

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**AVERAGE MANUFACTURER PRICE
DETERMINATIONS BY SELECTED DRUG
MANUFACTURERS GENERALLY WERE
CONSISTENT WITH FEDERAL
REQUIREMENTS**

*Inquiries about this report may be addressed to the Office of Public Affairs at
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Brian P. Ritchie
Assistant Inspector General

June 2014
A-06-13-00014

Office of Inspector General

<https://oig.hhs.gov>

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OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS

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EXECUTIVE SUMMARY

The methodologies that selected drug manufacturers used to determine average manufacturer prices for drugs reimbursed by Medicaid generally were consistent with Federal requirements.

WHY WE DID THIS REVIEW

The Patient Protection and Affordable Care Act (ACA) made major changes in the methodology used to determine Medicaid rebates paid to States for drugs reimbursed by Medicaid. Effective October 1, 2010, among other things, the ACA changed the definition of the average manufacturer price (AMP), which is a significant factor in determining manufacturers' rebate liabilities. In 2012, the Centers for Medicare & Medicaid Services (CMS) issued a proposed rule implementing the provisions of the ACA, but the final rule is still pending. As a result, manufacturers have been calculating AMPs without final regulations.

The objective of this review was to determine whether the methodologies that 20 selected drug manufacturers used to determine AMPs for drugs reimbursed by Medicaid were consistent with Federal requirements.

BACKGROUND

The Social Security Act (the Act) outlines the requirements relating to the Medicaid drug rebate program (section 1927 of the Act). In general, for a manufacturer's covered outpatient drugs to be eligible for Federal Medicaid funding under the program, the manufacturer must enter into a rebate agreement with CMS and pay quarterly rebates to the States. Under the program, manufacturers are required to report monthly and quarterly to CMS the AMP for each covered outpatient drug (section 1927(b)(3)(A)(i)(I)). CMS uses the AMP to calculate a unit rebate amount for each covered outpatient drug.

Prior to the ACA, the Act defined AMP as the average price paid to the manufacturer by wholesalers for drugs distributed to the retail pharmacy class of trade (section 1927(k)(1)(A)). However, the Act did not define the retail pharmacy class of trade, and CMS eventually interpreted the retail pharmacy class of trade to include entities other than retail community pharmacies, such as mail-order pharmacies and specialty pharmacies. In previous reviews, we found that such nontraditional pharmacies could often purchase drugs at a lower cost than traditional retail community pharmacies. Therefore, including sales to nontraditional pharmacies and any associated discounts or rebates (price concessions) could result in lower AMPs and thus lower rebates.

The ACA modified the definition of AMP, in part, by replacing retail pharmacy class of trade with retail community pharmacies (section 2503(a)(2)(A)). The ACA defined retail community pharmacy as an independent pharmacy, a chain pharmacy, a supermarket pharmacy, or a mass merchandiser pharmacy that dispenses medications to the general public at retail prices (section

2503(a)(4)). These changes significantly reduced the number and types of entities whose sales and price concessions are included in a manufacturer's AMP calculation.

We judgmentally selected 20 manufacturers and reviewed a detailed description of their AMP methodologies. We also obtained and reviewed the transactions supporting the monthly AMP calculation for one drug product for each manufacturer.

WHAT WE FOUND

The methodologies that selected drug manufacturers used to determine AMPs generally were consistent with Federal requirements. Specifically, the 20 selected manufacturers' methodologies consistently included transactions from retail community pharmacies rather than the more broadly defined retail pharmacy class of trade.

However, manufacturers treated authorized generic sales to a secondary manufacturer differently. Eleven manufacturers addressed authorized generic sales in their methodology: eight manufacturers included sales to secondary manufacturers in their AMP calculations but three did not. Including sales of authorized generics to secondary manufacturers has the potential to significantly lower a drug's AMP.

In addition, all 20 manufacturers followed what is known as the presumptive-inclusion methodology for wholesaler sales contrary to CMS's proposed rejection of this methodology. For the 20 drugs for which we reviewed transaction data, manufacturers would not have been able to calculate the AMP for 10 without following the presumptive-inclusion methodology.

