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LIMITATIONS IN MANUFACTURER REPORTING OF AVERAGE SALES PRICE DATA FOR PART B DRUGS

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EXECUTIVE SUMMARY: LIMITATIONS IN MANUFACTURER REPORTING OF AVERAGE SALES PRICE DATA FOR PART B DRUGS
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WHY WE DID THIS STUDY

Manufacturer-reported average sales prices (ASPs) serve as the basis for most Part B drug payment amounts. Complete ASP data ensure that payment amounts are accurate and are reflective of all manufacturer sales prices. Previous Office of Inspector General (OIG) work has shown that the Centers for Medicare & Medicaid Services (CMS) lacks complete ASP data for certain drugs because (1) not all manufacturers that are required to report ASPs are doing so and (2) not all manufacturers of Part B drugs are required to report ASPs. OIG has previously recommended that CMS consider seeking a legislative change to require all manufacturers of Part B drugs to submit ASPs. In response, CMS stated that it would be helpful if OIG provided a full analysis of the policy's implications.

HOW WE DID THIS STUDY

We compared data in CMS's background and crosswalk files—the agency's two ASP-related files—with two national drug compendia to determine the number of manufacturers that did not report required ASPs in the third quarter of 2012. We then determined the number of additional manufacturers that would be required to submit ASPs if reporting requirements were extended to all manufacturers of Part B drugs. We also identified national drug codes (NDCs) with incorrect product and pricing information in CMS's ASP files. Finally, we surveyed CMS officials and reviewed CMS policies to determine whether the agency has improved ASP collection and verification processes since the publication of OIG's prior work.

WHAT WE FOUND

At least one-third of the more than 200 manufacturers of Part B drugs did not submit ASPs for some of their products in the third quarter of 2012, despite being required to do so.
An additional 45 manufacturers of Part B drugs were not required to report ASPs that quarter. Furthermore, for a small number of drugs, inaccuracies in CMS's ASP files may have affected Medicare payments. Finally, CMS has improved its ASP-related processes and procedures; however, challenges remain.

WHAT WE RECOMMEND

We recommend that CMS (1) continue to assist OIG in identifying and penalizing manufacturers that do not meet ASP reporting requirements; (2) seek a legislative change to directly require all manufacturers of Part B drugs to submit ASPs; (3) ensure the accuracy of product information for NDCs listed in the background and crosswalk files; and (4) finalize the implementation of automated ASP-related procedures by using processes related to average manufacturer price as a model, and subsequently require all manufacturers to submit ASPs through the automated system. CMS concurred with our first, third, and fourth recommendations, but did not concur with our recommendation to seek a legislative change.

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OBJECTIVES

1. To determine whether manufacturers reported average sales prices (ASPs) for all Part B drugs in the third quarter of 2012.
2. To determine the effect on ASP reporting if all manufacturers of Part B drugs were required to submit ASPs.
3. To assess the validity and accuracy of data contained in the Centers for Medicare & Medicaid Services' (CMS's) ASP files.
4. To determine whether CMS has improved its processes for collecting and analyzing ASPs.

BACKGROUND

ASPs serve as the basis for most Part B drug payment amounts. However, previous OIG work has shown that not all manufacturers are reporting the required ASP data to CMS.[1] Furthermore, because ASP reporting requirements are linked to Medicaid drug rebate agreements, some manufacturers of Part B drugs—i.e., manufacturers that do not have such agreements—are not required to submit ASP data. The nonreporting of ASPs may result in Medicare payment amounts that are inaccurate and not reflective of all manufacturer sales prices.

Recent OIG reports recommended that CMS consider seeking a legislative change to require all manufacturers of Part B drugs to submit ASPs. In response to one such report, CMS stated that for a legislative change to be considered, it would be helpful if OIG provided a full analysis of the policy's implications (e.g., the number of additional drugs for which manufacturers would be reporting ASPs).[2]

Previous OIG work also found issues with the product data compiled by CMS (e.g., potentially inaccurate strengths or package sizes) for certain Part B drugs.[3] Inaccurate product data could result in incorrect Medicare payment amounts and incorrect beneficiary coinsurance. Further, OIG found that CMS's processes for collecting and analyzing ASPs could be improved. For example, unlike the automated system in place to collect average manufacturer price (AMP) data under Medicaid, CMS manually

[1] OIG, *Comparison of Average Sales Prices to Widely Available Market Prices for Selected Drugs*, OEI-03-10-00280, January 2012.

[2] OIG, *Comparison of Average Sales Prices and Average Manufacturer Prices: An Overview of 2010*, OEI-03-11-00410, November 2011.

[3] OIG, *Comparison of Second-Quarter 2012 Average Sales Prices and Average Manufacturer Prices: Impact on Medicare Reimbursement for Fourth Quarter 2012*, OEI-03-13-00100, December 2012.

imported ASP data, which could lead to data errors. OIG recommended that CMS develop an automated system for collecting ASP data.[4]

Medicare Part B Coverage and Payment for Prescription Drugs

Medicare covers a limited number of outpatient prescription drugs and biologicals (hereinafter referred to as drugs) under its Part B benefit, including injectable drugs used in the treatment of cancer, certain vaccines, oral anticancer drugs, and inhalation drugs used in conjunction with durable medical equipment.[5] To obtain payment for Part B drugs, providers submit claims to Medicare contractors using Healthcare Common Procedure Coding System (HCPCS) codes. Each HCPCS code defines the drug's name and the amount of drug represented by one unit of the code but does not specify manufacturer or package size information.

Payments for most Part B drugs are equal to 106 percent of the volume-weighted ASP among all drugs represented by the HCPCS code (or, if lower, the actual charge billed on the claim).[6] Medicare beneficiaries are responsible for 20 percent of this amount in coinsurance.[7] Medicare and its beneficiaries spent $13.6 billion for Part B drugs in 2012. Although Part B paid for more than 700 drug HCPCS codes that year, 95 percent of spending was concentrated on just 100 HCPCS codes.

