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Manufacturers May Need Additional Guidance To Ensure Consistent Calculations of Average Sales Prices

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Why OIG Did This Review

To address concerns about the accuracy of average sales prices (ASPs) for Medicare Part B drugs, Congress included a provision in the Consolidated Appropriations Act, 2021, that directs the Office of Inspector General (OIG) to review the accuracy of manufacturer-reported ASP data. Ensuring the accuracy of ASPs is vital because the Centers for Medicare & Medicaid Services (CMS) uses these prices to directly calculate payment amounts under Medicare Part B.

How OIG Did This Review

OIG has previously conducted several resource-intensive audits of manufacturer-reported pricing data that resulted in limited findings. In general, OIG's ability to identify noncompliance in price reporting is limited because of broad regulations that allow manufacturers to make reasonable assumptions in the absence of specific guidance. For this reason, OIG decided to try a different approach to assess the accuracy of ASPs. For this evaluation, we compared ASPs for the 30 highest-expenditure drugs in Medicare Part B to different benchmark prices for prescription drugs in the second quarter of 2021. We then surveyed the 20 manufacturers of these 30 drugs to determine what factors they take into consideration when calculating their ASPs.

The 30 drugs in our review accounted for nearly 64 percent of Medicare Part B drug spending in 2020. The entire body of drugs marketed by the 20 manufacturers included in our survey accounted for almost 80 percent of Part B drug spending.

Key Takeaway

OIG identified a small number of inconsistencies in how average sales prices (ASPs) for Part B drugs are calculated and nine specific areas for which manufacturers believe additional CMS guidance may be needed to ensure more accurate and consistent ASP calculations across the industry.

What OIG Found

Comparisons of ASPs to other benchmark prices provided little insight into potential inaccuracies. However, through manufacturer surveys, OIG was able to identify a small number of inconsistencies in manufacturer calculations of ASPs, such as in the treatment of TRICARE-related drug sales for military members or whether certain fees paid to third parties meet the criteria for being considered a "bona fide service fee" to be excluded from ASP. We also noted several areas where manufacturers would like additional CMS guidance, including the treatment of sales and rebates offered through value-based purchasing arrangements.

The manufacturers we surveyed also expressed concerns that CMS has published comparatively fewer regulations and less overall guidance regarding the calculation of the ASPs used in Medicare compared to the average manufacturer prices and best prices used in Medicaid. As a result, manufacturers say they must rely on reasonable assumptions to a much greater extent when calculating ASP than they do with these other payment benchmarks.

What OIG Recommends

We recommend that CMS actively review current guidance related to the areas identified in this report and determine whether additional guidance would ensure more accurate and consistent ASP calculations. Specifically, OIG noted nine areas for which manufacturers believe additional guidance may be needed to reduce distortions among reported ASPs and ensure consistency across the industry. We suggest that CMS prioritize issues that may have greater effect on pricing and payments (e.g., value-based arrangements). CMS should also give particular consideration to guidance regarding TRICARE-related sales and determinations of bona fide service fees—two areas where insufficient guidance may be leading to inconsistencies in manufacturer ASP calculations.

CMS concurred with our recommendation.

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GLOSSARY

Terminology	General Description*
Average Manufacturer Price (AMP)	The average price paid to the manufacturer for a drug in the United States by wholesalers for drugs distributed to retail community pharmacies and by retail community pharmacies that purchase drugs directly from the manufacturer, net of any applicable discounts.
Average Sales Price (ASP)	A manufacturer's sales of a drug to all purchasers in the United States in a calendar quarter (net of most discounts) divided by the total number of units of the drug sold by the manufacturer in that same quarter.
Best Price (BP)	For a single source drug or innovator multiple source drug of a manufacturer (including the lowest price available to any entity for an authorized generic drug), the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity in the United States in any pricing structure (including capitated payments) in the same quarter for which the AMP is computed.
Bona Fide Service Fees (BFSFs)	Fees paid by a manufacturer to an entity that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug.
Bundled Sales Arrangement	Any arrangement (1) under which the rebate, discount, or other price concession is conditioned upon (a) the purchase of the same drug, drugs of different types, or another product, or (b) some other performance requirement; or (2) whereby the resulting discounts or other price concessions are greater than those which would have been available had the bundled drugs been purchased separately or outside the bundled arrangement.
Group Purchasing Organization (GPO)	An organization that purchases, or arranges for or negotiates, the purchase of covered drugs, devices, biologicals, or medical supplies for a group of individuals or entities (i.e., health care providers), but not solely for use by the entity itself. Provider use of GPOs is voluntary and GPOs are often owned by their member providers.

GPO Administrative Fees	Fees designed, in part, to cover a GPO's operating expenses and serve as its main source of revenue. The amount of the fee is based on a percentage of the purchase price for a product obtained through GPO contracts. When negotiated, the fee is paid by a manufacturer each time a GPO's health care provider customer purchases a product through a GPO contract. In addition to using these fees to cover operating expenses, such as providing services to their customers, GPOs may distribute a portion of the fees to their customers or use them to finance other ventures such as investing in other companies.
Pharmacy Benefit Manager (PBM)	An organization that serves third-party payers, including commercial insurance companies, government payers, and employer organizations in the retail/outpatient prescription arena, by negotiating supply and reimbursement arrangements for pharmaceuticals.
PBM Administrative Fees	Fees paid by manufacturers for the various administrative functions conducted by PBMs on their behalf. For example, PBMs may charge administrative fees for managing drug formularies; claims processing; and to administer, invoice, allocate, and collect rebates under a PBM's rebate program. PBM administrative fees are determined on an individual basis according to contracts with manufacturers.
TRICARE	The U.S. military's health care program that functions as government-managed health insurance. TRICARE's various coverage plans provide health care for active-duty and retired uniformed services members and their families. TRICARE's pharmacy benefit allows enrollees to obtain prescription drugs either from military treatment facility pharmacies operated by DOD or from TRICARE's mail order and retail pharmacies operated through the private sector.
Value-Based Purchasing (VBP) Arrangements	Arrangements between a payer and drug manufacturer that tie payment for a drug to an agreed-upon measure (e.g., clinical outcome).
Wholesale Acquisition Cost (WAC)	The manufacturer's list price for a drug distributed to wholesalers or other direct purchasers, not including discounts or rebates.

