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Reasonable Assumptions in Manufacturer Reporting of AMPs and Best Prices

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In the absence of guidance to the contrary, the Centers for Medicare & Medicaid Services (CMS) allows manufacturers to make "reasonable assumptions" that are consistent with statute and regulation when they calculate the average sales prices (AMPs) and best prices (BPs) for Medicaid-covered drugs.

Key Takeaway
Reasonable assumptions that manufacturers make when calculating average manufacturer prices and best prices can have large financial ramifications for the cost of prescription drugs to Medicaid and to safety-net providers. However, under current practices, CMS never assesses the majority of these assumptions. The agency believes that its statutory authority in this area is limited.

What OIG Found

Our findings show that the use of reasonable assumptions is common practice among responding manufacturers, and that nearly two-thirds reported wanting additional guidance from CMS on assumptions-related issues. In our analysis of manufacturer responses, four areas stood out as warranting attention from CMS: oral specialty drugs; value based purchasing arrangements; bona fide service fees; and rebates to pharmacy benefits managers.

Historically, CMS has provided little formalized oversight of the reasonable assumptions process, specifically instructing manufacturers *not* to submit their reasonable assumptions to CMS. The agency has stated that it has limited authority to assess manufacturers' assumptions, and that it does so only on a case-by-case basis to support formal oversight inquiries, manufacturer recalculations, and requests for technical assistance. To that end, CMS has recently developed a process for specific manufacturer inquiries regarding calculations of AMP and BP.

Manufacturers and the Office of Inspector General (OIG) recognize that with hundreds of manufacturers, thousands of drugs, and a myriad of complex practices for pricing and sales, CMS is not in a position to review all assumptions on a regular basis. However, given the far-reaching importance of AMPs and BPs, OIG believes that—with the goal of ensuring compliance and consistency in the industry—CMS could take additional steps to improve oversight in the area.

What OIG Recommends and How the Agency Responded

We recommend that CMS (1) issue guidance related to specific areas identified in this report—specifically, value based purchasing agreements; (2) assess the costs and benefits of implementing a targeted process to review certain assumptions; and (3) implement a system to share responses to manufacturer inquiries for technical assistance. CMS concurred with all three recommendations.

Full report can be found at oig.hhs.gov/oei/reports/oei-12-17-00130.asp

Why OIG Did This Review

Ensuring the accuracy of manufacturer-reported AMPs and BPs is vital given that these prices are the primary benchmarks that the Federal Government uses to calculate the rebates and discounts available to Medicaid and certain safety-net providers. Previous OIG work has shown that manufacturers have made different assumptions when including or excluding certain sales in their price calculations, potentially leading to significantly lower or higher AMPs and BPs. AMPs and BPs are used to calculate the amount of rebates that manufacturers must pay to Medicaid. A lower AMP, for example, could reduce the rebate amount that a manufacturer must pay, thus increasing net costs for Medicaid. In addition, AMPs and BPs are also used to establish the prices paid by health care entities eligible for the 340B Drug Discount Program. In September 2016, Congress asked OIG to examine CMS's oversight of the Medicaid Drug Rebate Program (MDRP). This report is the last of three OIG evaluations related to this request.

How OIG Did This Review

OIG surveyed a sample of drug manufacturers participating in the MDRP to identify the primary areas in which they make assumptions when calculating AMP and BP. OIG also asked manufacturers to identify the areas in which they would like greater guidance or instruction from CMS on calculating AMP or BP. We also interviewed and surveyed CMS officials regarding their processes for collecting and reviewing the assumptions that manufacturers make.

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BACKGROUND

Objectives

1. To identify the extent to which drug manufacturers make reasonable assumptions when calculating average manufacturer prices (AMPs) and best prices (BPs).
2. To identify the extent to which manufacturers would like greater guidance or instruction from the Centers for Medicare & Medicaid Services (CMS) on calculating AMP and BP.
3. To describe CMS's processes for overseeing the reasonable assumptions made by drug manufacturers in the Medicaid Drug Rebate Program (MDRP).