Manufacturer Reporting Requirements for ASPs

Pursuant to section 1927(b)(3) of the Act, manufacturers with Medicaid rebate agreements must provide CMS with the ASP and sales volume for each of their Part B drugs on a quarterly basis.[8] Manufacturers typically report ASPs by national drug code (NDC), an 11-digit code that is divided into three segments identifying (1) the firm that manufactures, distributes,

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[4] OIG, *Average Sales Prices: Manufacturer Reporting and CMS Oversight*, OEI-03-08-00480, February 2010.

[5] 42 CFR § 414.900(b) and *Medicare Benefit Policy Manual*, ch. 15 § 50; 68 Fed Reg. 50428 (August 20, 2003).

[6] Section 1847A(c) of the Social Security Act (the Act) defines ASP as a manufacturer's sales of a drug (with certain exceptions) to all purchasers in the United States in a quarter divided by the number of units of the drug sold by the manufacturer in that same quarter. The ASP is net of any price concessions other than those obtained through the Medicaid drug rebate program (MDRP).

[7] Section 1847A(b)(1) of the Act. Part B claims dated on or after April 1, 2013, incur a 2-percent reduction in payment in accordance with the Budget Control Act of 2011 and the American Taxpayer Relief Act of 2012 (i.e., sequestration). This mandatory payment reduction is applied after the beneficiary's coinsurance has been determined, resulting in a payment rate for most Part B drugs of 104.3 percent of the volume-weighted ASPs. See CMS Medicare FFS Provider e-News, *Mandatory Payment Reductions in the Medicare Fee-for-Service (FFS) Program—"Sequestration,"* March 8, 2013.

[8] For Federal financial participation to be available for covered outpatient drugs provided under Medicaid, manufacturers must enter into rebate agreements with the Secretary of Health and Human Services and pay quarterly rebates to State Medicaid agencies. Sections 1927(a)(1) and (b)(1) of the Act.

or repackages the drug product (i.e., the labeler code); (2) the specific strength, dosage form, and formulation of the product; and (3) the product's package size.[9]

Manufacturers may face civil money penalties (CMPs) or suspension of their rebate agreements if they knowingly provide false information about their ASPs or fail to report ASP data within the required timeframe (i.e., within 30 days of the close of a quarter).[10] OIG has coordinated with CMS to identify manufacturers that do not submit ASP (or AMP) data in a timely fashion and has initiated actions against certain manufacturers that failed to satisfy their submission requirements.

CMS Calculation and Publication of Payment Amounts

Because payments for Part B drugs are based on HCPCS codes rather than on NDCs and because more than one NDC may meet the definition of a particular HCPCS code, CMS must first "crosswalk" manufacturers' NDCs to their matching HCPCS codes. In addition, because the amount of a drug represented by an NDC may differ from the amount of a drug specified by a HCPCS code, CMS staff often must convert "NDC units" to "HCPCS code units" to determine the amount of the drug contained within a given HCPCS code. Each quarter, CMS publishes a crosswalk file that lists the NDCs matching each Part B drug HCPCS code as well as the number of "NDC units" within the HCPCS code. CMS also develops a nonpublic quarterly ASP "background" file for internal use, which lists the ASPs and number of units sold for all NDCs that meet the definition of each Part B drug HCPCS code paid under the ASP methodology.[11]

CMS performs numerous checks on the data in the background file, and may seek clarification or correction regarding submitted data if the data do not pass CMS's checks. CMS then determines whether to include the submitted ASP for each NDC in its calculation of the volume-weighted ASP for the HCPCS code.[12] Finally, CMS calculates a payment amount by multiplying the volume-weighted ASP by 106 percent.

There is a two-quarter lag between the sales period for which ASPs are reported and the effective date of the reimbursement amounts. For

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[9] One manufacturer may have multiple labeler codes. Labelers will hereinafter be referred to as "manufacturers." In addition, a small number of Part B drugs are identified using alternative IDs, which do not necessarily include a labeler code, rather than NDCs.

[10] Sections 1927(b)(3)(C)(i) and (ii) of the Act and 42 CFR § 414.804(a)(5).

[11] A quarterly background file will include an NDC if its ASP has been previously reported by the manufacturer, regardless of whether its ASP was reported in that particular quarter. The background file also contains a few NDCs for which ASPs have not been reported but that CMS contractors have identified to be in the market.

[12] CMS assigns a status indicator in the ASP background file for each NDC that specifies whether the NDC's ASP was included in the calculation of volume-weighed ASP.

example, ASPs reported by manufacturers for the third quarter of 2012 served as the basis for first-quarter 2013 payment amounts. CMS posts an ASP payment amount file and an ASP crosswalk file on its Web site in the weeks before the start of the applicable quarter.

METHODOLOGY

Data Collection

Total Part B Expenditures and Utilization. We obtained expenditure and utilization data for all Part B drug HCPCS codes in all quarters of 2012 and the first quarter of 2013 from CMS's Part B Analytics Report (PBAR).

ASP Data Files. We obtained from CMS (1) the first-quarter 2013 payment amount file; (2) the third-quarter 2012 ASP background file (i.e., the ASPs on which first-quarter 2013 payment amounts were based) for drugs paid in noninstitutional Part B settings[13]; and (3) the third-quarter 2012 ASP crosswalk file.

MDRP-Participating Drug Manufacturer File. We obtained from CMS the list of manufacturers participating in the MDRP in the third quarter of 2012 and their associated labeler codes.

Drug Compendia. We obtained product information (e.g., strength, package size, and package quantity) for the third quarter of 2012 for all drugs under review from two national drug compendia: Truven Health Analytics' *Red Book* and First Databank's *National Drug Data File.*

External Web Sites and 2012 HCPCS Code Level II Reference Book. We referred to external Web sites, including those of the U.S. Food and Drug Administration (FDA) and individual pharmaceutical manufacturers, as well as the HCPCS code reference book, to confirm product and coding information when there were discrepancies between CMS's background/crosswalk files and the two national drug compendia.

CMS Documents and Interviews with Officials. We surveyed CMS staff in August 2013 and March 2014 and reviewed CMS policies regarding ASP submission procedures. The survey and document review identified whether CMS had automated the data collection process and made other improvements in collecting, entering, and verifying ASP data. We also asked CMS officials regarding challenges they face in improving these processes.

