acquisition cost currently range from approximately $2 per prescription to $12.50 per prescription.[9]

The Deficit Reduction Act and Medicaid Drug Prices

Enacted in February 2006, the DRA contains several provisions that impact Medicaid reimbursement for prescription drugs. Pursuant to the DRA, AMP and RSP data are to be made available to States for their use in Medicaid drug reimbursement. Furthermore, the DRA modifies the way FULs for Medicaid drugs will be calculated.

Average Manufacturer Prices. Sections 1927(a)(1) and (b)(1) of the Social Security Act (the Act) mandate that for Federal payment to be available for covered outpatient drugs provided under Medicaid, drug manufacturers enter into rebate agreements with the Secretary of the Department of Health and Human Services (HHS) and pay quarterly rebates to State Medicaid agencies. Under these rebate agreements and pursuant to section 1927(b)(3) of the Act, manufacturers must provide CMS with the AMP for each of their covered outpatient drugs by the national drug code (NDC). Pursuant to section 1927(b)(3)(A) of the Act, manufacturers must report AMP data no later than 30 days after the last day of the rebate period. Before the passage of the DRA, CMS did not provide AMP data to States. Although the DRA does not require States to use AMP data in their Medicaid drug reimbursement formulas, the dissemination of AMP data to States in accordance with the DRA would provide States with a new source of pricing data for establishing estimated acquisition cost.

AMP data are based on actual sales transactions and, during the time of our review, was defined as the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade, after deducting customary prompt pay discounts.[10] The AMP is calculated as a weighted average of all prices for all of a manufacturer's package sizes of a covered outpatient

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[9] This range excludes dispensing fees for home IV therapy. "Medicaid Prescription Reimbursement Information by State – Quarter Ending September 2006." Available online at http://www.cms.hhs.gov/MedicaidDrugRebateProgram/Downloads/RxReimbursementRateSeptember2006 Qtr.pdf. Accessed October 16, 2006.

[10] Section 1927(k)(1) of the Act. The DRA (section 6001(c)(1)(C)) modified the AMP definition effective January 1, 2007, and requires that AMP calculations be determined without regard to customary prompt pay discounts extended to wholesalers.

drug sold during a given time period and is reported for the lowest identifiable unit of the drug (e.g., 1 milligram, 1 milliliter, 1 tablet, 1 capsule).

Section 6001(b) of the DRA mandates that CMS share AMP data with States on a monthly basis beginning in July 2006. As required by the DRA, CMS sent AMP data in compact disc (CD) format to States on July 5, 2006.[11] According to CMS staff, AMP data will be provided to the States on an ongoing basis by the 12th of each month.

The DRA also mandated that the HHS Office of Inspector General (OIG) review and report on the requirements for, and the manner in which, AMPs are determined under the Act and recommend appropriate changes to the Secretary of HHS (hereafter referred to as the Secretary) and Congress.[12] Pursuant to the DRA, after considering OIG's findings and recommendations, the Secretary must promulgate a regulation that clarifies AMP requirements by July 1, 2007.[13] CMS issued a proposed regulation addressing AMP and other issues in December 2006.

In May 2006, CMS noted pharmacists' concerns that AMP data need to consistently include prices available to the retail pharmacy class of trade before they are used as reference points in setting pharmacy reimbursement. CMS also noted that "the more specific definition of AMP" that is to be included in the forthcoming regulation is not reflected in the current AMP data. CMS stated that it will release certain AMP data as the DRA mandates, but only to help States "set up their billing systems appropriately and not for the purposes of setting reimbursements."[14]

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[11] The following disclosure was printed on each CD sent to States, "Section 1927(b)(3)(D) of the Social Security Act requires that, notwithstanding any other provision of law, these AMPs be kept confidential and shall not be disclosed by a State agency (or contractor therewith) in a form which discloses the identity of the manufacturer or any prices charged for drugs by that manufacturer. States are restricted from disseminating, distributing, or using AMP data, except as specifically authorized by the drug rebate statute."

[12] Deficit Reduction Act of 2005, section 6001(c)(3)(A). In May 2006, OIG issued a report, "Determining Average Manufacturer Prices for Prescription Drugs Under the Deficit Reduction Act of 2005" (A-06-06-00063).

[13] Deficit Reduction Act of 2005, section 6001(c)(3)(B).