*Note: These descriptions are intended to be plain-language explanations rather than strict statutory or regulatory definitions.

BACKGROUND

OBJECTIVES

1. Determine how average sales prices (ASPs) for high-expenditure Part B drugs compare to other benchmark prices.
2. Examine the factors that manufacturers take into consideration when determining which sales, discounts, and fees to include in their ASP calculations.

Costs for prescription drugs under Medicare Part B continue to rise, with the program and its enrollees spending over $40 billion in 2020, more than double the amount spent a decade ago. Ensuring the accuracy of manufacturer-reported ASPs is vital given that the Centers for Medicare & Medicaid Services (CMS) uses these prices to directly calculate reimbursement amounts to providers. Instances in which ASPs do not accurately reflect acquisition costs may result in excessive payments for Medicare and its enrollees, or in contrast, lead to access issues if providers are paid below cost.

Congress has expressed concerns to the Office of Inspector General (OIG) regarding the accuracy of ASPs. To address this concern, the Consolidated Appropriations Act, 2021, directed OIG to review manufacturer-reported ASP data.[1] OIG has previously conducted several resource-intensive audits of manufacturer-reported pricing data that resulted in limited findings. In general, OIG's ability to identify noncompliance in price reporting is limited because of broad regulations that allow manufacturers to make reasonable assumptions in the absence of specific guidance.[2] For this reason, OIG decided to try a different approach to assess the accuracy of ASPs. This evaluation compares ASPs to other benchmark prices and provides insight from manufacturers on how ASPs are calculated.

Medicare Part B Coverage and Payment for Prescription Drugs

Medicare Part B covers a limited number of outpatient prescription drugs and biologicals (hereinafter referred to as drugs). These drugs are usually injected or infused in physicians' offices or other outpatient settings to treat a wide range of diseases including cancer, autoimmune disorders, and macular degeneration. Part B also covers several vaccines, and under certain conditions, self-administered drugs such as oral anticancer drugs and inhalation drugs used in conjunction with durable medical equipment.

Medicare Part B Drug Spending

Medicare Part B and its enrollees spent over $40 billion on more than 600 drugs in 2020; however, a relatively small number of drugs account for most Part B drug spending. For example, just 30 brand-name drugs in 2020 represented nearly two-thirds ($25.7 billion) of the total expenditures.[3, 4] These 30 drugs had average per-patient costs ranging from $2,200 to $351,000 in 2020, with 21 exceeding $20,000 per year.[5] Medicare enrollees were responsible for 20 percent of these annual drug costs through coinsurance.[6]

ASP Payment Methodology

Effective January 1, 2005, the Medicare Modernization Act of 2003 revised how Medicare reimburses health care providers for drugs covered under Part B, moving from a methodology based on average wholesale prices to one based on ASPs.[7] Federal law defines ASP as a manufacturer's sales of a drug to all purchasers in the United States in a calendar quarter (net of most discounts) divided by the total number of units of the drug sold by the manufacturer in that same quarter.[8]

Given the complexities of the pharmaceutical marketplace, manufacturers may find it difficult to determine how to treat certain sales practices when calculating ASPs. In the absence of guidance, manufacturers are permitted to make reasonable assumptions that are consistent with requirements and intent of federal law and regulations.[9] See Appendix A for more detail on the ASP payment methodology.

Manufacturer Reporting Requirements for Average Sales Price

Pursuant to section 1927(b)(3) of the Social Security Act (the Act), manufacturers must provide CMS with the ASP and sales volume for each of their Part B drugs on a quarterly basis. CMS also requires any reasonable assumptions to be submitted along with the ASP data.[10]

Manufacturers may face civil money penalties 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).[11] CMS provides information to OIG identifying manufacturers that do not submit ASP data timely. According to CMS, the agency also performs numerous quality checks on ASP data at the time they are reported by manufacturers and seeks clarification or correction if the data do not pass CMS's quality checks.

Other Benchmark Prices

Average Manufacturer Price

Medicaid drug rebates are calculated, in part, using average manufacturer prices (AMPs), a benchmark similar to ASP. An AMP is defined as "the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to retail community pharmacies and retail community pharmacies that purchase drugs directly from the manufacturer," net of any applicable discounts.[12, 13] Manufacturers are required to provide CMS with the AMPs on a monthly and a quarterly basis for their covered outpatient drugs to be eligible for Federal financial participation provided under Medicaid.[14] Manufacturers must calculate AMPs, which calculation includes determining which sales and discounts are included or excluded from their calculations, consistent with federal law and regulation.[15] However, as with ASPs, in the absence of guidance and adequate documentation to the contrary, manufacturers are permitted to make reasonable assumptions that are consistent with the requirements and intent of the Act and federal regulations.[16] Each manufacturer must maintain adequate documentation supporting its assumptions.

AMP has been used as a reference point for ASP since Congress established the latter as the reimbursement basis for Medicare Part B drugs. The Act mandates that OIG compare ASPs with AMPs each quarter.[17] If OIG finds that the ASP for a drug exceeds the AMP by 5 percent, CMS is required to substitute the ASP-based payment amount with a lower calculated rate based on the AMP.[18] In April 2013, CMS began substituting payment amounts for drugs identified by OIG when the drugs meet certain criteria established under the agency's published price substitution policy.[19]

Wholesale Acquisition Cost

Manufacturers regularly report wholesale acquisition costs (WACs)—also referred to as "list prices"—to national drug compendia (e.g., First Databank, IBM Micromedex Red Book, and Medi-Span). The WAC is defined as an estimate of the manufacturer's list price for a drug distributed to wholesalers or other direct purchasers, not including discounts or rebates.[20] WACs remain widely used as a payment benchmark for private insurance reimbursement to pharmacies, physicians, and other providers.[21] Given that WAC is a list price, it may vary widely from the ASP and AMP of a given drug due to a number of factors, including the amounts of discounts and rebates that are offered by the manufacturer.