[13] Our analysis does not include drugs paid for under the hospital outpatient prospective payment system, many of which are also paid on the basis of ASPs. CMS publishes a separate ASP file for hospitals. There is substantial overlap in the HCPCS codes listed in both files, and the same ASP data are used to derive payment amounts. We do not believe that including hospital files in our analysis would have affected our findings.

Data Analysis

Selection of Drugs. We used CMS's first-quarter 2013 payment amount file to identify all 539 HCPCS codes that were paid on the basis of ASPs that quarter.[14] Because there is a two-quarter lag between the sales period for which ASPs are reported and the effective date of the reimbursement amounts, the ASPs reflected sales from the third quarter of 2012. We also obtained from CMS' third-quarter 2012 ASP background file a list of all 4,330 active NDCs that CMS associated with the 539 HCPCS codes.

We selected a purposive sample of drugs for a portion of our analysis. We used PBAR to select 87 high-expenditure Part B drug HCPCS codes that constituted 86 percent of total Part B spending in 2012 (see Appendix A).[15]

Identifying NDCs Listed in the Background File with Unreported ASPs. We examined the status indicator variable for all 4,330 NDCs listed in the third-quarter 2012 background file to identify NDCs for which manufacturers did not submit ASP data. We matched the labeler codes for these NDCs to the participating-manufacturer file to determine whether or not the associated manufacturers had Medicaid rebate agreements and were thus required to report ASPs.

Identifying Part B Drug NDCs Not Listed in the Background File. For the 87 sampled HCPCS codes, we also identified NDCs with unreported ASPs that met the definition of a HCPCS code but were not included in the background file. Using *Red Book* and the *National Drug Data File*, we developed a list of all NDCs associated with the 87 HCPCS codes and matched this list against the background file. For NDCs that appeared in the compendia but not the background file, we used other external resources (such as the *HCPCS Code Level II Reference Book*) to determine whether the NDC should have been listed in the background file. Please see Appendix B for a detailed description of this comparison.

Identifying NDCs with ASPs Reported by Manufacturers Without Rebate Agreements. For all 539 HCPCS codes, we used the background file and the manufacturer file to determine the number of manufacturers that did not have rebate agreements yet still submitted ASPs in the third quarter of 2012. Although manufacturers without rebate agreements are not required to report ASPs, such reporting helps ensure that CMS has the information needed to calculate payment amounts that are reflective of all sales in the

[14] We excluded HCPCS codes that represent Not Otherwise Classified (NOC) drugs.

[15] We initially selected 100 HCPCS codes with the highest total expenditures in 2012 (constituting 95 percent of spending). We removed 3 of the 100 codes because they were paid for on the basis of average wholesale prices, 5 codes because they were priced by individual Medicare contractors, and 5 codes because they represented NOC drugs.

marketplace. We estimated the effect on payment amounts if these manufacturers had chosen not to report ASPs that quarter.[16]

Assessing the Accuracy and Validity of ASP Data in CMS's ASP Files. We identified any NDCs for which the product information (e.g., strength, package size, and package quantity) listed in the third-quarter 2012 ASP background and crosswalk files did not match the information published in the national drug compendia. We used external sources, such as manufacturer Web sites, to resolve any conflicts between CMS's files and the compendia. Using this product information, we also verified CMS's conversions of NDC units to HCPCS units for each code. Incorrectly converted units could result in inaccurate Medicare payment amounts and beneficiary coinsurance. In addition, many Medicaid State agencies use CMS's conversions on the crosswalk file to adjust the HCPCS units listed on Medicare "crossover" claims.[17]

Assessing Improvements in CMS's ASP-Related Processes. We reviewed CMS policies and surveyed CMS officials to determine whether the agency had automated manufacturer ASP submissions, as recommended by OIG, or had made other improvements to its collection, entry, and verification processes since the publication of OIG's earlier report.[18]

Limitations

We did not determine whether manufacturers' calculations of ASPs were correct. In addition, we did not verify the accuracy or completeness of drug product information listed in the national drug compendia, the FDA Web site, or in any of the other sources we used to evaluate CMS's ASP files. We also did not verify that NDCs listed in the compendia represented drugs that were actually manufactured and sold in the third quarter of 2012. Findings related to the purposive sample of 87 high-expenditure HCPCS codes cannot be generalized to all Part B drug HCPCS codes paid on the basis of ASPs in 2012.

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.

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[16] To do this, we removed any "nonrequired" NDCs (i.e., NDCs for which manufacturers were not required to report ASPs) and recalculated the volume-weighted ASP for each HCPCS code. We then calculated the percentage difference between the actual payment amount and new payment amount.

[17] "Crossover" claims are claims in which both Medicare and Medicaid pay a portion. Incorrect conversions are a frequent source of Medicaid drug rebate disputes.

[18] OIG, *Average Sales Prices: Manufacturer Reporting and CMS Oversight*, OEI-03-08-00480, February 2010.

FINDINGS

At least one-third of manufacturers did not submit ASPs for some of their Part B drugs in the third quarter of 2012, despite being required to do so

In the third quarter of 2012, at least 207 manufacturers of Part B drugs were operating under Medicaid drug rebate agreements and were thus required to report ASPs.[19] At least 74 of these manufacturers did not report ASPs for one or more of their Part B NDCs that quarter (see Table 1).

Table 1: Impact of Nonreporting by Manufacturers With Rebate Agreements

Presence in Background File	Number of Manufacturers	Number of NDCs	Number of Affected HCPCS Codes
NDC listed in background file, but ASP not reported	63	176	80
NDC not listed in background file but met HCPCS code definition (from sample)	21	81	17
Overlap in above categories	(10)	(0)	(4)
Totals	**74**	**257**	**93**

Source: OIG analysis of CMS's third-quarter 2012 background file, national drug compendia, CMS's MDRP-participating manufacturer file, the HCPCS Code Level II Reference Book, and external Web sites.

Sixty-three manufacturers that had rebate agreements did not report ASPs for one or more NDCs listed in the third-quarter 2012 background file

In the third quarter of 2012, 63 manufacturers did not report ASPs for 176 NDCs listed in the background file (6 percent of the total number of required NDCs in the background file) despite being required to do so. The majority of manufacturers associated with the missing ASPs failed to report for only a small percentage and/or small number of their NDCs.[20, 21] However, 24 manufacturers that had rebate agreements did not report ASPs for any of their NDCs listed in the third-quarter 2012 background file.