[14] "National Community Pharmacists Association's (NCPA) 38th Legislation and Government Conference, Remarks of Mark B. McClellan, MD, Ph.D., as delivered to the NCPA 38th Legislation and Government Conference, May 22, 2006." Available online at http://www.cms.hhs.gov/apps/media/press/speech.asp?Counter=1866. Accessed July 26, 2006.

Retail Sales Prices. Section 6001(f) of the DRA also contains provisions on the collection and dissemination of RSPs to States. These provisions state that the Secretary is permitted to contract with a vendor to collect information on RSPs that represent a nationwide average of consumer purchase prices, net of all discounts and rebates (to the extent information on discounts and rebates is available) for Medicaid covered outpatient drugs.[15] This vendor will provide RSP data to the Secretary on a monthly basis. According to CMS staff, the vendor was selected and a kickoff meeting was held on October 5, 2006. Furthermore, the DRA directs the Secretary to provide a means for States to access RSP data on at least a monthly basis.[16] CMS staff expect that RSP data will be made available to States by January or February 2007.

As outlined in section 6001(f)(3) of the DRA, the Secretary is to compare RSP data to Medicaid price data for the 50 most widely prescribed Medicaid outpatient drugs by State. The Secretary is also to ensure that annual reports on these rankings are available for review by Congress and the States. The vendor will also produce these annual reports and provide them to CMS starting in March 2008.[17]

Changes to the Federal Upper Limit. Pursuant to the DRA, the FUL for multiple source drugs will be based on 250 percent of the AMP (instead of 150 percent of the lowest published price) for the least costly therapeutic equivalent effective January 1, 2007.[18] The DRA also requires that at that time Medicaid drugs have two therapeutic equivalents (instead of three) to be included on the FUL list.[19]

Related Office of Inspector General Work

Average Manufacturer Prices and the Deficit Reduction Act. Pursuant to DRA requirements, OIG released a report in May 2006, "Determining Average Manufacturer Prices for Prescription Drugs Under the Deficit Reduction Act of 2005" (A-06-06-00063), which concluded, among other things, that manufacturers' methods of calculating AMPs were inconsistent. Specifically, the report found that manufacturers did not consistently define the retail pharmacy class of trade when compiling

[15] Deficit Reduction Act of 2005, section 6001(f)(1).

[16] Deficit Reduction Act of 2005, section 6001(f)(1)(E).

[17] The planned timeframe of these annual reports is specified in CMS's request for proposals, "Survey of Retail Prices; Payment and Utilization Rates; and Performance Rankings" (RFP-CMS-2006-0010ERD).

[18] Deficit Reduction Act of 2005, section 6001(a).

[19] Ibid.

AMP calculations. OIG recommended that the Secretary direct CMS, in promulgating AMP regulation, to clarify requirements in regard to the definition of retail pharmacy class of trade and the treatment of pharmacy benefit manager rebates and Medicaid sales and to consider addressing issues raised by industry groups. OIG also recommended that the Secretary direct CMS to issue, in the near future, guidance that specifically addresses the implementation of the AMP-related reimbursement provisions of the DRA and encourage States to analyze the relationship between AMPs and pharmacy acquisition costs to ensure that the Medicaid program appropriately reimburses pharmacies for estimated acquisition costs.

Published Prices and Sales-Based Prices. Previous OIG work shows that Medicaid reimbursement for prescription drugs often exceeds actual pharmacy drug acquisition costs.[20] In addition, more recent studies have found that published prices (i.e., AWP and WAC) used by States to estimate drug acquisition costs are higher than prices based on actual sales transactions.[21] Specifically, one OIG report found that the AMP is 59 percent lower than the AWP at the median and 25 percent lower than the WAC at the median.[22] The report also found that the difference between the AMP and published prices currently used by States is even more pronounced for generic drugs, for which the AMP is 70 percent lower than the AWP at the median.

METHODOLOGY

Scope and Data Source

To determine whether States are planning to use the new pricing data for Medicaid drug reimbursement, we surveyed Medicaid pharmacy directors in all 51 States.

Data Collection and Analysis

A survey was e-mailed to State Medicaid pharmacy directors on September 7, 2006, and data collection was completed on October 3,

[20] "Medicaid Pharmacy – Additional Analyses of the Actual Acquisition Cost of Prescription Drug Products" (A-06-02-00041, September 2002).