Other OIG Work Assessing the Accuracy of ASP and AMPs

In addition to this evaluation, OIG is conducting a companion study that provides insight into CMS's oversight of ASP data, including how the agency assesses an ASP's accuracy before using it to calculate Medicare Part B payment amounts.

In the 3 years following the implementation of ASP-based payments, OIG audited the ASP calculations of eight drug manufacturers. Given the confidential nature of the

data being audited, any findings were not released publicly. On average, these manufacturer audits took over 2 years to complete. Similarly, between 2003 and 2014, OIG audited the AMP calculations of six drug manufacturers, at an average of 1.5 years to complete. In general, OIG's ability to identify noncompliance in ASP and AMP reporting is limited because of broad regulations that allow manufacturers to make reasonable assumptions in the absence of specific guidance. In instances in which OIG could support findings of noncompliance, the overall impact was relatively minor or was soon addressed by new guidance. In balancing the time and costs of these efforts with our limited findings, OIG has not conducted any additional audits of ASPs or AMPs since 2014.

As previously noted, the Social Security Act mandates that OIG compare ASPs with AMPs. From 2005 to the present, OIG has conducted ASP-AMP comparisons each quarter and provided our findings to CMS. We also issue annual public reports summarizing the findings of these quarterly comparisons.[22]

Methodology

Scope

Given that the resource-intensive nature of our past manufacturer audits resulted only in limited findings, OIG elected to examine existing price benchmark data as well as information gleaned from manufacturer surveys to identify potential inaccuracies in reported ASPs. In this study, OIG compared the ASPs for the 30 highest-expenditure drugs in Medicare Part B to different benchmark prices in the second quarter of 2021 to identify any anomalies. These 30 drugs accounted for nearly 64 percent of Medicare Part B drug spending in 2020. We then surveyed the 20 manufacturers of these 30 drugs regarding the factors they consider when determining which sales, discounts, and fees to include in their ASP calculations for all the drugs they market (i.e., not only the highest-expenditure products). In total, all drugs marketed by the 20 manufacturers included in our survey accounted for almost 80 percent of Part B drug expenditures in 2020.

Data analysis

Sample

We obtained 2020 data on Medicare drug expenditures at the Healthcare Common Procedure Coding System (HCPCS) code level from CMS's Medicare Part B Drug Spending Dashboard.[a] We selected a purposive sample of the top 30 drugs (distinct HCPCS) with the highest Medicare expenditures in Part B, and categorized each of the drugs by common characteristics, such as the type of disease being treated, the amount of time on the market, or the availability of biosimilars or competitor

[a] To obtain reimbursement for Part B drugs, health care 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.

products.[b] We then identified the 75 national drug codes (NDCs) that are crosswalked to the 30 HCPCS codes using CMS's ASP files.[c]

Comparison of Benchmark Pricing

We obtained ASP, AMP, and WAC data from CMS for the 75 NDCs associated with the 30 highest-expenditure Part B drugs for the second quarter of 2021. To ensure that all prices represented comparable units, we calculated volume-weighted ASPs, AMPs, and WACs at the HCPCS code level (i.e., a single price across all associated NDCs of a drug) using sales and product data from CMS's ASP files. Finally, we compared the quarterly volume-weighted ASPs against their corresponding AMPs and WACs.[23]

Survey of Drug Manufacturers

The 30 drugs included in our review are marketed by 20 different pharmaceutical manufacturers. On February 22, 2022, we sent an electronic survey to each manufacturer with questions based on our analysis of the benchmark prices; previous evaluations related to manufacturer pricing data (including our study examining manufacturer reasonable assumptions in calculating AMPs); and experiences with auditing manufacturer ASPs and AMPs. We asked the manufacturers (1) to identify what types of sales, discounts, and fees were and/or were not included in their ASP calculations; (2) to explain how their ASP calculations differed from their AMP calculations; and (3) if they had any concerns about the accuracy of ASPs reported to CMS. All 20 manufacturers responded to our survey.

Limitations

We selected a purposive sample of 30 high-expenditure Medicare drugs produced by 20 drug manufacturers; therefore, our findings are limited to the drugs and manufacturers in our sample and not generalizable to all drugs and manufacturers. We did not verify the accuracy of manufacturer-reported ASP and AMP data, nor did we verify the underlying methodology that manufacturers used to calculate ASPs and AMPs. Manufacturers are required to submit their quarterly ASP and AMP data to CMS within 30 days of the close of the quarter. We did not determine whether manufacturers later provided any updated data to CMS. We relied on manufacturer responses to our survey and did not request that manufacturers provide documentation supporting their responses.

Standards

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

[b] The influenza vaccine (HCPCS 90662) was removed from our list of top 30 Part B Drugs because vaccines are not reimbursed using ASP.

[c] Manufacturers typically report ASPs by NDC, an 11-digit code that is divided into 3 segments identifying (1) the firm that manufactures, distributes, 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.

FINDINGS

Comparing the ASPs of the highest-expenditure drugs in Medicare Part B to other benchmark prices provided little insight into potential inaccuracies

The relationship between ASPs and WACs varied widely among the 30 highest-expenditure drugs, limiting any conclusions about potential inaccuracies

The comparison of ASPs to WACs did not result in the identification of any potential inaccuracies. The WACs exceeded the ASPs for all 30 high-expenditure Part B drugs in our review, which is to be expected given that WACs represent list prices (i.e., sticker prices) and do not reflect any available discounts. ASPs, in contrast, are determined on the basis of actual sales made by manufacturers and include many of the discounts available to purchasers.