[19] We use the term "at least" throughout the first two findings because a portion of the total number of manufacturers in question was identified through our purposive sample of high-expenditure HCPCS codes. Because we cannot extrapolate this sample to all HCPCS codes, there may be additional manufacturers of Part B drugs that we did not identify.

[20] For example, one manufacturer failed to report ASPs for only 20 of its 304 NDCs (i.e., 7 percent). Another manufacturer failed to report ASPs for one of its NDCs but had only two NDCs in the marketplace that quarter (i.e., 50 percent).

[21] As a result, the Medicare payment amount for 80 of the associated HCPCS codes did not reflect all market prices.

At least 21 manufacturers that had rebate agreements should have reported ASPs for additional NDCs not listed in CMS's background file

Based on our purposive sample of high-expenditure drugs, 21 manufacturers that had rebate agreements should have reported ASPs for 81 additional NDCs not listed in the third-quarter 2012 background file.[22, 23] Because this portion of our analysis reflects only a subset of high-expenditure drugs, there are likely other NDCs for which manufacturers have never reported the required ASPs. This would result in additional HCPCS codes having payment amounts that are not reflective of all marketplace sales prices.

At least 45 manufacturers were not required to report ASPs for 443 Part B NDCs in the third quarter of 2012

Current law requires manufacturers to report ASPs to CMS only if they have signed a Medicaid drug rebate agreement. However, for many reasons, not all manufacturers of Part B drugs participate in the rebate program.[24] In the third quarter of 2012, at least 45 manufacturers of Part B drugs did not have rebate agreements and thus were not required to report ASPs for any of their NDCs.

That quarter, 22 of the 45 manufacturers that did not have rebate agreements voluntarily reported ASPs

In the third quarter of 2012, 22 manufacturers reported ASPs for 272 of their 274 Part B NDCs despite not being required to do so under current law. Manufacturers reported ASPs for an additional 73 products represented by alternative IDs rather than NDCs.[25] ASPs associated with these NDCs and alternative IDs were included in payment amount calculations for 86 HCPCS codes.

Payment amounts for 36 of 86 HCPCS codes were calculated solely on the basis of ASPs submitted by manufacturers that did not have rebate agreements. If these manufacturers had elected not to report ASPs for

[22] Ten manufacturers are included among the 63 with NDCs in the background file for which ASPs were not reported in the third quarter of 2012.

[23] These NDCs matched the definition of 17 HCPCS codes included in our purposive sample of 87 high-expenditure drugs selected for additional review.

[24] For example, manufacturers of products paid as drugs under Part B but considered devices and not drugs by Medicaid and FDA typically do not have rebate agreements and therefore are not required to report ASPs.

[25] Because these products did not have NDCs (and thus no labeler codes), we could not determine the exact number of manufacturers represented. The products were skin substitutes (used to aid in wound closure and wound healing) and certain injections for knee pain, which are not classified as drugs by FDA.

their products, Part B payment amounts for the 36 HCPCS codes could not have been calculated on the basis of ASPs. CMS would typically have calculated payment amounts using list prices published in compendia, which OIG has found do not accurately reflect actual market prices.[26, 27]

For example, NDCs associated with a high-expenditure "device" HCPCS code representing hyaluronan (HCPCS code J7321) were associated solely with manufacturers that did not have rebate agreements. If these manufacturers had chosen not to report ASPs for their NDCs in the third quarter of 2012, payment amounts for the HCPCS code could not have been based on ASPs. Part B spent a total of $67 million for this HCPCS code in 2012. If the payment amount were calculated on the basis of WACs, Part B expenditures would have substantially increased because the associated WACs were much greater than the ASPs.[28]

Payment amounts for 50 of 86 HCPCS codes were calculated on the basis of third-quarter 2012 ASPs submitted both by manufacturers that had rebate agreements and by manufacturers that did not. If the manufacturers without rebate agreements had chosen not to report ASPs for their products, payment amounts for the corresponding HCPCS codes could have still been based on ASPs (because other manufacturers were still required to report). However, the payment amounts for 5 of the codes would have increased (between 3 and 40 percent) and those for 7 of the codes would have decreased (between 1 and 49 percent). For the remaining 38 codes, payment amounts would have remained the same.

The remaining 23 manufacturers did not report ASPs for any of their NDCs in the third quarter of 2012

At least 23 manufacturers that did not have rebate agreements did not report ASPs for any Part B NDCs in third quarter of 2012.[29] If these manufacturers had been required to report ASPs that quarter, CMS could have received data for 169 additional NDCs associated with 36 HCPCS codes. In total, 124 of the 169 "nonrequired" NDCs were already listed in the ASP background file. The remaining 45 NDCs were not listed in the

[26] CMS used published prices to set payment amounts for four HCPCS codes in the first quarter of 2013 because none of the manufacturers were required to report ASPs and (1) the manufacturers did not submit ASPs; (2) the manufacturers submitted unusable ASPs; or (3) the NDCs were obsolete, near obsolete, or represented terminated drugs. In three of the cases CMS used wholesale acquisition costs (WACs) as the basis for payment amounts, and in the other case it used average wholesale prices.

[27] OIG, *Medicaid Drug Price Comparisons: Average Manufacturer Price to Published Prices*, OEI-05-05-00240, June 2005.

[28] The WACs of associated NDCs exceeded ASPs by between 52 and 96 percent.

[29] Twenty of the twenty-three were repackagers. Repackagers purchase drugs from manufacturers to resell in smaller packages. Many do not participate in the MDRP, and their drugs are not eligible for Federal financial participation under Medicaid.

ASP background file but matched the definition of at least one high-expenditure HCPCS code.

For a small number of drugs, inaccuracies in CMS's ASP files may have affected Medicare payments

The product information (e.g., package sizes and billing units per package size) listed in the background and crosswalk files for an NDC sometimes differed from the product information listed in the national compendia.[30] After performing numerous checks, we believe that inaccurate product information for 27 NDCs may have affected payment amount calculations for 23 HCPCS codes in the third quarter of 2012. For 19 of these 23 codes, the discrepancies had little impact on Part B payments, with the overall effect on first-quarter 2013 expenditures being less than $7,500 per code.[31] For the remaining four codes, the impact was likely more substantial, ranging from $15,000 to $203,000 per code in that quarter.