[21] "Medicaid Drug Price Comparison: Average Sales Price to Average Wholesale Price" (OEI-03-05-00200, June 2005) and "Medicaid Drug Price Comparisons: Average Manufacturer Price to Published Prices" (OEI-05-05-00240, June 2005).

[22] "Medicaid Drug Price Comparisons: Average Manufacturer Price to Published Prices" (OEI-05-05-00240, June 2005).

2006. Forty-seven pharmacy directors completed the survey, for a response rate of 92 percent.

State pharmacy directors were asked about their review of the AMP data provided by CMS, including whether they found the data format useful and whether they had noted any potential problems with the data file (such as outliers). We asked pharmacy directors to indicate whether their States plan to use AMP data for Medicaid drug reimbursement, do not plan to use AMP data, or had not yet decided on its use. Pharmacy directors of States that were planning to use the AMP were asked how they plan to use the data, either in their drug acquisition cost formulas or State MACs. These pharmacy directors were asked to describe any influencing factors in their decisions to use AMP data as well as any obstacles that might prevent their use of the data. We asked pharmacy directors what information would help them to make decisions about using AMP data for Medicaid drug reimbursement. For pharmacy directors who indicated that their States do not plan to use AMP data, we requested reasons that the data would not be used. We also asked pharmacy directors if their States plan to use RSP data for Medicaid drug reimbursement when the data became available and what information would help them to make decisions about using RSP data.

From the survey data, we determined the frequency counts of closed-ended survey questions. We reviewed open-ended survey questions and categorized the responses for analysis and reporting. The term "State" is used interchangeably with "pharmacy director" throughout the report to describe the responses of individual State Medicaid pharmacy directors who provided information on behalf of their States' Medicaid programs.

Standards

This study was conducted in accordance with the "Quality Standards for Inspections" issued by the President's Council on Integrity and Efficiency and the Executive Council on Integrity and Efficiency.

Most States have not decided whether to use AMP data for Medicaid drug reimbursement

Thirty-nine of forty-seven States have not decided whether to use AMP data for Medicaid drug reimbursement. Of the remaining eight States, four are planning to use AMP data for Medicaid drug reimbursement but have not yet implemented changes. Of these four States, two are unsure as to how they plan to use AMP data for Medicaid drug reimbursement, one State plans to use the AMP for estimated acquisition costs, and another State plans to compare it's MACs to its current drug prices and to the new AMP-based FULs. Another three States do not plan to use AMP data. One State indicated that it is using AMP data to help determine MACs for most drug products under its MAC program.

Fourteen of the thirty-nine States that are undecided reported that they would consider using the AMP to determine estimated acquisition costs. Four States reported that they would consider using the AMP to establish State MACs. The remaining undecided States either did not know or did not indicate how they would consider using AMP data.

States that are undecided want to perform analysis of AMP data

Fifteen States that are undecided about using the AMP reported that they want to perform an analysis to determine how incorporating the AMP into their reimbursement methodology would affect reimbursement amounts. Three of these States would like to further determine how a new pricing methodology would compare to current methodologies. States reported that an analysis must be conducted to determine the impact of a new reimbursement methodology on State budgets, providers, and beneficiaries.

States raised concerns about the AMP data received from CMS

Thirty-three of forty-seven States expressed at least one concern about AMP data. Of the 33 States that have data concerns, 30 were undecided about using the AMP, 2 do not plan to use the AMP, and 1 plans to use the AMP. Five States described inconsistencies between the AMP units reported by CMS to States and the typical unit definition of the associated drug products. For example, one of these States commented that there are "discrepancies between the units used for AMP pricing and the units used for other pricing methodologies," and another State commented that "the AMPs that have been provided appear to have different unit definitions than those provided by the drug file vendors." Nine States

would like the unit definition on which the AMP is based to be included in the AMP files provided by CMS. Five States also questioned whether the vendors that already provide them with drug pricing information for claims processing would have access to AMP data. States raised other concerns about the AMP data they received:

- Six States reported that some drug products did not have associated AMPs in the data file that CMS provided. For example, one pharmacy director reported that "approximately 7 percent (over 2,600) of the NDCs listed have no data supplied."
- Four States described problems with both unusually high or low values (outliers) in the AMP files. One State pointed out that the aberrantly low AMPs that it found in the AMP file are problematic because FULs are based on the lowest AMP for the drug product.
- Four States commented that there was little correlation between the AMP data supplied to them and pharmacy acquisition costs. For example, one State's analysis of AMP data showed that values were often "far below or far above the average acquisition cost" they calculate among providers in their State.