Among the drugs included in our review, the gap between ASP and WAC varied greatly, with ASPs ranging from .5 percent to 68 percent below their WACs (see Exhibit A). None of the market-based factors we examined (e.g., the type of disease being treated, the amount of time on the market, or the availability of biosimilars or competitor products) reliably explained these large variations among individual drugs.

Exhibit A. The ASPs for the 30 highest-expenditure drugs in our review ranged from .5 percent to 68 percent below their WACs.

Percent ASP Was Below WAC	Number of Drugs
0.0-2%	4
2.1-5%	4
5.1-10%	7
10.1-25%	8
25.1-50%	3
50.1-75%	4
75.1-100%	0

Source: OIG analysis of 2Q-2021 volume-weighted ASPs and WAC at the HCPCS level.

Four drugs in our review had ASPs that were within 2 percent of their WACs. However, even such surprisingly small differences between ASPs and WACs do not necessarily signal that the former were inaccurate, as it is not altogether uncommon for manufacturers to offer little in the way of discounts or other price concessions for certain drugs. For each of these four drugs, manufacturers did report offering two to four different types of discounts for these products.[24] Nevertheless, given that these price reductions may have been quite small or available only to a limited number of

purchasers, OIG has no basis to conclude that the ASPs for these drugs are potentially inaccurate. Moreover, WACs for three of the four drugs rose by at least 2 percent when reported in the following quarter, raising the possibility that a reporting lag was partially responsible for the unusually small differences with the ASPs.

Comparisons of ASPs to AMPs help constrain Part B pricing, but are not generally effective in identifying inaccuracies in ASPs

ASPs and AMPs are calculated using similar methodologies but, in theory, are subject to opposite incentives. Practically speaking, manufacturers would prefer higher ASPs because the subsequent increased reimbursement under Medicare may encourage providers to prescribe their drug. In contrast, manufacturers would prefer lower AMPs, as these would result in manufacturers owing less in rebates under Medicaid. Congress recognized these competing incentives and mandated that OIG conduct regular comparisons of ASPs and AMPs, and that CMS lower Medicare payment amounts on the basis of our findings as a means to constrain ASPs.[25]

Over a 5-year period (2016 through 2020), OIG identified 96 drugs for which the ASP exceeded the AMP by more than 5 percent, the threshold set forth in statute. CMS subsequently lowered the payment amounts for 37 of these drugs after meeting criteria established through regulation.[26] These reduced payment amounts have led to nearly $31 million in savings for Medicare and its enrollees.[27] None of the 30 highest-expenditure drugs in our review were subject to price reductions during this period. Notably, only three drugs subject to price substitutions were ranked in the 100 highest-expenditure drugs in any year from 2016 to 2020, and in three-quarters of instances, the drugs were ranked below 300.

As we did for the WACs, OIG compared manufacturer-reported ASPs for the 30 highest-expenditure Part B drugs in 2020 to their AMPs from the second quarter of 2021 (see Exhibit B). For 24 of the 30 drugs, ASPs were less than the AMPs by as much as 10 percent (note: for 17 of the 24, the ASPs and AMPs were within 2 percent). However, in six cases, ASPs were actually higher than their AMPs, but never by more than 1 percent (i.e., all were well below the 5-percent threshold set forth in statute). According to the manufacturers of these drugs, several factors contributed to their ASPs slightly exceeding their AMPs. For example, ASPs are calculated at the package level while AMPs are calculated at the product level, or discounts may be applied during different quarters for one benchmark compared to the other.

Exhibit B. The ASPs for 24 of the highest-expenditure drugs in our review were less than their AMPs by as much as 10 percent.

Difference Between ASP and AMP	Number of Drugs
0.0-1%	6
-0.01-2%	17
-2.1-5%	3
-5.1-10%	4

Source: OIG analysis of 2Q-2021 volume-weighted ASPs and AMP at the HCPCS level.

Manufacturers reported a small number of inconsistencies in their ASP calculations

In general, all 20 manufacturers we surveyed were in full agreement as to which types of sales and discounts should be included in their ASP calculations (see Appendix B and Appendix C for how manufacturers treated each type of transaction listed in our survey), with the primary exception being certain TRICARE-related transactions. Manufacturers also reported inconsistent practices in the treatment of bona fide service fees (BFSFs).[d]

As many as 30 percent of manufacturers included certain TRICARE-related drug sales in their ASP calculations

As shown in Exhibit C, most of the manufacturers we surveyed reported excluding sales made to all types of TRICARE entities from their calculations. However, two manufacturers reported including sales to military treatment facilities, two reported including sales to TRICARE mail order pharmacies, and six included sales to TRICARE retail pharmacy (TRRx) programs.

Exhibit C. Surveyed manufacturers disagreed on whether to include TRICARE-related drug sales in their ASP calculations.

For all Part B drugs for which you report data to CMS, do you generally include the following types of sales (if applicable) in your ASP calculations?	Yes	No	N/A*
TRICARE:			
Military treatment facilities	2	16	2
TRICARE mail order pharmacy	2	17	1
TRICARE retail pharmacy program	6	13	1

Source: OIG analysis of manufacturer responses to OIG's 2022 Accuracy of Manufacturer-Reported ASPs survey.
* Not applicable.
Note: See Glossary for definitions of sales types.

A small number of manufacturers reported variations in how they determine whether a fee should be considered a bona fide service fee

Manufacturers must determine whether certain fees—such as administrative, product distribution, and data collection fees—are considered discounts that are included in their ASP calculations or BFSFs that are excluded from ASP. Three manufacturers expressed concerns that competitors may be taking disparate approaches when applying CMS's four-part test to make these determinations.[e]

[d] See Glossary for the definition of a bona fide service fee (BFSF).