Rationale

Ensuring that manufacturer-reported AMPs and BPs for prescription drugs are accurate is vital because these prices are used in administering programs (i.e., the MDRP and the 340B Drug Discount Program) that enable the Federal Government, State Medicaid agencies, and certain health care entities to reduce their costs by billions of dollars a year. However, given the complexities of pharmaceutical industry sales practices and—in certain scenarios—the absence of explicit Federal guidance, drug manufacturers may encounter challenges when calculating AMPs and BPs for covered outpatient drugs. For this reason, CMS allows manufacturers to make "reasonable assumptions" as long as those assumptions are consistent with statutory and regulatory requirements.

Prior to this report, OIG had not undertaken a systematic review of the reasonable assumptions that manufacturers make when calculating AMPs and BPs, or of CMS's oversight of the reasonable assumptions process. However, previous OIG work has shown that manufacturers often differ in determining whether to include or exclude certain types of sales in their price calculations.[1] These differences have the potential to significantly lower or raise a drug's AMP or BP, and thereby to affect (1) the rebate amount that a manufacturer owes to the government[2] and (2) the prices

[1] OIG, *Average Manufacturer Price Determinations by Selected Drug Manufacturers Generally Were Consistent With Federal Requirements*, A-06-13-00014, June 2014.

[2] For example, see OIG's report entitled *Medicaid Could Save Hundreds of Millions by Excluding Authorized Generic Drug Transactions to Secondary Manufacturers from Brand Name Drugs' Average Manufacturer Price Calculations* (A-06-18-04002), April 2019. The President's Budget for Fiscal Year 2020 includes a provision to address the issue discussed in this report.

that eligible health care providers pay for drugs under the 340B Drug Discount Program.[3]

In September 2016, OIG received a congressional request to examine CMS's oversight of the MDRP, stemming from concerns related to the misclassification of drugs (specifically, EpiPen) by manufacturers and the subsequent effect on rebate obligations. As part of OIG's response to this request, this report examines the extent to which manufacturers make assumptions when calculating AMPs and BPs; identifies areas in which manufacturers may need additional guidance or instruction; and describes CMS's processes for overseeing assumptions. The current report is the third in a series responding to the congressional request. The first report found that potential misclassifications may have led to $1 billion in lost Medicaid rebates.[4] The second report determined that 1 percent of drugs paid for under Medicaid in 2016 had not been approved by the Food and Drug Administration.[5]

Medicaid Drug Rebate Program

The Omnibus Budget Reconciliation Act of 1990 created the MDRP to help offset State and Federal Medicaid expenditures for prescription drugs.[6] For Federal financial participation (i.e., Federal matching funds) to be available for covered outpatient drugs provided under Medicaid, manufacturers must enter into rebate agreements with the Secretary of Health and Human Services (the Secretary) and pay quarterly rebates to State Medicaid agencies.[7] Statutory rebates enabled Federal and State governments to recoup $30 billion of the $54 billion that Medicaid spent on prescription drugs in fiscal year 2016.[8]

The rebate amount that a manufacturer owes for each drug is based on the manufacturer-reported AMP and—in some circumstances—BP. Under their rebate agreements and pursuant to section 1927(b)(3) of the Social Security Act, manufacturers must provide CMS with the AMP for each of their drugs on a monthly and quarterly basis. In general, AMP is defined as the average price paid to the manufacturer for the drug in the United States by (1) wholesalers for drugs distributed to retail community pharmacies and (2) retail community pharmacies that purchase drugs directly from the