Finally, 16 manufacturers used a 12-month rolling average to estimate and remove indirect sales to ineligible customers from their AMP calculations even though the use of such an average is prescribed only for manufacturer price concessions.

WHAT WE RECOMMEND

We recommend that CMS:

- clarify the conditions for including authorized generic sales to a secondary manufacturer in the AMP calculation,
- keep the policy permitting a presumptive-inclusion methodology for wholesaler sales, and
- expand the use of a 12-month rolling average to estimate and remove indirect sales related to ineligible customers.

CENTERS FOR MEDICARE & MEDICAID SERVICES COMMENTS

In written comments on our draft report, CMS stated that it is currently considering public

comments to its proposed rule and that it intends to address our recommendations in the final rule. CMS also provided a technical comment, which we addressed.

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INTRODUCTION

WHY WE DID THIS REVIEW

The Patient Protection and Affordable Care Act (ACA) made major changes in the methodology used to determine Medicaid rebates paid to States for drugs reimbursed by Medicaid. Effective October 1, 2010, among other things, the ACA changed the definition of the average manufacturer price (AMP), which is a significant factor in determining manufacturers' rebate liabilities. In 2012, the Centers for Medicare & Medicaid Services (CMS) issued a proposed rule implementing the provisions of the ACA, but the final rule is still pending. As a result, manufacturers have been calculating AMPs without final regulations.

OBJECTIVE

Our objective was to determine whether the methodologies that 20 selected drug manufacturers used to determine AMPs for drugs reimbursed by Medicaid were consistent with Federal requirements.

BACKGROUND

Medicaid Drug Rebate Program

The Social Security Act (the Act) outlines the requirements relating to the Medicaid drug rebate program (section 1927 of the Act). For a manufacturer's covered outpatient drugs to be eligible for Federal Medicaid funding under the program, the manufacturer must enter into a rebate agreement with CMS and pay quarterly rebates to the States. Under the program, manufacturers are required to report monthly and quarterly to CMS the AMP for each covered outpatient drug (section 1927(b)(3)(A)(i)(I)).¹ A quarterly AMP is calculated as a weighted average of the monthly AMPs. CMS uses the AMP to calculate a unit rebate amount for each covered outpatient drug and provides the unit rebate amounts to the States. The States determine the total rebate amounts that participating manufacturers owe by multiplying the unit rebate amount by the number of units of the drug dispensed to Medicaid beneficiaries.

Average Manufacturer Price

Prior to the ACA, the Act defined AMP as the average price paid to the manufacturer by wholesalers for drugs distributed to the retail pharmacy class of trade.² However, the Act did not define the retail pharmacy class of trade, and CMS eventually interpreted the retail pharmacy class of trade to include not only retail community pharmacies but entities such as mail-order

¹ The calculations of monthly and quarterly AMPs are discussed in proposed regulations (42 CFR §§ 447.504(e) and 447.510). See 77 Fed. Reg. 5318 at 5362 and 5365 (Feb. 2, 2012).

² The Medicaid drug rebate program was established by the Omnibus Reconciliation Act of 1990, and the definition of AMP as described above was included as section 1927(k)(1)(A) of the Act.

pharmacies and specialty pharmacies.³ Previous OIG reviews⁴ have found that nontraditional pharmacies such as these could often purchase drugs at lower costs than traditional retail community pharmacies. Therefore, including sales of nontraditional pharmacies and any associated discounts or rebates (price concessions) could result in lower AMPs and thus lower rebates.

The ACA modified the definition of AMP, in part, by replacing the retail pharmacy class of trade terminology with retail community pharmacies (section 2503(a)(2)(A)). The ACA defined retail community pharmacy as an independent pharmacy, a chain pharmacy, a supermarket pharmacy, or a mass merchandiser pharmacy that dispenses medications to the general public at retail prices (section 2503(a)(4)).⁵ These changes significantly reduced the number and types of entities whose sales and price concessions are included in a manufacturer's AMP calculation.