[e] 42 CFR § 447.502. Under the four-part test for the purpose of calculating ASPs, a fee that is paid by a manufacturer to an entity is considered a bona fide service fee (BFSF) if (1) the fee is for a bona fide, itemized service that is actually performed on

Under the four-part test, a fee that is paid by a manufacturer to an entity—such as a group purchasing organization (GPO) or a pharmacy benefit manager (PBM)—cannot be considered a BFSF if the fee is passed through, in whole or in part, to one of its clients or customers.[f] For example, if a small portion of an administrative fee that is paid to a PBM is then transferred to a third-party health insurance plan that contracts with the PBM, the fee does not pass the four-part test and therefore cannot be considered a BFSF. Instead, the fee would be considered a discount and result in a lower ASP.

When calculating ASP, manufacturers are allowed to presume, in the absence of evidence or notice to the contrary, that the fee paid is not passed on.[28] However, five manufacturers made statements in their survey responses that highlight disagreement on what constitutes sufficient evidence of knowledge that a fee is passed through for purposes of the four-part test.[9] More specifically, some manufacturers reportedly require that GPOs and PBMs include a representation and warranty in their agreements that they will not pass their fees through, in whole or in part, to a client or customer of an entity, whether or not the entity takes title to the drug.[29] If a GPO or PBM refuses to provide this guarantee, the manufacturers do not consider the fee paid to be a BFSF. However, other manufacturers seem to take a less active approach by presuming that a fee is not passed through unless they are informed otherwise by their customer or an employee.

Manufacturers expressed concerns that a lack of CMS guidance on a range of ASP issues may result in inconsistencies

Ten of the 20 manufacturers surveyed indicated that there is a lack of clear guidance from CMS on issues related to the treatment of sales and discounts that affect ASP calculations. According to these manufacturers, CMS has published comparatively fewer regulations and less overall guidance regarding the calculation of ASPs used in Medicare than regarding the AMPs and best prices (BPs) used in Medicaid. As a result, manufacturers say they must rely on reasonable assumptions to a much greater extent when calculating ASPs than when calculating other payment benchmarks, thus creating the potential for inconsistent ASP calculations across manufacturers and products.

behalf of the manufacturer; (2) the manufacturer would otherwise perform or contract for the service in the absence of the service arrangement; (3) the fee represents fair market value; and (4) the fee is not passed on, in whole or in part, to a client or customer of any entity.

[f] See Glossary for a detailed explanation of a group purchasing organization (GPO), a pharmacy benefit manager (PBM), and their associated administrative fees.

[9] This includes two of the three manufacturers that expressed concerns that competitors may be taking disparate approaches when applying CMS's four-part test to make these determinations. OIG used manufacturer responses to open-ended survey questions to identify inconsistencies in determinations of BFSFs.

Manufacturers are seeking additional guidance in two sales-related areas

TRICARE Retail Pharmacy Sales

Four manufacturers expressed concerns that CMS has never sufficiently addressed how to treat sales to TRRx programs when calculating ASPs and therefore they need to make reasonable assumptions in their calculations. In discussing these reasonable assumptions, three manufacturers said they included such sales in their ASP calculations on the basis of CMS guidance related to AMP.[30] The fourth manufacturer excluded such sales on the basis of different guidance related to ASP and BP that does not specifically refer to TRRx programs.[31] These disparate approaches are reflected in the inconsistent practices related to TRRx described earlier.

Sales in U.S. Territories

Four manufacturers are seeking clarification on whether the ASP calculation should also include sales to the U.S. Territories once the requirement takes effect for AMP and BP. Beginning January 1, 2023, manufacturers must begin including sales in five U.S. Territories in their AMP and BP calculations.[32]

Manufacturers would also like additional guidance in four discount-related areas

Value-Based Purchasing Arrangements

Four manufacturers noted in their survey responses that there was insufficient guidance on the treatment of value-based and outcomes-based purchasing arrangements in the calculation of ASP.[h] Without clear guidance, manufacturers argue that they will need to adopt varying reasonable assumptions that could create distortions among reported ASPs. Specifically, three of these manufacturers cited issues raised by the multiple best prices (BPs) option recently created under the Medicaid Drug Rebate Program that removes some disincentives to the broader use of value-based purchasing (VBP) models.[33, 34, 35] These manufacturers believe CMS should clarify that sales and rebates for purchasing arrangements reported under the multiple BPs option for Medicaid rebate purposes should be excluded from ASP calculations.

Bundled Sales Price Concessions

It was noted in the manufacturer survey responses that CMS has not adopted a definition of the term "bundled sale" for the purpose of ASP calculations and instead directed manufacturers to adopt reasonable assumptions.[36] Two manufacturers also

[h] Value-based and outcomes-based purchase arrangements are intended to align pricing or payments to an observed or expected therapeutic or clinical value in a population using evidence-based or outcomes-based measurements.

stated that they would like additional guidance from CMS on the appropriate methodology for allocating bundled sales in ASP.

One of these two manufacturers specified three additional areas pertaining to bundled sales discounts for which it would like additional guidance:

- Whether unbundling a bundled arrangement should include just the discounts contingent on purchase or performance requirements or all discounts that may be part of the underlying arrangement.
- How to treat bundled sales that include both covered products and noncovered products (i.e., products for which there is no government price reporting obligation).
- How manufacturers should identify and reallocate discounts associated with sales that may be considered bundled across time periods. The manufacturer asserts that CMS guidance on these types of temporal bundling will be critical because they will play an important role in the implementation and evaluation of value- and outcomes-based arrangements, which may require assessing the efficacy of a drug over multiple reporting periods.

Bona Fide Service Fees

One manufacturer noted in its survey response that CMS has never defined the term "fair market value" for the purposes of the "bona fide service fee" definition.[i] The manufacturer would like additional guidance from CMS on the methodology that should be used to assess fair market value and the time period after which manufacturers should reassess the fair market value of fees to ensure consistency across the industry.

The same manufacturer also stated that it would welcome additional guidance from CMS regarding what constitutes sufficient evidence of knowledge that a fee is passed through for purposes of the four-part test.[j] This is supported by the three manufacturers' concerns—as described earlier—that competitors may be taking disparate approaches when applying CMS's four-part test to make these determinations.