[3] The 340B Drug Discount Program enables eligible health care providers—generally, those that serve that serve the underinsured or uninsured—to purchase prescription drugs at statutorily discounted prices.
[4] OIG, *Potential Misclassifications Reported by Drug Manufacturers May Have Led to $1 Billion in Lost Medicaid Rebates*, OEI-03-17-00100, December 2017.
[5] OIG, *One Percent of Drugs With Medicaid Reimbursement Were Not FDA-Approved*, OEI-03-17-00120, May 2019.
[6] CMS, *Medicaid Drug Rebate Program*. Accessed at https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/index.html on September 15, 2017.
[7] Sections 1927(a)(1) and (b)(1) of the Social Security Act.
[8] CMS, *Actuarial Report on the Financial Outlook for Medicaid*, 2018.

manufacturer.[9] For brand-name products, manufacturers must also provide CMS with the BP of the drug each quarter.[10] BP is defined as the lowest price available from the manufacturer to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States, with certain exceptions.[11]

The basic rebate amount for a generic drug is 13 percent of the AMP. The basic rebate amount for a brand-name drug is the greater of 23.1 percent of the AMP or the difference between the AMP and BP.[12] Further, the drug's manufacturer must pay an additional rebate over and above the basic rebate if the AMP for a drug has risen faster than inflation.[13]

Lower AMPs and higher BPs would typically result in lower rebate obligations for a manufacturer. These lower rebate obligations subsequently cause Medicaid to pay more for prescription drugs, and also affect the prices paid by 340B covered entities.

AMPs and BPs calculated under the MDRP are also used by the Health Resources and Services Administration to establish reduced prices under the 340B Drug Discount Program for health care entities that serve vulnerable patient populations.[14] Manufacturers must sell their covered outpatient drugs at or below discount prices (known as 340B ceiling prices) to health care entities participating in the 340B Drug Discount Program (known as covered entities). The 340B ceiling price for a drug is equal to its AMP minus the Medicaid rebate amount.[15] Congress intended for the savings from these discounted prices to enable covered entities "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[16]

Reasonable Assumptions

Manufacturers must calculate AMPs and BPs—and determine which sales are included or excluded in their calculation—consistent with the Social Security Act and regulation. However, given the complexities of sales practices in the pharmaceutical industry, manufacturers may find it difficult

[9] Section 1927(k)(1) of the Social Security Act.
[10] Section 1927(b)(3)(A)(i)(II) of the Social Security Act. For this report, "brand-name" refers to single-source and innovator multiple-source drugs as defined in 42 CFR § 447.502. "Generic" refers to noninnovator multiple-source drugs.
[11] Section 1927(c)(1)(C) of the Social Security Act.
[12] Section 1927(c)(1) of the Social Security Act.
[13] Section 1927(c)(2)(A)(ii)(II) of the Social Security Act.
[14] 42 CFR § 256b(a)(1-2).
[15] 42 CFR § 10.10.
[16] House Report No. 102-384(II) (which accompanied H.R. 2890, the Medicaid and Department of Veterans Affairs Drug Rebate Amendments of 1992), at 12 (1992)(Conf. Rep.).

to determine how to treat certain sales practices when calculating prices. In the absence of guidance and adequate documentation to the contrary, manufacturers may make reasonable assumptions that are consistent with statutory requirements and intent as well as with regulatory requirements.[17] For example, manufacturers may feel the need to make assumptions regarding when a pharmacy qualifies as a "retail community pharmacy," or what constitutes "fair market value" for a service. CMS requires manufacturers to maintain adequate documentation supporting their assumptions.[18] The different assumptions that a manufacturer adopts have the potential to significantly lower or raise a drug's AMP and/or BP, and in turn to affect the manufacturer's rebate obligations. Lower rebate obligations would result in Medicaid's paying more for prescription drugs.

CMS's Final Rule. CMS published a final rule related to the MDRP on February 1, 2016.[19] Among other things, the rule addresses changes that the Affordable Care Act required to the definition of AMP.[20] The final rule also offers substantial guidance to manufacturers on numerous issues, but it does not provide complete clarity for some common pricing scenarios that manufacturers adopt.