States that are undecided about using the AMP would like assurances from CMS that AMP data are accurate and valid. States are anticipating CMS's final regulations to clearly explain how the AMP will be defined and calculated, including how the AMP would take into account price differences among different pharmacy types (e.g., independent, chain, long term care, specialty, mail order) within the retail pharmacy class of trade. Nine States expressed hesitation about using AMP data before CMS has issued final regulations regarding its definition.

Few States have decided whether to use RSP data for Medicaid drug reimbursement

Of the 47 States, 1 indicated that it plans to use RSP data and 3 indicated that they do not. The remaining 43 States have not decided whether to use RSP data. Two of the three States that do not plan to use the RSP are also not planning to use the AMP. Until they received our survey, 16 of the 47 States surveyed were not aware that CMS is collecting and will be disseminating RSP data.

States want more information about RSP data before making decisions

States had many of the same concerns regarding RSP data that they had regarding AMP data and wanted additional information about the RSP:

- Twenty States wanted to know how RSP data will be determined or defined before they make decisions about their use. Some States emphasized the importance of knowing the types of pharmacies that will be included in RSP calculations or preferred that RSP data be provided separately for the different pharmacy types.
- Nine States wanted information about the methods that will be used to collect RSP data or how frequently RSP data will be updated. For example, one pharmacy director asked whether RSP information will be gathered by "phone surveys, walk-in, [or] e-mail" or whether pharmacies would be aware that they are being surveyed.
- Seven States reported that they want assurances that RSP data are valid and accurate before using them for Medicaid drug reimbursement.
- Seven States wanted to know the geographical area that will be represented by the RSP data, with a few States specifying that they want the data to be representative of their States before deciding on their use.
- Six States commented that, before deciding whether to use the data, they would want to evaluate how RSPs compare to their current drug prices. Three States would want to evaluate how RSPs compare to AMPs.

RECOMMENDATIONS

Pursuant to the DRA, CMS must promulgate regulations clarifying the requirements for the AMP and make the AMP and the RSP available to States for their use in Medicaid drug reimbursement. In a May 2006 report, mandated by the DRA, OIG made recommendations to CMS regarding the clarification of AMP definitions and the issuance of guidance to the States regarding AMP-related reimbursement provisions of the DRA.

In this study, we conducted an early assessment of whether States are considering using new pricing data for Medicaid prescription drug reimbursement. Overall, many States have not decided whether they will use either AMP or RSP data for Medicaid drug reimbursement. Many of these States have concerns regarding AMP and RSP data. Concerns about the AMP were focused both on the quality of the AMP data provided and on the need for clearly defined CMS regulations. States want the AMP and the RSP to be defined appropriately and consistently before using the data to implement Medicaid drug reimbursement changes. States reported that AMP and RSP data must be accurate, reliable, and accessible if they are to use these data in their Medicaid prescription drug programs.

To ensure this, CMS should:

Explicitly detail AMP's definition and calculation, including the definition of retail pharmacy class of trade, when promulgating final regulations regarding the AMP. Consistent with our previous recommendations, States' concerns about how the AMP will take into account different types of pharmacies reinforce the need for CMS to clarify requirements in regard to the definition of retail pharmacy class of trade.

Furnish States with interim guidance and/or information regarding AMP data. We continue to recommend that CMS issue guidance to States that addresses AMP-related reimbursement provisions of the DRA. More specifically, based on the concerns raised by States in this review, we recommend that CMS provide States with the unit definition for drug products in AMP files distributed to States. In addition, before the final regulations are published, CMS should work with States to address their concerns regarding whether and how data would be provided to their vendors for incorporation into their pricing and claims processing systems.