Rebates for Drug Wastage Associated with Single-Use Vials

One manufacturer is seeking clarification on whether rebates related to discarded drugs from single-use vials should be included in ASP calculations. Every year, significant amounts of drugs left over and unused from single-dose vials are discarded.[37] Under Medicare Part B, health care providers receive payment for the

[i] Under the four-part test, a fee must represent fair market value to be considered a bona fide service fee (BFSF).

[j] Under the four-part test, a fee that is paid by a manufacturer to an entity cannot be considered a BFSF if the fee is passed through, in whole or in part, to one of its clients or customers. If a manufacturer has determined that a fee paid meets the other elements of the definition of "bona fide service fee," then the manufacturer may presume, in the absence of evidence or notice to the contrary, that the fee paid is not passed on. 71 Fed. Reg. 69669.

total amount of the drug indicated on the vial, including that which is discarded. Beginning January 1, 2023, manufacturers will be required to issue rebates to CMS for the portion of single-dose vials that are discarded when the drug is administered to Medicare Part B enrollees.[38, 39]

Manufacturers expressed a need for additional guidance on several administrative reporting issues

Several manufacturers briefly mentioned other areas where they would like to receive additional guidance from CMS, particularly related to administrative reporting questions. These included the following:

- The circumstances under which manufacturers should or must refile ASP data or the historical period for which such refiling should be considered.
- The reporting of potential negative ASPs (e.g., an ASP for which the amount of the discounts exceeds total sales in a quarter) as well as the lack of any guidance from CMS regarding how a negative ASP would be used in Medicare reimbursement rate calculations.
- Whether or how to use information in the NDC-HCPCS Crosswalk to identify the insulin products for which they should report ASPs.

CONCLUSION AND RECOMMENDATION

Ensuring the accuracy of manufacturer-reported ASPs is vital considering that CMS uses these prices to directly calculate reimbursement amounts under Medicare Part B. To address these concerns, the Consolidated Appropriations Act, 2021, directed OIG to review manufacturer-reported ASP data.

OIG has previously conducted several resource-intensive audits of manufacturer-reported pricing data that resulted in limited findings. In general, OIG's ability to identify noncompliance in price reporting is limited because of broad regulations that allow manufacturers to make reasonable assumptions in the absence of specific guidance. For this reason, OIG elected to try a different approach to assess the accuracy of ASPs.

In the end, our comparisons of ASPs to other benchmark prices provided little insight into potential inaccuracies. However, through the manufacturer surveys, OIG was able to identify a small number of inconsistencies in manufacturer calculations of ASPs, such as in the treatment of TRICARE-related drug sales or whether certain fees meet the criteria for being considered a "bona fide service fee." We also identified nine specific areas where manufacturers would like additional CMS guidance.

The manufacturers we surveyed also expressed concerns that CMS has published comparatively fewer regulations and less overall guidance regarding the calculation of the ASPs used in Medicare than regarding the AMPs and BPs used in Medicaid. As a result, manufacturers say they must rely on reasonable assumptions to a much greater extent when calculating ASP than they do with these other payment benchmarks. We therefore recommend that CMS:

Actively review current guidance related to the areas identified in this report and determine whether additional guidance would ensure more accurate and consistent ASP calculations

OIG noted nine specific areas for which manufacturers believe additional guidance may be needed to reduce distortions among reported ASPs and ensure consistency across the industry. CMS should review current guidance and determine whether additional clarification may prove beneficial, prioritizing issues that may have greater effects on pricing and payments (e.g., value-based arrangements). CMS should also give particular consideration to guidance regarding TRICARE-related sales and determinations of bona fide service fees—two areas where insufficient guidance may be leading to inconsistencies in manufacturer ASP calculations.

AGENCY COMMENTS AND OIG RESPONSE

CMS concurred with OIG's recommendation. The agency stated that it will review current guidance related to the areas identified in this report and determine whether additional guidance would help ensure more accurate and consistent ASP calculations. CMS went on to note that in some cases, additional guidance could be sub-regulatory, and in others, it may require rulemaking. CMS also briefly described steps it takes to vet and verify the accuracy of ASP data upon their submission by manufacturers.

OIG appreciates CMS's commitment to work within its authority to ensure the accuracy of manufacturer-reported ASP data and maximize the affordability and availability of drugs for individuals with Medicare.

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

APPENDICES

Appendix A: CMS Calculation of Medicare Part B Drug Payment Amounts

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, 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. However, to obtain reimbursement for Part B drugs, health care 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 the drug represented by one unit of the code but does not specify manufacturer or package size information. 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. CMS then uses this information to calculate a single volume-weighted ASP across all NDCs associated with a covered 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.

There is a two-quarter lag between the sales period for which ASPs are reported and the effective date of the reimbursement amounts. For example, manufacturers' ASPs from the first quarter of 2020 were used to establish reimbursement amounts for the third quarter of 2020. CMS posts an ASP payment amount file and an ASP crosswalk file on its website before the start of the applicable quarter.

Appendix B: How Surveyed Manufacturers Treat Various Types of Sales When Calculating ASPs

For all Part B drugs for which you report data to CMS, do you generally include the following types of sales (if applicable) in your ASP calculations?	Yes	No	N/A*
Wholesalers	18	0	2
Pharmaceutical repackagers	3	0	17
Consolidated service centers	12	0	8
Hospitals (inpatient/outpatient) and hospital-operated pharmacies	20	0	0
Clinics and outpatient facilities	20	0	0
Independent physician offices	20	0	0
Retail community pharmacies	19	0	1
Specialty pharmacies	20	0	0
Long-term care pharmacies	19	0	1
Health maintenance organizations (HMOs), including HMO operated pharmacies	20	0	0
Managed care organizations (MCOs), included MCO operated pharmacies	14	0	6
Pharmacy benefit manager (PBM) mail order pharmacies	17	0	3
Retail mail order pharmacies	18	0	2
Sales related to value-based purchasing (VBP) agreements	9	0	11
TRICARE:			
Military treatment facilities	2	16	2
TRICARE mail order pharmacy	2	17	1
TRICARE retail pharmacy program	6	13	1

Source: OIG analysis of manufacturer responses to OIG's 2022 Accuracy of Manufacturer-Reported ASPs survey.
* Not applicable.