Federal Regulations

In 2007, CMS issued regulations implementing provisions of the Deficit Reduction Act but withdrew the portion of the regulation relating to the determination of AMP in 2010.⁶ In 2012, CMS issued a proposed rule implementing provisions of the ACA that revised requirements for covered outpatient drugs,⁷ but the final regulation is still pending. Manufacturers must comply with the ACA requirements relevant to this report as of October 1, 2010, regardless of whether final regulations have been promulgated (ACA, section 2503(d)).

In the absence of specific guidance, CMS has permitted manufacturers to make reasonable assumptions in their AMP calculations that are consistent with the general requirements and intent of section 1927 of the Act, Federal regulations, and the rebate agreement they have with CMS.⁸

HOW WE CONDUCTED THIS REVIEW

We judgmentally selected 20 manufacturers for our review. For each manufacturer, we obtained and reviewed a detailed description of their AMP methodologies, including any reasonable

³ See, e.g., 2 CFR § 447.504(e), 72 Fed. Reg. 39142, 39241 (July 17, 2007).

⁴ *Medicaid Pharmacy – Additional Analyses of the Actual Acquisition Cost of Prescription Drug Products* (A-06-02-00041), issued September 16, 2002, and *Medicaid Pharmacy – Actual Acquisition Cost of Brand Name Prescription Drug Products*, issued August 10, 2001 (A-06-00-00023).

⁵ This definition is now included in section 1927(k)(10) of the Act.

⁶ The 2007 regulations were issued in July 2007. 72 Fed. Reg. 39142 (July 2007 Regulations). The determination of AMP was discussed in 42 CFR § 447.504 of those regulations. In November 2010, CMS removed 42 CFR. § 447.504, 75 Fed. Reg. 69591, 69597 (Nov. 15, 2010).

⁷ 77 Fed. Reg. 5318 (Feb. 2, 2012) (Feb. 2012 Proposed Rule).

⁸ Section II(i) of Sample Rebate Medicaid Drug Agreement. Available online at <http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Downloads/SampleRebateAgreement.pdf>. Accessed on August 15, 2013.

assumptions they made for their calculations. We also obtained and reviewed the transactions supporting the October 2012⁹ monthly AMP calculation for one drug product for each manufacturer.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Appendix A contains the details of our audit scope and methodology.

FINDINGS

The methodologies that selected drug manufacturers used to determine AMPs generally were consistent with Federal requirements. Specifically, the 20 selected manufacturers' methodologies consistently included transactions from retail community pharmacies rather than the more broadly defined retail pharmacy class of trade.

However, manufacturers treated authorized generic sales to a secondary manufacturer differently. Eleven manufacturers addressed authorized generic sales in their methodology: eight manufacturers included sales to secondary manufacturers in their AMP calculations but three did not. Including sales of authorized generics to secondary manufacturers has the potential to significantly lower a drug's AMP.

In addition, all 20 manufacturers followed what is known as the presumptive-inclusion methodology for wholesaler sales contrary to CMS's proposed rejection of this methodology. For the 20 drugs for which we reviewed transaction data, manufacturers would not have been able to calculate the AMP for 10 without following the presumptive-inclusion methodology.

Finally, 16 manufacturers used a 12-month rolling average to estimate and remove indirect sales to ineligible customers from their AMP calculations even though the use of such an average is prescribed only for manufacturer price concessions.

MANUFACTURERS' METHODOLOGIES CONSISTENTLY INCLUDED TRANSACTIONS FROM RETAIL COMMUNITY PHARMACIES

The ACA redefined AMP as the average price paid by wholesalers for drugs distributed to retail community pharmacies or by retail community pharmacies that purchase directly from manufacturers.¹⁰ The methodologies that the 20 selected drug manufacturers used to determine

⁹ One of the selected manufacturers was acquired by another manufacturer effective December 31, 2012. We permitted the acquiring manufacturer to submit the sales transactions for the selected drug for January 2013.

¹⁰ Section 1927(k)(1) of the Act as modified by section 2503(a)(2)(A) of the ACA.