For example, because of incorrectly listed package sizes and package quantities for NDCs crosswalked to HCPCS code Q3025, Medicare may have inadvertently underpaid providers by 9 percent in the first quarter of 2013; the Part B payment amount for the HCPCS code should have been $319.09 instead of $291.64. Part B expenditures for this code were $2.2 million in the first quarter of 2013. In contrast, Medicare apparently overpaid providers by 12 percent for HCPCS code J1170 in the first quarter of 2013 as a result of an incorrect unit conversion for one NDC. Medicare should have paid providers $1.42 per unit instead of $1.61 per unit. Part B expenditures for this code were $898,330 that quarter.

For an additional 161 NDCs, potential discrepancies in the ASP files had zero effect on payment amounts—in many cases, because of CMS's quality control efforts. For example, half of the 161 NDCs represented contrast agents, for which manufacturers have consistently reported their ASPs by vial rather than by NDC. CMS took this reporting anomaly into account when calculating the payment amount.[32] In other cases, the NDCs in question were excluded altogether from the payment amount calculations or the data was incorrect in the crosswalk file but correct in the background file.

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[30] When there were differences in the product information listed in CMS's files and the national compendia, we reviewed information from other sources (such as drug package labels from FDA's Web site) to determine the reasons for the discrepancies.

[31] In these cases, either the "corrected" payment amount changed only slightly (less than 1 percent for 9 codes) and/or the HCPCS code was associated with minimal expenditures.

[32] For example, an NDC may represent 10 vials of a drug, but the manufacturer reports the ASP for a single vial. If CMS recognizes this, the background file would then "incorrectly" list a package size of 1 rather than 10 so that the issue is accounted for when CMS calculates the volume-weighted ASP for the HCPCS code.

Because the crosswalk file is often used by State Medicaid agencies when invoicing manufacturers for rebates, inaccuracies in the published crosswalk file may impact the amount of rebates paid to States even when payment amounts were not affected. However, CMS staff informed us that users of the crosswalk file, such as State Medicaid agencies, should be aware that crosswalk data are intended solely for Part B drug payment purposes and that some of the data as presented in the crosswalk may not be suitable for other uses.

CMS has improved its ASP-related processes and procedures; however, challenges remain

A previous OIG study found that CMS's procedures for collecting, entering, and verifying manufacturer-reported ASP data for Part B drugs reduce efficiency and lead to potential errors. As a result, OIG recommended improvements to ASP-related processes, including the development of an automated system for submitting ASP data.[33] CMS has made progress in addressing OIG's recommendation; however, certain areas of concern still remain.

CMS has yet to implement an automated system for manufacturer submission of ASP data

Unlike with its system for reporting AMP data under Medicaid, CMS does not have a fully automated system for collecting ASP data from manufacturers. Previously, we found that manufacturers instead typically mailed disks containing ASP data to CMS.[34] CMS staff then manually transferred every data element from the submissions into the ASP files. CMS now gives manufacturers the option of emailing the data to agency staff. CMS also provides manufacturers with a template to complete prior to submitting ASP data. CMS staff no longer manually transfer manufacturer-reported data, but instead use software such as Microsoft Excel and SAS to partially automate importation.

When we surveyed CMS in August 2013, the agency expected an automated system for ASP submission to be ready for manufacturer testing in the first quarter of 2014, with full implementation in the second quarter of the year. However, as of March 2014, CMS had not begun testing the automated system. Rather, the project was still in the pre-production phase and prototypes had been presented to CMS staff. CMS staff stated that testing with manufacturers had been postponed because of budget constraints and that the agency could not commit to a new implementation

[33] OIG, *Average Sales Prices: Manufacturer Reporting and CMS Oversight*, OEI-03-08-00480, February 2010.
[34] Ibid.

date at that time. According to CMS staff, the agency may not wish to preclude alternative methods for submitting ASP data once the new system is implemented, meaning that manufacturers may still have the option of sending files by mail or email.

CMS staff still conduct many data validation procedures manually

The efficiency of the ASP collection process should be substantially improved by an automated data collection system similar to the one that manufacturers use to report AMPs. However, once the data are submitted, CMS staff will still need to validate the manufacturer-reported data, group the appropriate NDCs into their associated HCPCS codes, and calculate volume-weighted ASPs.

According to CMS, staff manually check manufacturer-reported ASPs (with the assistance of Microsoft Excel and SAS) and seek clarification from manufacturers that submitted ASP data with certain errors.[35] If CMS receives corrected data, the agency incorporates it into payment amount calculations as soon as it is available. If data are not resubmitted prior to the payment-amount files being put into use by claims processing contractors, CMS may reissue new files to be used by pricing contractors.

CMS staff stated that although the planned automated reporting system will better structure some of the data verification procedures, some manual checks are unlikely to be fully automated because they require interpretation using specialized experience and knowledge of pharmaceutical packaging and clinical drug use.

CMS does not maintain a comprehensive list of manufacturers that are required to submit ASP data

All drug manufacturers that have rebate agreements are required to report pricing data to CMS. However, a 2010 OIG study found that CMS does not have a list of all manufacturers that have rebate agreements and produce Part B drugs.[36] CMS still does not maintain such a list. Instead, CMS's quarterly background files list only those NDCs for which manufacturers have previously reported ASPs and NDCs that have been identified by CMS contractors.

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[35] Staff check ASP data for issues including, but not limited to, incorrect NDCs; aberrant ASPs and number of units sold; incorrect product information; terminated NDCs; over-the-counter products; non-FDA-approved products; and non-Part B products. CMS seeks clarification if manufacturers submit ASPs with the following errors: incorrect NDCs; aberrant number of units sold and ASPs; and incorrect product information.

[36] OIG, *Average Sales Prices: Manufacturer Reporting and CMS Oversight*, OEI-03-08-00480, February 2010.