Appendix C: How Surveyed Manufacturers Treat Various Types of Discounts When Calculating ASPs

In general, are the following types of discounts/rebates (if applicable) subtracted from total sales in your ASP calculations?	Yes	No	N/A*
Volume discounts	18	0	2
Prompt pay discounts	19	0	1
Group purchasing organization discounts/rebates	20	0	0
Consolidated service center discounts/rebates	11	0	9
Insurer discounts/rebates	16	0	4
Value-based purchasing agreement discounts/rebates	11	0	9
Bundled sales discounts, not including VBP agreements:			
Contingent on purchase or performance requirements	17	0	3
NOT contingent on purchase or performance requirements	8	0	12
Pharmacy benefit manager (PBM) discounts/rebates:			
Mail order pharmacy purchases	17	0	3
Price protection agreements	19	1	0
PBM discounts/rebates that are designed to adjust prices at the retail or provider level	18	0	2
TRICARE discounts/rebates:			
Military treatment facilities	0	18	2
TRICARE mail order pharmacy	0	18	2
TRICARE retail pharmacy program	0	19	1
Manufacturer programs in which the full value is passed on to the consumer:			
Manufacturer coupons	0	14	6
Manufacturer-sponsored programs that provide free goods	0	19	1
Manufacturer-sponsored drug discount programs	0	10	10
Manufacturer-sponsored patient refund/rebate programs	0	11	9
Manufacturer copayment assistance programs	0	19	1

Source: OIG analysis of manufacturer responses to OIG's 2022 Accuracy of Manufacturer-Reported ASPs survey.
* Not applicable.

Appendix D: Agency Comments

Following this page are the official comments from CMS.

DATE: December 9, 2022

TO: Ann Maxwell
Deputy Inspector General for Evaluation and Inspections
Office of Inspector General

FROM: Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services

SUBJECT: Office of Inspector General (OIG) Draft Report: Manufacturers May Need Additional Guidance To Ensure Consistent Calculations of Average Sales Prices (OEI-BL-21-00330)

The Centers for Medicare & Medicaid Services (CMS) appreciates the opportunity to review and comment on the Office of Inspector General's (OIG) draft report.

CMS serves the public as a trusted partner and steward, dedicated to advancing health equity, expanding coverage, and improving health outcomes. As such, CMS strives to maximize the affordability and availability of drugs for individuals with Medicare while protecting taxpayer dollars. CMS uses manufacturer reported average sales price (ASP) product data to calculate Part B drug payment limits. Manufacturer reported data is vetted by CMS to verify that the reported values are consistent with the reported quantity of the drug. For example, files are reviewed to identify outliers and potential discrepancies are addressed on a case by case basis. Additionally, CMS works with manufacturers to mitigate and address concerns identified with the data. This includes providing technical assistance when manufacturers inquire about how to properly report their data.

We appreciate the OIG's work on this area and look forward to working collaboratively on this and other issues in the future.

The OIG's recommendations and CMS' responses are below.

OIG Recommendation

The OIG recommends that CMS actively review current guidance related to the areas identified in this report and determine whether additional guidance would ensure more accurate and consistent ASP calculations.

CMS Response

CMS concurs with this recommendation. CMS will review the current guidance related to the areas identified in this report and determine whether additional guidance would help to ensure more accurate and consistent ASP calculations. It should be noted that in some cases, additional guidance could be sub-regulatory, and in others, it may potentially require notice and comment rulemaking.

ACKNOWLEDGMENTS AND CONTACT

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This report was prepared under the direction of Dave Tawes, Regional Inspector General for Evaluation and Inspections in the Baltimore regional office; Heather Barton, Deputy Regional Inspector General; and Louise Schoggen, Assistant Regional Inspector General.

Contact

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ABOUT THE OFFICE OF INSPECTOR GENERAL

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ENDNOTES

[1] Division CC, Title IV, Section 401(d), of the Consolidated Appropriations Act, 2021, P.L. 116-260 (Dec. 27, 2020).

[2] Section 1847A(c) of the Social Security Act.

[3] Based on OIG analysis of the publicly available Medicare average sales price (ASP) quarterly pricing files for 2020 from CMS's website (https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/2020-asp-drug-pricing-files).

[4] Not including vaccines, as they are not reimbursed using ASP.

[5] For Medicare Part B, average spending per enrollee for each drug is based on total spending in 2020 divided by the total number of enrollees who received the drug. Because an enrollee may have received a drug for only part of the year (e.g., he or she began treatment in November), the numbers presented here likely underestimate the actual annual cost for many patients.

[6] 42 CFR § 405.2410.

[7] H.R.1 - 108th Congress (2003-2004): Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Dec. 8, 2003).

[8] Section 1847A(c) of the Social Security Act (the Act), as added by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, P.L. 108-173. Pursuant to § 1847A(c) of the Act, ASP is net of any price concessions, such as volume discounts, prompt pay discounts, cash discounts, free goods contingent on purchase requirements, chargebacks, and rebates other than those obtained through the Medicaid Drug Rebate Program. Sales that are nominal in amount are exempted from the ASP calculation, as are sales excluded from the determination of best price (BP) in the Medicaid Drug Rebate Program.

[9] 71 Fed. Reg. 69624, 69669 (Dec. 1, 2006).

[10] Prior to 2022, ASP reporting requirements applied only to Part B drugs subject to Medicaid drug rebate agreements. Congress addressed this reporting gap by requiring ASP reporting for manufacturers without a Medicaid drug rebate agreement through Division CC, Title IV, Section 401, of the Consolidated Appropriations Act, 2021, P.L. 116-260, with an implementation date of January 1, 2022.