During the rulemaking process, manufacturer and stakeholder comments often expressed general support for the continued practice of allowing reasonable assumptions for AMP and BP calculations, while also voicing a need for additional guidance. For example, CMS received a comment supporting less specificity in definitions, thereby allowing for the flexibility to accommodate changes in the industry and allow reasonable assumptions to fill in the details needed as the industry evolves.[21] In contrast, other comments questioned the lack of specific guidance, such as one that asked whether detailed instructions would be forthcoming for manufacturers, or if manufacturers would be mostly on their own to interpret which sales to include or exclude from AMP.[22]

Medicaid Drug Rebate Program Oversight

Drug manufacturers may be subject to penalties for failure to comply with requirements of the MDRP. CMS may terminate a manufacturer from the program for violating the requirements of the rebate agreement or for

[17] 81 Fed. Reg. 5170, 5209 (Feb. 1, 2016).
[18] 42 CFR § 447.510(f).
[19] 81 Fed. Reg. 5170 (Feb. 1, 2016).
[20] Prior to the Affordable Care Act, the Social Security Act defined AMP as the average price paid to the manufacturer by wholesalers for drugs distributed to the retail pharmacy class of trade.
[21] 81 Fed. Reg. 5170, 5209 (Feb. 1, 2016).
[22] 81 Fed. Reg. 5170, 5209 (Feb. 1, 2016).

other good cause.[23] In addition, OIG is authorized to impose civil monetary penalties for certain conduct in three types of situations:

- If a wholesaler, manufacturer, or direct seller refuses a request by the Secretary for information about charges or prices, or knowingly provides false information in connection with a survey.
- If a manufacturer knowingly provides false pricing information.
- If a manufacturer fails to provide timely pricing information, including AMPs or BPs.[24]

CMS provides very limited oversight of the assumptions that manufacturers make in their AMP and BP calculations. The MDRP Manufacturer Release No. 78—published in 2007—is CMS's most recent instruction to manufacturers regarding the reasonable assumptions process. It includes a request that manufacturers *not* provide their assumptions to the agency:

> We request that manufacturers not submit their assumptions for the monthly nor quarterly AMP and [BP] methodology to CMS. However, a record (written or electronic) outlining these assumptions must be maintained by the manufacturer in accordance with the recordkeeping requirements in [42 CFR § 447.510(f)]. Should a manufacturer disregard these instructions and submit such assumptions, they will not be reviewed and their receipt should not be considered as acquiescence by CMS to the submitted assumptions.[25]

Methodology

Data Collection and Analysis

Identification of Areas for Reasonable Assumptions. We worked with CMS and industry stakeholders to develop a list of 15 common areas in which manufacturers are making reasonable assumptions subsequent to the final rule of February 1, 2016. On the following page, Exhibit 1 presents a list of the common areas and their descriptions.

[23] Section 1927(b)(4)(B)(i) of the Social Security Act.
[24] Sections 1927(b)(3)(B) and (C) of the Social Security Act and 42 CFR § 1003.1200.
[25] CMS, Medicaid Drug Rebate Program, *Manufacturer Release No. 78*, June 26, 2007. Since CMS's original release, the regulatory provision has been renumbered.

Exhibit 1. Sales Products, Sales Practices, and/or Sales Calculation Types Included in Manufacturer Survey

