Recent OIG Updates (ASP and CMS): ASP and BFSF continue to be a focus

Recently, the Department of Health and Human Services Office of Inspector General (OIG) published their findings regarding the accuracy of Average Sale Price (ASP) data as well as the Centers for Medicare & Medicaid Services' (CMS) oversight of ASP data. The growth of specialty infused, and physician administered injectables to market has increased the focus on ASP which is a key reimbursement metric in Medicare Part B and for commercial and other payers is also used as a key metric in future Medicare Part B inflation rebates and Medicare price negotiations introduced as part of the Inflation Reduction Act. These reports provide valuable insights for manufacturers regarding CMS processes and oversight as well as differences in ASP calculation methodology and assumptions.

Below we summarize the key highlights, findings, and recommendations from the OIG studies and what manufacturers should take into consideration.

Overview of OIG Studies

Over the past decade, the costs for prescription drugs under Medicare Part B have nearly doubled to over $40 billion as reported in 2020. Due to this large increase, congress appointed the OIG to review manufacturer-reported ASP data to verify and authenticate the accuracy.[1] In conjunction with reviewing manufacturer-reported ASP data, OIG conducted an evaluation into CMS's oversight of ASP data including assessing their accuracy before using them to calculate Medicare Part B payment amounts.

To review manufacturer reported ASP, for 20 manufacturers with the 30 Medicare Part B highest expenditure drugs, OIG examined price benchmark data and information collected from manufacturer surveys to identify potential inaccuracies in ASPs reported.

To determine how CMS oversees the accuracy of manufacturer-submitted ASP data, the OIG collected and reviewed CMS's standard operating procedures for oversight of ASP data and interviewed CMS staff regarding CMS's oversight processes and challenges to conducting effective oversight. [2]

Key Findings

- As many as 30 percent of manufacturers included certain TRICARE-related drug sales in their ASP calculations.
- Manufacturers reported variations in how they determine whether a fee should be considered a bona fide service fee (BFSF).
    - Manufacturers are expected to determine whether certain fees are considered discounts that are included in their ASP calculations or BFSFs that are excluded from ASP. 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. As determined from survey responses, manufacturers expressed concern that competitors may be taking different approaches when applying CMS's four-part test to make these determinations.
    - When calculating ASP, in the absence of evidence, manufacturers are allowed to presume that the fee paid is not passed on. Given the discrepancies in the survey responses, it was determined that manufacturers showed differences on what is considered to be sufficient evidence that a fee is passed through in accordance with the four-part test.
- Manufacturers also expressed concerns that there was a lack of guidance from the CMS on a range of ASP issues and could possibly be the reasoning for inconsistencies in the ASP calculations.
    - Ten of the twenty manufactures that were surveyed felt that CMS has published far fewer guidelines, regulations, and overall guidance on calculations for ASPs used in Medicare in comparison to the regulations and guidance that is provided for Average Manufacturer Prices (AMPs) and Best Prices (BPs) used in Medicaid.
    - Four manufacturers are seeking clarification on whether the ASP calculations should also include sales to U.S. Territories once the requirement takes effect for AMP and BP. Beginning January 1st, 2023, manufacturers must begin including sales in five U.S. Territories in the AMP and BP calculations.

1. Manufacturers May Need Additional Guidance To Ensure Consistent Calculations of Average Sales Prices, OEI-BL-21-00330 (hhs.gov)
2. CMS Should Bolster Its Oversight of Manufacturer-Submitted Average Sales Price Data To Ensure Accurate Part B Drug Payments, OEI-03-21-00390 (hhs.gov)

Key Findings, Continued

- Four manufacturers noted in their surveys that they felt there was insufficient guidance on the treatment of value-based and outcome-based purchasing arrangements in the calculation of ASP.
- 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.
- Manufacturers also stated that they would like additional guidance from CMS on the appropriate methodology for allocating bundled sales in ASP. It was noted 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.

➢ OIG discovered gaps in CMS oversight that allowed inaccurate data to impact Medicare Part B payment amounts

- CMS's quality assurance procedures do not include checks to ensure the accuracy of manual processes it employs to analyze the data used to calculate Part B payment amounts.
- CMS also does not leverage its ASP data collection system to produce analytical reports that would monitor ASP data quality and maximize its oversight capabilities.

➢ OIG determined that because of invalid or missing ASP data, CMS could not calculate an ASP-based payment amount for 8 percent of drug codes at least once between 2016 and 2020 potentially resulting in higher drug payment amounts due to the use of alternate payment methodology used by CMS when ASP data is not available or is invalid.

- CMS was unable to calculate an ASP-based payment amount for several reasons, including that the manufacturer reported a negative sales or ASP value or the manufacturer had no sales to report for that quarter.
- CMS reported that late ASP data submissions from manufacturers substantially hindered its ability to conduct effective oversight.

OIG Conclusion & Recommendations

In conclusion, OIG was able to identify a small number of inconsistencies in manufacturer calculations of ASPs as well as instances where CMS allowed inaccurate data to impact Medicare Part B payment amounts.

The inconsistencies related to the manufacturer calculations of ASPs included the treatment of TRICARE-related drug sales and the ability to determine whether certain fees meet the criteria for being considered a "bona fide service fee". In addition to these inaccuracies, the survey identified nine specific areas where manufacturers would like additional CMS guidance.