AMPs for drugs reimbursed by Medicaid consistently included transactions from retail community pharmacies rather than the more broadly defined retail pharmacy class of trade.

MANUFACTURERS TREATED AUTHORIZED GENERIC DRUG SALES TO SECONDARY MANUFACTURERS DIFFERENTLY

An authorized generic drug is any drug product that is marketed under the innovator (brand) manufacturer's New Drug Application¹¹ but labeled with a different national drug code¹² from the brand name product.¹³ That is, an authorized generic drug is a brand name drug that the brand manufacturer permits a secondary manufacturer to sell as a generic.

In its 2007 regulation, CMS required that manufacturers include sales of authorized generic drugs in the calculation of AMP only when the drugs were sold directly to wholesalers.¹⁴ In its 2012 proposed rule, CMS defined primary and secondary manufacturers and has proposed that primary manufacturers include in their AMP calculations the sales of authorized generic drugs to secondary manufacturers if the secondary manufacturer is acting as a wholesaler.¹⁵ In part, CMS has suggested this change in response to a provision in the ACA that provides the first statutory definition of wholesaler.¹⁶ The ACA's definition of wholesaler includes manufacturers (section 2503(a)(4)).

Of the 20 manufacturers we reviewed, 11 manufacturers provided information regarding the sales of authorized generic drugs to secondary manufacturers. Eight of the manufacturers stated that they include in their AMP calculations the sales of an authorized generic drug to secondary manufacturers, and three manufacturers stated that they did not include such sales in their AMP calculations. Officials for six of the eight manufacturers that included sales to secondary manufacturers said that they did so based on the change in the statutory definition of wholesaler. The other three manufacturers did not include sales to secondary manufacturers for different reasons. Officials for one manufacturer stated that it was unclear whether the statutory definition of wholesaler was intended to expand the definition of AMP-includable sales to sales of an authorized generic drug to a secondary manufacturer. Officials for another manufacturer said that they did not include these sales because it was not clear what acting as a wholesaler meant in the context of a secondary manufacturer. Officials at the third manufacturer stated that they

¹¹ The Food and Drug Administration (FDA) approves new drugs through the New Drug Application process, and generic drugs are approved under an Abbreviated New Drug Application.

¹² The National Drug Code is a code set that identifies the vendor (manufacturer), product, and package size of all drugs and biologics recognized by the FDA. It is maintained and distributed by the Department of Health and Human Services in collaboration with drug manufacturers.

¹³ 42 CFR § 447.506(a) as set forth in the July 2007 regulations at 39243.

¹⁴ 42 CFR § 447.406(b) as set forth in the July 2007 regulations at 39243.

¹⁵ 42 CFR § 447.506 as set forth in the February 2012 proposed rule at 5363.

¹⁶ February 2012 proposed rule at 5337. The definition of wholesaler is now included in section 1927(k)(11) of the Act.

considered Federal regulations at 42 CFR § 447.506 from the July 2007 regulation to still be in effect.

Including sales of authorized generics to secondary manufacturers has the potential to significantly lower a drug's AMP. The AMP calculation for 3 of the 20 drugs selected for review included authorized generic sales to a secondary manufacturer. We recalculated AMP for the three drugs by removing the sales to the secondary manufacturers and determined that the AMPs would have been substantially higher. (See the table below.)

Table: Average Manufacturer Prices With and Without Sales of Authorized Generic Drugs to Secondary Manufacturers

Sales to Secondary Manufacturers	Drug A	Drug B	Drug C
Included (as reported)	\$1.66	\$1.97	\$4.01
Excluded	\$9.88	\$6.22	\$10.07

MANUFACTURERS TREATED SALES TO WHOLESALERS CONTRARY TO CMS'S PROPOSED RULE

CMS established a presumptive-inclusion policy under which manufacturers include sales to wholesalers in their AMP calculations except for sales that can be identified as being subsequently sold by those wholesalers to customers that are not eligible for inclusion in AMP.¹⁷ CMS confirmed the presumptive-inclusion policy in the regulation published in 2007.¹⁸ In practice, presumptive-inclusion has allowed manufacturers to include all wholesaler sales in their AMP calculations and then remove sales to ineligible customers that are identified from wholesaler chargebacks or other information.