Sales Products, Sales Practices, and/or Sales Calculations Types	General Description*
Authorized Generics	A brand-name drug that the brand manufacturer permits a secondary manufacturer or subsidiary to sell as a generic.
5i Drugs	5i drugs are inhalation, infusion, instilled, implanted or injectable drugs that are not generally dispensed through retail community pharmacies.
Oral Drugs Not Dispensed Through Retail Community Pharmacies	Oral solid drugs (therefore non-5i) that are not generally dispensed through retail community pharmacies. These drugs are often high-cost specialty products dispensed through specialty mail-order pharmacies.
Line Extensions	A new formulation of an existing brand-name drug.
Drugs Primarily Dispensed Through the Mail	Drugs that are primarily dispensed through the mail rather than by a retail community pharmacy.
Bona Fide Service Fees	Fees paid by a manufacturer to an entity that represents 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 is 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	Any arrangements (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) where 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.
Prompt Pay Discounts	A discount that a manufacturer offers to a wholesaler for paying within a specified timeframe (e.g., within 10 days rather than 30 days).
Returned Goods	Goods that are returned to a manufacturer for reasons such as having been recalled, being damaged, being expired, or being unsaleable.
Sales to Wholesalers	Wholesalers purchase drugs directly from manufacturers with the intent to then distribute the drugs to dispensers (i.e., pharmacies).
"Stacked" (i.e., Aggregated) Price Concessions	Manufacturers may "stack"—i.e., aggregate—in their price concessions the discounts that they offer to customers.
Value Based Purchasing Arrangements	Arrangements between payers and drug manufacturers that tie payments for drugs to agreed-upon measures (e.g., clinical outcomes).
Negative AMP Units and/or Dollars	When manufacturers calculate AMP, they may encounter scenarios in which their AMP units and/or dollars are negative.
Lagged Price Concessions	Any discounts or rebates that are realized after the sale of the drug, except for customary prompt pay discounts.
Sales Through Pharmacy Benefit Managers	Pharmacy benefit managers are third-party entities that often negotiate rebates (discounts) on behalf of their clients with the drug manufacturers.

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

Manufacturer Survey. We selected a stratified random sample of 71 larger manufacturers and 100 smaller manufacturers out of the 362 total manufacturers participating in the MDRP as of June 2017.[26] We sent an electronic survey to the selected manufacturers in November 2017. We asked manufacturers (1) whether they are making assumptions in the areas described in Exhibit 1, (2) whether current guidance in these areas is sufficient subsequent to the MDRP final rule, and (3) what their experiences have been with CMS oversight related to reasonable assumptions. In total, 103 manufacturers completed a survey, a 60-percent response rate. The 103 responding manufacturers corresponded to 304 individual labeler codes and accounted for 78 percent of total Medicaid reimbursement for drugs in 2016. Given this response rate, our findings cannot be generalized to all manufacturers that participate in the MDRP; rather, throughout this report we provide simple percentages for the responses from the manufacturers in our sample. For further breakdown of the sample counts by strata, see Appendices A, D, and E.

CMS Survey. We requested information and reviewed relevant documents regarding CMS's processes for reviewing the reasonable assumptions made by drug manufacturers participating in the MDRP. We also asked CMS to describe the technical assistance that it provides to drug manufacturers related to the calculation of AMPs and BPs, as well as how the agency decides when topics merit the issuance of formal guidance (e.g., Frequently Asked Questions documents, Manufacturer Releases).

See Appendix A for a detailed description of our methodology, including a full description of our sample-selection methodology.

Scope

This inspection summarizes CMS's oversight of reasonable assumptions being made by manufacturers in the MDRP after the implementation of the February 1, 2016, MDRP final rule. This study did not assess the specific assumptions made by manufacturers in their AMP and BP methodologies.

Limitations

The findings in this report apply only to the 103 manufacturers that responded to our survey. Because of the limited response rate, we could not generalize the results to all manufacturers that participate in the MDRP. Furthermore, we did not request that manufacturers provide documentation of their reasonable assumptions and we were therefore unable to verify the accuracy of survey responses.

[26] The 362 manufacturers corresponded to 618 labeler codes listed on CMS's State Drug Utilization Data file. The latter figure excludes any labeler codes for which Medicaid had no associated reimbursement in 2016 (i.e., Medicaid did not pay for any of the labeler code's drugs).

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.