After reviewing the information gathered from the studies and surveys, OIG recommended

- CMS review current guidance to manufacturers and determine whether additional clarification should be added to have greater effects on pricing and payments (i.e., value-based arrangements) and consider guidance regarding TRICARE-related sales and determinations of bona fide service fees, two areas where there were many inconsistencies amongst manufacturers according to the surveys.
- CMS build a strategy to strengthen its internal controls for ensuring the accuracy of Part B drug payments to bolster its oversight of manufacturer-reported ASP data.

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FCS Perspective

We routinely work with our manufacturer clients and our client's legal counsel to navigate CMS's guidance and lack of guidance to help ensure that our clients are calculating ASP and other government price types accurately based on their understanding of the guidance. This includes developing and documenting methodology, polices and procedures, and reasonable assumptions complete with rationale for decisions and leading practices to determine whether a fee should be considered bona fide. Although guidance may not be clear, there are mitigating actions companies can take to reduce risk.

For Bona Fide Service Fee Evaluation, we recommend manufacturers:

- ✓ Develop processes and incorporate tools (i.e., checklist/questionnaires/FMV estimators) to help facilitate and incorporate BFSF evaluations in contracting process. This is a key item to help ensure that service arrangements are being evaluated not only from a fair market value perspective but also takes into account the qualitative prongs of the test (i.e., is this a service on our behalf, is their pass-through evidence or notice, services itemized in the contract). Framework in place should also include an evaluation of when to seek counsel advice. In practice, we've seen it work well when manufacturers incorporate BFSF review as part of the contracting process to ensure appropriate stakeholders are aligned and there are no surprises when it comes to government pricing or gross to net.
- ✓ Perform periodic BFSF/FMV training so business teams are aware of process and mindful of current rules, regulations, and understand that the company creates and maintains documentation of the BFSF analysis and treats the fees appropriately in government pricing.
- ✓ Monitor and track performance of service providers and overall spend and evaluate whether there's an opportunity to mitigate risks.
- ✓ If your contracts allow the vendor to invoice net of service fees, discounts, and other adjustment on their invoices, ensure that you are reviewing them and treating the fees appropriately. Note this is an area that is commonly overlooked especially as it relates to items like price appreciation credits. It's important to note that CMS has made clear that price appreciation credits are not BFSF and should be included in calculations
- ✓ Document your BFSF evaluation, follow your BFSF process, perform FMV, and ensure that fees are treated appropriately based on the results of the BFSF evaluation. As a reminder, there is no conservative approach for BFSF (i.e., depending on your product, what's conservative in one government program may be aggressive in another). Note we generally recommend checking with counsel; especially for new or complex arrangements, if it's your first evaluation, or if it's a sensitive matter that should be performed under privilege.
- ✓ If you've already performed FMV and BFSF evaluation, keep a tracker and perform periodic refreshes as needed. We typically recommend every 2-3 years, unless something significantly changes (i.e., sales or service changes, new rules/guidance, etc..).

Below is an Illustrative list of service arrangement types that may require analysis. Note the below is not all inclusive and Manufacturers must determine the ultimate list of entities that require this analysis.

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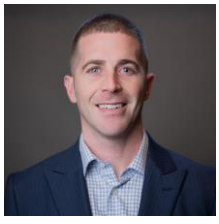
For ASP Calculations, we recommend manufacturers:

- ✓ Develop and document policies and procedures as well as reasonable assumptions related to the methodology and calculation of ASP and all government price types (e.g., BP, AMP, Nonfederal Average Manufacturer Price). This is one of the best safeguards a manufacturer can take to reduce risk given lack of clear guidance. Also, the processes should capture key controls including ensuring that items where ASP is greater than WAC are reviewed, evaluated, and corrected prior to being submitted to CMS.
- ✓ Consult with your advisors including internal or external counsel for guidance on areas where guidance may be unclear as noted in the OIG studies and other common areas such as: What products are subject to ASP reporting, identification of sales to 340B entities, valuation of Prompt Pay Discounts, how to handle restatements, etc.
- ✓ Submit methodology and assumptions documentation to CMS as ASP system permits assumptions to be uploaded.
- ✓ Evaluate all current and proposed contracts including service and discount arrangements and model impacts to ASP to ensure that the company is aware of any and all potential impacts to ASP and corresponding reimbursement dynamics before entering into the arrangement.
- ✓ Perform periodic government pricing assessments to ensure calculations are accurate and complete, appropriate reasonable assumptions and methodology are documented, policies and procedures are current, and service fee treatment in calculations aligns to BFSF documentation and that all service arrangements are reviewed.
- ✓ Routinely monitor CMS's posting of payment limits to ensure that they align to expectations based on reported ASP.
- ✓ Keep informed on changing regulations and guidance related to government price calculations.

HHS OIG studies often provide valuable insight to future potential changes in regulation or other guidance put out by CMS. As such we suggest that manufacturers review these studies and closely monitor future changes in regulation and guidance.

Please feel free to reach out with any questions or to discuss with our team. We are happy to help!



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For more information on the recent updates:

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