Manufacturers often negotiate with wholesalers' customers prices that are lower than the price paid by the wholesaler. When a wholesaler sells to a customer that has negotiated a price with a manufacturer that is lower than the wholesaler's price, the wholesaler submits a chargeback to the manufacturer to recover the amount lost on the sale. Through chargeback data, manufacturers are able to identify whether wholesalers sold to eligible or ineligible customers.

In its proposed 2012 rule, CMS proposed to reject a presumptive-inclusion policy, instead requiring manufacturers essentially to include sales to wholesalers when the manufacturer can identify the wholesalers' customers as retail community pharmacies.¹⁹ All 20 manufacturers that we reviewed followed the presumptive-inclusion methodology for sales to wholesalers. For the 20 drugs for which we reviewed transaction data, manufacturers would not have been able to calculate the AMP for 10 because there were no direct sales to retail community pharmacies, and there were no chargebacks to wholesalers for sales to retail community pharmacies. If

¹⁷ 1997 Medicaid Drug Rebate Program Release No. 29.

¹⁸ 42 CFR § 447.504(g) in the July 2007 regulations at 39241.

¹⁹ February 2012 proposed rule at 5330.

manufacturers can not presume that wholesaler sales are included in AMP, manufacturers may be unable to calculate AMPs for many drugs.

MANUFACTURERS USED AN UNPRESCRIBED METHOD TO REMOVE INDIRECT SALES TO INELIGIBLE CUSTOMERS

Section 2503(a) of the ACA amended section 1927(e) of the Act to require CMS to implement a smoothing, or averaging, process for AMP calculations, similar to the smoothing process used in determining the average sales price (ASP) of a drug or biological under Medicare Part B.²⁰ In response to the ACA requirement, CMS implemented a smoothing process that uses a 12-month rolling average to estimate the value of lagged (or late-arriving) price concessions (2011 Medicaid Drug Rebate Release No. 83). CMS included that smoothing process in its proposed rule.²¹

In neither the release nor the proposed rule did CMS provide for the use of a 12-month rolling average to estimate indirect sales to ineligible customers. Of the 20 manufacturers that we reviewed, 16 removed indirect sales to ineligible customers using a 12-month rolling average to estimate the amount of sales to remove. According to three manufacturers, the use of a 12-month rolling average to remove indirect sales to ineligible customers should result in more stable and reliable AMP calculations. We do not believe that using a 12-month rolling average to remove indirect sales to ineligible customers would negatively impact the amount of rebates paid.²²

RECOMMENDATIONS

We recommend that CMS:

- clarify the conditions for including authorized generic sales to a secondary manufacturer in the AMP calculation,
- keep the policy permitting a presumptive-inclusion methodology for wholesaler sales, and

²⁰ Pursuant to Title XVIII of the Social Security Act, the Medicare program provides health insurance for people aged 65 and over and those who are disabled or have permanent kidney disease. Part B of the Medicare program provides supplementary medical insurance for medical and other health services, including outpatient services such as the injection of drugs. CMS administers the program. Medicare Part B pays for most covered drugs using a reimbursement methodology based on ASP. In certain aspects, manufacturers calculate ASP similar to how they calculate AMP. See, e.g., 42 U.S.C. § 1395w-3a and 42 CFR § 414.800 *et seq.*

²¹ 42 CFR § 447.510(d) as set forth in the February 2012 proposed rule at 5365.

²² As previously discussed, CMS has proposed eliminating the presumptive-inclusion policy and requiring manufacturers to include sales to wholesalers only when the manufacturer can identify that the sales were to retail community pharmacies. If the proposal were to become final, manufacturers would no longer need to remove indirect sales to ineligible customers.

- expand the use of a 12-month rolling average to estimate and remove indirect sales related to ineligible customers.