FINDINGS

Almost all responding manufacturers reported making reasonable assumptions that affected the AMPs and BPs used to determine Medicaid rebates and 340B discounts

In total, 91 of 103 manufacturers reported making assumptions in at least 1 of the 15 identified areas.[27] Only 12 manufacturers reported that they currently do not make any assumptions.[28] In all but 1 of the 15 areas, more than half of the responding manufacturers with the underlying product types, sales practices, and/or sales calculations reported making related assumptions (see Exhibit 2).

More than four out of five manufacturers reported making reasonable assumptions related to bona fide service fees, bundled sales, and stacked price concessions

Bona Fide Service Fees. In general, a bona fide service fee is a fee that a manufacturer pays to an entity to perform a service that the manufacturer would otherwise perform itself. To qualify as bona fide, the fee cannot be passed on to a client or customer of an entity.[29] Examples include distribution service fees, inventory management fees, product stocking allowances, and fees associated with patient care programs (such as medication compliance programs and patient education programs).

Of the 74 manufacturers that reported paying bona fide service fees, 67 (91 percent) made assumptions about the fees when calculating AMP and/or BP.

Bundled Sales. In general, a bundled sale refers to an arrangement under which a price concession for a drug is contingent upon the purchase of another product or a certain volume of the same product.[30] For example, a manufacturer might offer a 10-percent discount on drug A when a wholesaler purchases 1,000 units of drug B.

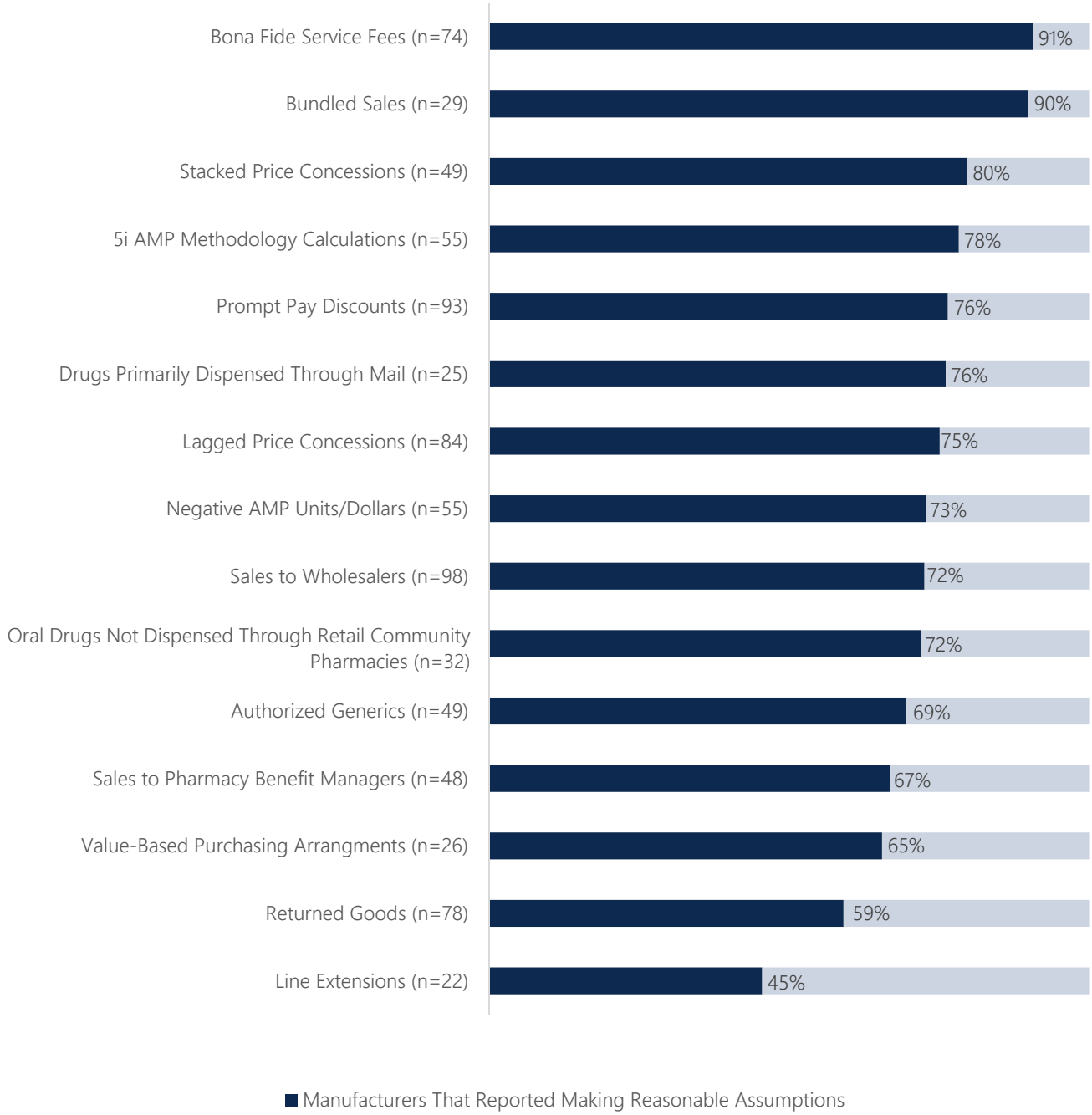
Of the 29 manufacturers that reported offering bundled sale discounts, 26 (90 percent) made assumptions about the sales when they calculated AMP and/or BP.