CONCLUSION AND RECOMMENDATIONS

When setting payment amounts for drugs covered under Medicare Part B, CMS relies on ASP data and product information reported by manufacturers. Our findings—like those of OIG's previous studies in this area—demonstrate that a number of manufacturers are not reporting the required ASP data for all of their drugs. Furthermore, because ASP reporting requirements are linked to Medicaid drug rebate agreements, some manufacturers of Part B drugs are not required to submit ASP data because they do not have a rebate agreement in effect. Even when ASPs were reported, we identified a small number of instances in which product and pricing information listed in CMS's background and crosswalk files were incorrect.

Unreported ASPs (whether required or not) and incorrect product and pricing information may result in Medicare payment amounts that are inaccurate and not reflective of all manufacturer sales prices. To improve the process for collecting ASP data and calculating ASP-based payment amounts, CMS is developing an automated system for manufacturer submissions, as previously recommended by OIG. However, even when this system has been implemented, certain issues may still present the potential for errors and inefficiencies.

Therefore, we recommend that CMS:

Continue to assist OIG in identifying and penalizing manufacturers that do not meet ASP reporting requirements

Pursuant to the Act, manufacturers may face CMPs or suspension of their rebate agreements if they fail to report ASP data in the required timeframe. CMS has worked with OIG to identify manufacturers that do not submit pricing data in a timely fashion, and OIG has initiated actions against certain manufacturers that failed to satisfy their submission requirements.

Seek a legislative change to directly require all manufacturers of Part B drugs to submit ASPs

The ASPs included in payment amount calculations for 86 HCPCS codes in the third quarter of 2012 were associated with manufacturers that were not required to provide ASPs under the current system because they did not have Medicaid rebate agreements in effect. Payment amounts for 36 of the 86 HCPCS codes were based solely on data reported by manufacturers that did not have rebate agreements, meaning that payment amounts would not be calculated on the basis of ASPs if the manufacturers chose to stop reporting ASPs for their Part B-covered products. Instead, payment amounts would be calculated on the basis of other pricing methodologies that do not reflect actual marketplace prices.

Also, additional manufacturers of Part B drugs are not submitting ASP data because they do not have a rebate agreement in effect, yet their products meet the definition of at least one Part B HCPCS code. Under the current system, CMS has no recourse to obtain pricing data from these manufacturers, even though this nonreporting results in Part B payment amounts that are not reflective of all marketplace prices.

As OIG similarly recommended in 2010, legislation that would directly require all manufacturers of Part B drugs to submit ASPs, regardless of whether the manufacturers have Medicaid drug rebate agreements in effect, should be included in the President's budget for a future year. Any provision should also include corresponding penalty language that mirrors the language in section 1927(c) of the Act to clearly allow for enforcement actions against manufacturers who fail to timely report information or provide false information. This would ensure that Medicare payment amounts are reflective of all Part B drugs.

Ensure the accuracy of product information for NDCs listed in the background and crosswalk files

According to our analysis, CMS's background and crosswalk files listed incorrect product information for a small portion of NDCs in the third quarter of 2012. In the vast majority of these cases, payment amounts were either unaffected or minimally affected. However, for 4 HCPCS codes, incorrect product information had a larger impact, ranging from $15,000 to $203,000 per quarter. We have provided CMS with a list of the NDCs for which we believe product information may be incorrect.

Finalize the implementation of automated ASP-related procedures by using AMP-related processes as a model, and subsequently require all manufacturers to submit ASPs through the automated system

When manufacturers electronically enter drug product data and AMP data for each of their covered NDCs into the automated system used in Medicaid, the system electronically reviews manufacturers' pricing submissions for data errors, notifies manufacturers about potential problems, and may reject files with detected errors. In other words, the processes for collection, entry, and validation of data occur simultaneously upon data collection with minimal manual steps for CMS staff, allowing for more timely and accurate Medicaid payment amount calculations.

In 2010, OIG recommended that CMS establish automated processes for collecting ASP data to, among other goals, limit the possibility of data entry errors and to increase efficiency. CMS concurred with the recommendation and stated that it was working with contractors to improve the efficiency of ASP-related processes. As of March 2014, an

automated system for the collection of ASP data was still in the development phase and CMS could not estimate when the system would actually be implemented.

Furthermore, according to CMS staff, the agency may still allow manufacturers to submit ASP data files by mail or email even when the automated system has been fully implemented and functions reliably. This could greatly limit the system's efficiency and ability to prevent potential errors. CMS also stated that it has not determined the extent to which data verification will be automated, but there will likely be no substantial changes to the overall checks. According to CMS, many of the processes that are automated in AMP collection, such as verifying NDCs prior to accepting the associated pricing data, may not be automated in ASP collection.

Many manufacturers that submit ASPs already submit AMPs and thus are familiar with the concept of an automated price-reporting system. Therefore, we believe that CMS should finalize the implementation of automated ASP-related processes as soon as possible and should use the AMP data system as a model for automated ASP-related systems.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In its comments on the draft report, CMS concurred with our first, third, and fourth recommendations. CMS stated that it will continue to assist OIG with ongoing efforts to identify and penalize manufacturers that do not meet ASP reporting requirements. Further, the agency stated that it either has corrected or will correct the product information errors OIG identified. Finally, CMS stated that it is continuing its plans to implement an automated system for collecting ASPs. However, the agency has not yet set an implementation date and is reluctant to eliminate manual data collection processes.

In nonconcurring with our second recommendation, CMS stated that a proposal to require manufacturers of Part B drugs to submit ASPs was not included in the annual President's budget. We continue to recommend that CMS draft, and submit for review, such a legislative proposal for consideration for inclusion in future budget and legislative agendas. While CMS cannot dictate what legislative proposals are included in the President's budget, CMS does have the authority to develop legislative proposals for Medicare.

For the full text of CMS's comments, see Appendix C.