Explicitly detail RSP's definition, calculation, and method of collection when distributing RSP data to States. CMS should detail whether and how it will take into account differences in prices among pharmacy types and within various geographical areas when determining the RSP.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS believes the timing of our report caused inconclusive results because it would have been premature for States to have made decisions about the use of the new drug prices as early as September 2006. However, CMS generally agreed with our recommendations and has taken several steps toward addressing them. CMS published a proposed regulation on December 22, 2006, addressing the definition, calculation, and method of collection for the AMP and reported that it will also address these issues when it promulgates the final regulations. CMS stated that it provided guidance to State Medicaid directors on December 15, 2006, concerning AMP issues and provides the unit definition of the AMP on its Web site. CMS also reported it will provide sufficient detail regarding the RSP when those data are provided to States. The full text of CMS's comments is provided in the Appendix.

While CMS believes this study was premature, OIG believes it was important to conduct this study to provide an early assessment of States' plans and concerns regarding the new drug pricing data, so that CMS could address these concerns in its regulations and other guidance. CMS has taken steps toward addressing our first two recommendations; however, we recommend additional actions in those areas. The guidance provided by CMS in December does not address the States' concerns regarding whether and how the new pricing data could be provided to their vendors for incorporation into their pricing and claims processing systems. We continue to recommend that CMS provide this information to States as they consider the use of the new drug prices. Also, while unit definitions are available on CMS's Web site, we recommend incorporating this information in the AMP data file to make the file a more effective and efficient tool for States.

APPENDIX

Agency Comments

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: MAR 14 2007

TO: Daniel R. Levinson
Inspector General

FROM: Leslie V. Norwalk, Esq.
Acting Administrator

SUBJECT: The Office of Inspector General (OIG) Draft Report: States' Use of New Drug Pricing Data to Establish Medicaid Reimbursement for Prescription Drugs," (OEI-03-06-00490)

Thank you for the opportunity to comment on the above draft report. This report looks at whether States plan to use new pricing data to establish Medicaid reimbursement for prescription drugs. As discussed in this report, States offer prescription drug coverage under Medicaid. In accordance with the Deficit Reduction Act of 2005 (DRA), the Centers for Medicare & Medicaid Services (CMS) will be providing States with sales-based sources of drug pricing information that were previously not available for use for pricing drugs. These data include average manufacturer prices (AMPs) and retail survey prices (RSPs).

The OIG surveyed Medicaid pharmacy directors on September 7, 2006, to ask them whether they are planning to use AMP and/or RSP data for Medicaid drug reimbursement. The OIG also asked States to describe any factors that are influencing their decisions, and what additional information they would like to receive before deciding whether to use the new drug pricing data.

OIG Finding

The OIG found that most States have not decided whether to use AMP data for Medicaid drug reimbursement. In addition, States raised concerns about the AMP data received from CMS, including inconsistencies in the data, missing data, and outliers. Finally, the OIG found that almost all States have not decided whether to use RSP data for Medicaid drug reimbursement, citing many of the same concerns as for AMP data.

CMS Response
The CMS recognizes that most States have not decided whether to use AMP or RSP data for Medicaid drug reimbursement, and we are not surprised by this finding. We believe the timing of this report caused such inconclusive results because we would not have expected States to have made these decisions as early as September 2006. We believe it would be premature for any State to have made such decisions until they have had an opportunity to examine these data, particularly in light of the changes that will occur in the determination of AMP as a result of the DRA, publication of the final AMP regulation, and the fact that the RSP data have not yet been provided to States.

OIG Recommendation
CMS explicitly detail AMP's definition, calculation, and method of collection when promulgating final regulations regarding AMP.

CMS Response
The CMS addressed the definition, calculation, and method of collection of AMP in our proposed regulation published on December 22, 2006, including details regarding what classes of trade should be included in the determination of AMP. We will also address these issues when we promulgate final regulations.

OIG Recommendation
CMS should furnish States with interim guidance and/or information regarding AMP data.

CMS Response
The CMS issued guidance to State Medicaid Directors on December 15, 2006 regarding AMP data in the form of a Medicaid Drug Rebate Program, release No. 144. This guidance can be found on our Website at: http://www.cms.hhs.gov/DeficitReductionAct/Downloads/rel144.pdf. Unit Type and Units Per Package Size are defined in the drug data definitions on the CMS Website at: http://www.cms.hhs.gov/medicaiddrugrebateprogram/downloads/proddata.pdf.

OIG Recommendation
CMS should explicitly detail RSP's definition, calculation, and method of collection when distributing RSP data to States.

CMS Response
The CMS will provide sufficient detail regarding the RSP when those data are provided to States.

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