CENTERS FOR MEDICARE & MEDICAID SERVICES COMMENTS

In written comments on our draft report, CMS stated that it is currently considering public comments to its proposed rule and that it intends to address our recommendations in the final rule. CMS also provided a technical comment, which we addressed. CMS's comments, excluding the technical comment, are included as Appendix B.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

We judgmentally selected 20 manufacturers and reviewed a detailed description of their AMP methodologies, including any reasonable assumptions they made for their calculations. We also obtained and reviewed the transactions supporting the October 2012²³ monthly AMP calculation for one drug product for each manufacturer. Because our objective focused on the methodologies that the 20 selected drug manufacturers used to determine AMPs for drugs reimbursed by Medicaid and not the reported AMP, we did not perform any procedures to verify the validity of the transactions provided.

Section 202 of the Education Jobs and Medicaid Assistance Act (P.L. No. 111–226) provides for an alternative AMP calculation for drugs that are not generally dispensed through retail community pharmacies. We did not include this alternative AMP calculation in our review of manufacturers' methodologies.

Our objective did not require that we identify or review any internal controls.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and CMS guidance;
- obtained the national Medicaid drug utilization data, including reimbursement amounts, for calendar year (CY) 2011 from the CMS Web site;
- judgmentally selected 20 manufacturers that had Medicaid reimbursement from CY 2011 and judgmentally selected 1 drug from each manufacturer;
- obtained and reviewed, from each manufacturer, a detailed description of its AMP methodology, including any reasonable assumptions made as well as the transactions that supported the October 2012 AMP calculation for the selected drug;
- reviewed the customer classifications manufacturers included and excluded in their AMP calculations;
- reviewed the price concessions that manufacturers included in their AMP calculations;
- reviewed the 12-month rolling average methodologies used to smooth transactions; and
- discussed our findings with CMS.

²³ One of the selected manufacturers was acquired by another manufacturer effective December 31, 2012. We permitted the acquiring manufacturer to submit the sales transactions for the selected drug for January 2013.

APPENDIX B: CENTERS FOR MEDICARE & MEDICAID SERVICES COMMENTS



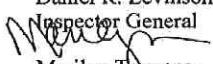
DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: FEB 11 2014

TO: Daniel R. Levinson
Inspector General

FROM: 
Marilyn Tavenner
Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: "Average Manufacturer Price Determinations by Selected Drug Manufacturers Generally Were Consistent With Federal Requirements" (A-06-13-00014)

Thank you for the opportunity to review and comment on the above subject OIG draft report. The Centers for Medicare & Medicaid Services (CMS) appreciates the information presented in the report and offers the following comments.

The Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively referred to as the Affordable Care Act (ACA)) made significant changes to the Medicaid Drug Rebate Program. The ACA changed the definition of the average manufacturer price (AMP) which is a significant factor in determining manufacturer's Medicaid rebate liabilities. CMS issued a proposed rule (77 FR 5318 (Feb. 2, 2012)) implementing the provisions of the ACA. The purpose of OIG's review was to determine whether the methodologies that 20 selected drug manufacturers used to determine AMPs for drugs reimbursed by Medicaid were consistent with Federal requirements since manufacturers have been calculating AMPs without final regulations implementing the AMP provisions of ACA.

OIG Findings

The OIG found that the methodologies the 20 selected drug manufacturers used to determine AMPs generally were consistent with Federal requirements. The 20 selected manufacturers' methodologies included transactions from retail community pharmacies rather than the more broadly defined retail pharmacy class of trade.

However, OIG found that manufacturers treated authorized generic sales to a secondary manufacturer differently. Of the eleven manufacturers that addressed authorized generic sales in their AMP methodology, eight manufacturers included sales to secondary manufacturers in their AMP calculations and three did not include sales of authorized generics to secondary manufacturers.

Additionally, OIG found that all 20 manufacturers used the presumptive-inclusion methodology for wholesaler sales, contrary to CMS proposed elimination of the requirement. For the 20 drugs for which OIG reviewed transaction data, manufacturers would not have been able to calculate AMP for ten drugs without following the presumptive-inclusion methodology.