APPENDIX A

Descriptions and 2012 Medicare Part B Spending for Sample of 87 High-Expenditure HCPCS Codes

HCPCS Code	Description	HCPCS Dosage	2012 Part B Spending
J0129	Abatacept injection	10 mg	$206,136,065
J0152	Adenosine injection	30 mg	$23,708,630
J0475	Baclofen injection	10 mg	$19,208,292
J0490	Belimumab injection	10 mg	$20,634,278
J0585	Botulinum toxin type a	1 unit	$127,779,481
J0641	Levoleucovorin injection	0.5 mg	$57,932,049
J0718	Certolizumab pegol injection	1 mg	$32,045,412
J0775	Collagenase, clost hist injection	0.01 mg	$18,281,400
J0878	Daptomycin injection	1 mg	$23,614,809
J0881	Darbepoetin alfa	1 mcg	$224,915,934
J0885	Epoetin alfa	1000 units	$233,726,603
J0894	Decitabine injection	1 mg	$85,857,807
J0897	Denosumab injection	1 mg	$347,264,989
J1300	Eculizumab injection	10 mg	$44,153,474
J1325	Epoprostenol injection	0.5 mg	$23,924,996
J1440	Filgrastim injection	300 mcg	$31,108,731
J1441	Filgrastim injection	480 mcg	$73,962,548
J1453	Fosaprepitant injection	1 mg	$30,406,416
J1459	Immune globulin (privigen) injection	500 mg	$17,461,364
J1559	Hizentra injection	100 mg	$131,956,964
J1561	Gamunex injection	500 mg	$87,051,809
J1568	Octagam injection	500 mg	$43,113,356
J1569	Gammagard liquid injection	500 mg	$100,888,948
J1745	Infliximab injection	10 mg	$704,243,666
J1786	Imuglucerase injection	10 units	$19,257,388
J2260	Milrinone lactate injection	5 mg	$97,917,244
J2323	Natalizumab injection	1 mg	$96,127,091
J2353	Octreotide depot injection	1 mg	$161,290,474
J2357	Omalizumab injection	5 mg	$74,723,773
J2469	Palonosetron hydrochloride injection	25 mcg	$142,771,327
J2505	Pegfilgrastim injection	6 mg	$642,878,567
J2778	Ranibizumab injection	0.1 mg	$1,220,360,809
J2785	Regadenoson injection	0.1 mg	$126,757,965
J2796	Romiplostim injection	10 mcg	$62,699,749
J3262	Tocilizumab injection	1 mg	$66,021,878
J3285	Treprostinil injection	1 mg	$158,706,362
J3315	Triptorelin pamoate	3.75 mg	$17,143,907
J3487	Zoledronic acid	1 mg	$163,850,642
J3488	Reclast injection	1 mg	$115,147,875
J7187	Humate-P, injection	1 IU	$16,768,045
J7189	Factor viia	1 mcg	$104,920,500
J7190	Factor viii	1 IU	$30,207,228
J7193	Factor IX non-recombinant	1 IU	$17,760,145

(continued on next page)

Descriptions and 2012 Medicare Part B Spending for Sample of 87 High-Expenditure HCPCS Codes (continued)

HCPCS Code	Description	HCPCS Dosage	2012 Part B Spending
J7195	Factor IX recombinant	1 IU	$43,404,226
J7198	Anti-inhibitor	1 IU	$40,190,843
J7308	Aminolevulinic acid hydrochloride	354 mg	$19,006,023
J7321	Hyalgan/supartz injection	per dose	$67,142,161
J7323	Euflexxa injection	per dose	$47,210,237
J7324	Orthovisc injection	per dose	$56,618,033
J7325	Synvisc or Synvisc-One	1 mg	$144,640,590
J7507	Tacrolimus oral	1 mg	$195,177,053
J7517	Mycophenolate mofetil oral	250 mg	$81,812,303
J7518	Mycophenolic acid	180 mg	$111,639,367
J7520	Sirolimus oral	1 mg	$48,927,996
J7605	Arformoterol inhalation solution	15 mcg	$110,200,481
J7606	Formoterol fumarate inhalation solution	20 mcg	$54,001,470
J7613	Albuterol non-comp unit	1 mg	$26,604,246
J7620	Albuterol and ipratropium bromide	2.5 mg/0.5 mg	$45,068,105
J7626	Budesonide inhalation solution	up to 0.50 mg	$214,727,879
J7682	Tobramycin non-compounded unit	300 mg	$28,084,657
J7686	Treprostinil inhalation solution	1.74 mg	$127,959,381
J9025	Azacitidine injection	1 mg	$141,956,248
J9033	Bendamustine injection	1 mg	$160,131,900
J9035	Bevacizumab injection	10 mg	$624,753,554
J9041	Bortezomib injection	0.1 mg	$278,371,303
J9043	Cabazitaxel injection	1 mg	$51,432,612
J9055	Cetuximab injection	10 mg	$153,516,065
J9070	Cyclophosphamide injection	100 mg	$18,900,266
J9171	Docetaxel injection	1 mg	$123,393,142
J9179	Eribulin mesylate injection	0.1 mg	$31,799,237
J9201	Gemcitabine hydrochloride injection	200 mg	$44,953,525
J9217	Leuprolide acetate suspension	7.5 mg	$233,311,653
J9228	Ipilimumab injection	1 mg	$85,176,620
J9263	Oxaliplatin	0.5 mg	$308,803,693
J9264	Paclitaxel protein bound	1 mg	$86,545,808
J9303	Panitumumab injection	10 mg	$30,394,295
J9305	Pemetrexed injection	10 mg	$291,644,303
J9310	Rituximab injection	100 mg	$876,309,447
J9330	Temsirolimus injection	1 mg	$20,141,980
J9355	Trastuzumab injection	10 mg	$272,619,113
J9395	Fulvestrant injection	25 mg	$96,635,702
Q0138	Ferumoxytol, non-ESRD	1 mg	$21,218,364
Q2037	Fluvirin vaccine	0.5 ml	$60,260,767
Q2038	Fluzone vaccine	0.5 ml	$40,468,584
Q2043	Sipuleucel-T	minimum 50 million cells	$156,176,155
Q4074	Iloprost inhalation solution	up to 20 mcg	$59,385,872
Q4106	Dermagraft skin substitute	1 SQ CM	$22,869,459
Total			**$11,798,273,705**

Source: OIG analysis of 2012 PBAR data.

APPENDIX B

Detailed Methodology for Identifying Part B Drug NDCs Not Listed in the Background File

CMS's background file generally includes an NDC only if an ASP for the drug has been previously reported by the manufacturer. Therefore, in addition to determining the number of NDCs listed in the third-quarter background file for which ASPs were not reported, we also identified NDCs that met the definition of a HCPCS code but were not included in the background file. Because of the complex steps required to identify these NDCs, we focused this segment of the analysis on our purposive sample of 87 high-expenditure HCPCS codes.