Stacked Price Concessions. When calculating BPs, manufacturers may "stack"—i.e., aggregate—in their price concessions the discounts that they offer to customers. For example, a manufacturer may offer a prompt-pay discount to a wholesaler and a separate back-end rebate to a pharmacy for the same drug purchase.

[27] Of the 91 manufacturers that reported making assumptions in at least 1 of the 15 identified areas, 46 were smaller manufacturers and 45 were larger manufacturers.
[28] Of the 12 manufacturers that reported they currently do not make any assumptions, 11 were smaller manufacturers and 1 was a larger manufacturer.
[29] 42 CFR § 447.502.
[30] Ibid.

Of the 49 manufacturers that reported stacking discounts that they offered to customers, 39 (80 percent) made assumptions on this issue, most commonly with regard to when it is and is not appropriate to stack price concessions in determining BP.

Exhibit 2: At least half of manufacturers reported making reasonable assumptions when calculating AMPs and/or BPs in all but one of the identified areas



Source: OIG analysis of responses to survey of drug manufacturers in the Medicaid Drug Rebate Program, 2018.
Note: The sample percentages of manufacturers reported in Exhibit 2 are only for manufacturers in our sample that reported having the underlying product types, sales practices, and/or sales calculations.

Nearly two-thirds of responding manufacturers reported wanting additional guidance from CMS regarding AMP and BP calculations

Sixty-six of 103 manufacturers wanted additional guidance from CMS in at least 1 of the 15 assumption areas highlighted in the OIG survey.[31] Most requested additional guidance in multiple areas. The manufacturers that did not want additional guidance typically stated that current direction is sufficient or that they had engaged with CMS regarding the topic to their satisfaction.

In nine assumption areas, more than 40 percent of manufacturers with the underlying product types, sales practices, and/or sales calculations reported wanting additional guidance from CMS (see Appendix B). These areas included oral drugs not dispensed through retail community pharmacies; value based purchasing arrangements; bona fide service fees; bundled sales; line extensions; drugs primarily dispensed through mail; sales to pharmacy benefit managers (PBMs); authorized generics; and stacked price concessions.