[11] Sections 1927(b)(3)(C)(i) and (ii) of the Social Security Act.

[12] 42 CFR § 447.504.

[13] A retail community pharmacy is "an independent pharmacy, a chain pharmacy, a supermarket pharmacy, or a mass merchandiser pharmacy that is licensed as a pharmacy by the State and that dispenses medications to the general public at retail prices." The definition excludes "a pharmacy that dispenses prescription medications primarily through the mail, nursing home pharmacies, long-term care facility pharmacies, hospital pharmacies, clinics, charitable or not-for-profit pharmacies, government pharmacies, or pharmacy benefit managers." 42 CFR § 447.504.

[14] 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)(A) of the Social Security Act.

[15] Section 1927(b)(3)(A) of the Social Security Act.

[16] 81 Fed. Reg. 5170, 5209 (Feb. 1, 2016).

[17] Section 1874A(d)(2) of the Social Security Act.

[18] For example, see *Medicare Part B Drug Payments: Impact of Price Substitutions Based on 2019 Average Sales Prices* (OEI-03-21-00130), June 2021.

[19] 42 CFR § 414.904(d)(3). CMS outlined that it would make this price substitution only if the ASP for a drug exceeds the AMP by 5 percent in the previous two quarters, or three of the previous four quarters.

[20] Section 1847A(c)(6) of the Social Security Act.

[21] In the case of a public health emergency or during the initial period (not to exceed a full calendar quarter) of a drug's sales, a drug's WAC may be used to determine its Medicare Part B payment amount when data are not currently accurate or sufficiently available from a manufacturer to calculate an ASP for that drug. Sections 1847A(c)(4) and (e) of the Social Security Act.

[22] OIG also published the quarterly comparisons as individual reports through 2012.

[23] An AMP is reported for the lowest identifiable quantity of the drug in the NDC (e.g., one milligram, one milliliter, one tablet, or one capsule). In contrast, ASP and WAC are reported for the entire amount of the drug contained in that NDC (e.g., for 50 milliliters or for 100 tablets).

[24] The types of discounts or price concessions include volume, prompt pay, bundled sale, insurer, consolidated service centers, group purchasing organization (GPO), and pharmacy benefit manager (PBM) discounts or price concessions. See Glossary for a detailed explanation of the different types of sales, discounts, and fees.

[25] Sections 1847A(d)(2)(B) and (3) of the Social Security Act.

[26] 42 CFR § 414.904(d)(3).

[27] The estimated $30.7 million in savings from calendar year (CY) 2016 through 2020 does not include $2.8 million in savings lost during CY 2020 due to CMS pricing errors. There were 11 drugs eligible for price reductions based on 2020 ASPs. However, CMS did not correctly implement price reductions for seven of these eligible drugs. Consequently, the price reductions made by CMS based on 2020 ASP data amounted to only $8,158 in actual savings—a loss of $2.8 million in savings to Medicare and its enrollees. OEI-03-22-00170.

[28] 71 Fed. Reg. 69624, 69669 (Dec. 1, 2006).

[29] GPO and PBM fees may include such fees as administrative, data, enterprise, gateway, and portal fees.

[30] 81 Fed. Reg. 5170, 5223 (Feb. 1, 2016).

[31] 71 Fed. Reg. 69624, 69671 (Dec. 1, 2006).

[32] 42 CFR 447.502. Effective January 1, 2023, manufacturers must begin including sales in five U.S. Territories—the Commonwealth of Puerto Rico, the Virgin Islands of the United States, Guam, the Commonwealth of the Northern Mariana Islands, and American Samoa—in their AMP and BP calculations. Prior to this date, manufacturers are only required to report drug sales within the 50 U.S. States and the District of Columbia.

[33] 42 CFR § 447.502. "Value-based purchasing arrangement" means an arrangement or agreement intended to align pricing or payments to an observed or expected therapeutic or clinical value in a select population and includes but is not limited to (1) evidence-based measures, which substantially link the cost of a drug product to existing evidence of effectiveness and potential value for specific uses of that product; and (2) outcomes-based measures, which substantially link payment for the drug to the drug's actual performance in a patient or to a population, or a reduction in other medical expenses.

[34] 42 CFR § 447.505(a). "Best price" means, for a single source drug or innovator multiple source drug of a manufacturer (including the lowest price available to any entity for an authorized generic drug), the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity in the United States in any pricing structure (including capitated payments) in the same quarter for which the AMP is computed. If a manufacturer offers a value-based purchasing (VPB) arrangement (as defined at § 447.502) to all states, the lowest price available from a manufacturer may include varying best price points for a single dosage form and strength as a result of that VBP arrangement.

[35] CMS, *Medicaid Drug Rebate Program Notice for Participating Drug Manufacturers*, Release No. 116. Accessed at Technical Guidance - Value-Based Purchasing (VBP) Arrangements for Drug Therapies using Multiple Best Prices (medicaid.gov) on June 2, 2022.

[36] "Bundled sales" is defined in the Medicaid context under § 447.502. CMS declined to provide a definition for bundled arrangements, and has declined to establish a specific methodology for the treatment of bundled price concessions for the purpose of ASP calculations and instead directed manufacturers to adopt reasonable assumptions. 72 Fed. Reg. 66258. For the purpose of this study, we refer to "bundled sales," the term used in survey responses by the manufacturers, interchangeably with "bundled arrangements" and "bundled priced concessions."

[37] National Academies of Sciences, Engineering, and Medicine, *Medications in single-dose vials: implications of discarded drugs*, 2021.

[38] Sometimes, portions of fixed-dose drugs in single-dose vials are discarded. This is, in part, because some prescription drugs are administered in variable doses based on a patient's weight or body size. These vials contain standard amounts of the drug which typically exceed the required dosage for the average patient.

[39] Section 9004 of the Infrastructure Investment and Jobs Act, P.L. 117-58 (Nov. 15, 2021).