Lastly, OIG found that 16 manufacturers used a 12-month rolling average to estimate and remove indirect sales to ineligible customers from their AMP calculations even though the use of such an average is prescribed only for manufacturer price concessions.

OIG Recommendation

The OIG recommend CMS clarify the conditions for including authorized generic sales to a secondary manufacturer in the AMP calculation.

CMS Response

The CMS is in the process of considering public comments to its proposed rule regarding the conditions for including authorized generic sales to a secondary manufacturer in AMP calculations. CMS intends to address this question in the final rule.

OIG Recommendation

The OIG recommend CMS keep the presumptive-inclusion requirement for wholesaler sales.

CMS Response

The CMS is in the process of considering public comments to its proposed rule regarding the presumptive-inclusion methodology. CMS intends to address this question in the final rule.

OIG Recommendation

The OIG recommend CMS expand the use of a 12-month rolling average to estimate and remove indirect sales related to ineligible customers.

CMS Response

The CMS is in the process of considering public comments to its proposed rule regarding expanding the use of a 12-month rolling average to estimate and remove indirect sales related to ineligible customers. CMS intends to address this question in the final rule.

The CMS appreciates the opportunity to review and comment on this OIG draft report, and look forward to working with OIG on this and other issues.

April 2, 2012

HAND DELIVERED

Marilyn Tavenner
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-2345-P
P.O. Box 8016
Baltimore, MD 21244-8016

Re: Joint Stakeholder Letter concerning CMS-2345-P; Medicaid Proposed Rule on Covered Outpatient Drugs

Dear Ms. Tavenner:

This letter provides a joint statement on the above-referenced proposed rule¹ from the following organizations: Biotechnology Industry Organization (BIO); Generic Pharmaceutical Association (GPhA); Healthcare Distribution Management Association (HDMA); National Association of Chain Drug Stores (NACDS); and Pharmaceutical Research and Manufacturers of America (PhRMA). We appreciate the opportunity to comment on the proposed rule, which if finalized could have a major impact on the calculation of Average Manufacturer Price (AMP), with repercussions throughout the pharmaceutical distribution chain. Our organizations collectively represent the stakeholders across the entire pharmaceutical distribution chain that will be affected by the AMP provisions in CMS' final rule. We are coming together to write this Joint Stakeholder Letter in order to provide a clear, unified voice on one of the key issues addressed in the proposed rule.

We urge CMS to maintain the traditional default rule on the treatment of sales to wholesalers in the AMP calculation. Under this rule, formerly codified at 42 C.F.R. §447.504(g)(1), AMPs include "[s]ales to wholesalers, except for those sales that can be identified with adequate documentation as being subsequently sold to any [excluded entity]."² CMS should not finalize its proposal to reverse the traditional default rule. All of the undersigned stakeholders agree that CMS should preserve the traditional default rule. We are each concerned that the CMS proposal (which would base AMPs on a smaller set of sales than under the traditional default rule), could: (1) cause greater volatility in the AMPs; (2) create AMPs that may be less rather than more representative of prices to retail community pharmacies; and (3) generate unnecessary burdens and unintended costs for companies involved in the distribution chain. We urge CMS to avoid these risks and maintain a long-standing principle that has worked well over many years.

¹ Medicaid Program; Covered Outpatient Drugs, 77 Fed. Reg. 5318 (Feb. 2, 2012).

² 42 C.F.R. § 447.504(g)(1)(2010).

Marilyn Tavenner
April 2, 2012
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Each of our organizations has submitted individual comment letters on the proposed rule, and you will find further detail on this issue in our individual letters. Please feel free to contact any of the undersigned if you have any questions or would like additional information.

We thank CMS again for the opportunity to submit comments on the proposed rule, and we hope this letter will assist CMS in developing final regulations.

Sincerely,

Biotechnology Industry Organization

Generic Pharmaceutical Association

Healthcare Distribution Management Association

National Association of Chain Drug Stores

Pharmaceutical Research and Manufacturers of America