Using CMS's third-quarter background file, we first created a list of all known NDCs associated with the 87 HCPCS codes. For these NDCs, we then obtained the generic formulation code (GFC) from *Red Book* and the generic code number (GCN) from the *National Drug Data File*. GFCs and GCNs are unique six-digit codes that identify drugs with common active ingredients, master dosage forms, strengths, and routes of administration. A HCPCS code may be associated with more than one GFC or GCN, and multiple HCPCS codes may be associated with the same GFC or GCN. We developed a list of all NDCs in *Red Book* and the *National Drug Data File* with GFCs or GCNs associated with the 87 HCPCS codes and identified the NDCs that were not included in the background file. We used the *HCPCS Code Level II Reference Book* to confirm that each of the NDCs we identified actually met the definition of the HCPCS code.

Manufacturers associated with the remaining NDCs have likely never reported ASPs for the drugs to CMS, even though the NDCs represent drugs that are in the market and meet the definition of at least one Part B HCPCS code. We matched the labeler codes for these NDCs to the MDRP-participating manufacturer file to determine whether the associated manufacturers were required to report ASPs. We also counted the number of manufacturers that did not have rebate agreements to estimate the additional number that would be required to report ASP data if previous OIG recommendations had been implemented.

APPENDIX C

Agency Comments

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: JUN 19 2014

TO: Daniel R. Levinson
Inspector General

FROM: Marilyn Tavenner /S/
Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: Limitations in Manufacturer Reporting of Average Sales Price Data for Part B Drugs (OEI-12-13-00040)

The Centers for Medicare & Medicaid Services (CMS) appreciates the opportunity to review and comment on the above subject OIG draft report. OIG's objectives were to determine whether manufacturers reported average sales prices (ASPs) for all Part B drugs in the third quarter of 2012; to determine the effect on ASP reporting if all manufacturers of Part B drugs were required to submit ASPs; to assess the validity and accuracy of data contained in CMS's ASP files; and to determine whether CMS has improved its process for collecting and analyzing ASPs since the publication of OIG's earlier report.

The OIG compared CMS data from internal ASP data files and the public ASP crosswalk file against national price compendia data. CMS's files were associated with payment limits that were in effect during the first quarter of 2013. Using these files, OIG determined how many manufacturers did not report ASP data to CMS, and OIG determined if CMS and compendia information for specific drug products as identified by National Drug Codes (NDCs) were consistent. OIG also conducted a survey of CMS's policies to determine if ASP data collection processes were being improved.

Based on the data comparison described above, OIG determined that up to one-third of manufacturers with Medicaid drug rebate agreements (that is, manufacturers that must report ASP data to CMS) did not submit ASP data for at least some of their Part B drugs. OIG also noted that 45 manufacturers without Medicaid drug rebate agreements submitted ASP data. OIG's assessment of CMS's ASP-related processes and procedures found improvements compared to previous studies. However, OIG also found potentially inaccurate product information for 27 NDCs that may have affected ASP payment limit calculations. OIG believes that little impact on payment amounts has resulted in most of these cases. However, for NDCs associated with four Healthcare Common Procedural Coding System (HCPCS) codes, OIG estimated a payment impact ranging from $15,000 to $203,000 per code during the study period. The report also discussed the impact of information that is published on the ASP crosswalk.

The OIG recommendations and CMS responses to the recommendations are discussed below.

OIG Recommendation

The OIG recommends that CMS continue to assist the OIG in identifying and penalizing manufacturers that do not meet ASP reporting requirements.

CMS Response

The CMS concurs with the recommendation. OIG and CMS have worked together cooperatively on ASP issues in the past and we plan to continue assisting OIG with its ongoing compliance and enforcement efforts.

OIG Recommendation

The OIG recommends that CMS seek a legislative change to directly require all manufacturers of Part B drugs to submit ASPs.

CMS Response

The CMS does not concur with this recommendation at this time. The President's budget for the upcoming fiscal year does not include any proposals to require manufacturers of Part B drugs to submit ASPs. However, we will take this recommendation into consideration in the future.

OIG Recommendation

The OIG recommends that CMS ensure the accuracy of product information for NDCs listed in the background and crosswalk files.

CMS Response

The CMS concurs with the recommendation. We appreciate OIG's detailed evaluation of our internal and crosswalk files. OIG identified errors associated with the product information for 27 NDCs. We had identified and corrected several of the errors prior to the completion of the report, including a HCPCS change associated with one code identified by OIG as having significant potential impact. We are incorporating OIG's findings into our internal files so our calculations for the July 1, 2014 price files will be based on more accurate data. We will then examine and update the crosswalk files as needed so that Part B drug payment needs are met.

We would like to further add that OIG's report notes that the ASP price files and the crosswalk are for use in Medicare Part B pricing and claims payment activities and may not be suitable for purposes other than the payment of Medicare Part B drug claims. We concur with this statement by OIG.

OIG Recommendation

The OIG recommends that CMS finalize the implementation of automated ASP-related procedures by using AMP-related processes as a model, and subsequently require all manufacturers to submit ASPs through the automated system.

CMS Response

The CMS concurs with the recommendation. We are continuing with testing and planning for the final phases of the project. Although we have not set an implementation date, we intend to continue work on the automation project pending availability of budgeted funds. We agree with automating as much of the process as possible; however, we also note that because some validation of Part B drug payment data requires an understanding of nuances in Part B drug payment policy, manual intervention may still be required in order for payments to be calculated correctly. Further, we are reluctant to eliminate the possibility of using alternative methods to deliver manufacturers' data to CMS. We believe it is important to preserve alternative approaches for the transmission of data as a backup, particularly during the early phase of the transition.

The CMS thanks OIG for the work done on this issue and looks forward to working with OIG in the future.

ACKNOWLEDGMENTS

This report was prepared under the direction of Dave Tawes, Regional Inspector General for Evaluation and Inspections in the Baltimore regional office.

Bahar Adili served as the lead analyst for this study. Central office staff who provided support include Mandy Brooks, Althea Hosein, Meghan Kearns, and Christine Moritz.

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