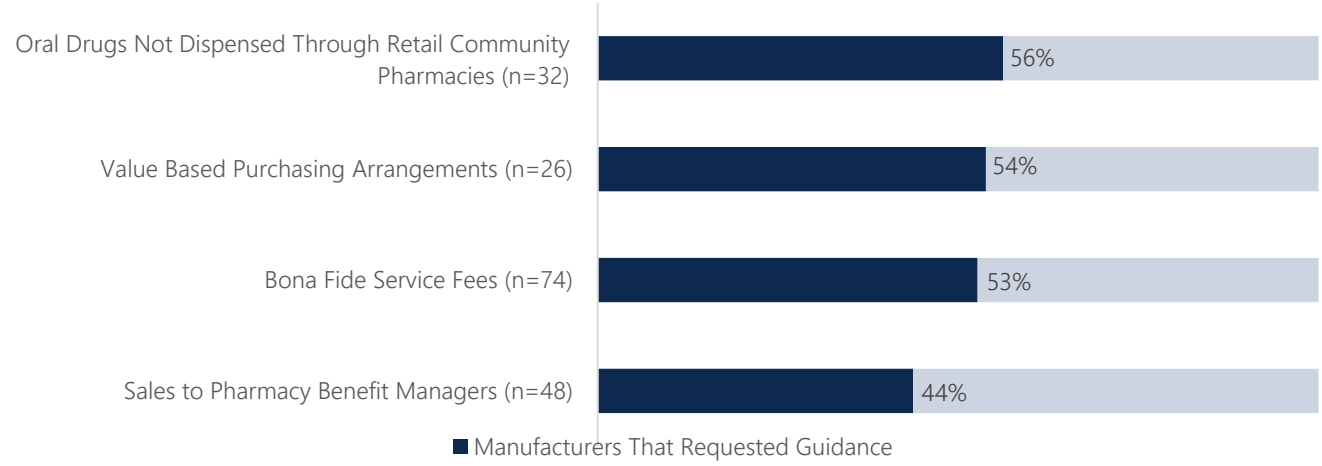
From manufacturer responses, four areas likely warrant additional CMS guidance

For four of these areas, manufacturers' desires for greater clarity, mixed with—at times—widely divergent assumptions illustrate a particular need for additional CMS guidance. See Exhibit 3. In some cases, this variation in assumptions may have led to a manufacturer's reporting lower AMPs and/or higher BPs than its counterparts and resulted in lower rebate obligations for the manufacturer. In turn, these lower manufacturer rebate obligations would have resulted in Medicaid's paying more for prescription drugs.

In the case of value based purchasing arrangements, manufacturers told OIG that the lack of guidance from CMS could be resulting in decreased adoption of these potentially cost-saving approaches. The variety of price concessions and services that a manufacturer offers to a payer in a value based purchasing arrangement may lower the manufacturer's BP by a substantial margin, thus increasing its Medicaid rebate and 340B discount obligations to the point where the manufacturer chooses to forgo any such arrangement. Appendix C provides a summary of what manufacturers believed to be lacking from current guidance in the other five areas in which at least 40 percent of manufacturers requested guidance.

[31] Of the 66 manufacturers that wanted additional guidance from CMS in at least 1 of the 15 assumption areas highlighted in the OIG survey, 30 were smaller manufacturers and 36 were larger manufacturers.

Exhibit 3. Percentages of manufacturers that requested additional guidance in each of the four areas



Source: OIG analysis of responses to survey of drug manufacturers in the Medicaid Drug Rebate Program, 2018.
Note: The sample percentages of manufacturers reported in Exhibit 3 are only for manufacturers in our sample that reported having the underlying product types, sales practices, and/or sales calculations.

Oral Drugs Not Dispensed Through Retail Community Pharmacies. Typically, drugs are dispensed through retail community pharmacies, i.e., the grocery or drug store pharmacies that fill a prescription after a patient visits a doctor. However, there are certain oral drugs—often, high-cost specialty products—that are primarily dispensed through specialty mail-order pharmacies. In regulation, CMS stated that sales to pharmacies that dispense primarily through the mail would not be included in AMP (because these pharmacies are not considered to be retail community pharmacies).[32]

At the same time, these oral drugs do not fit the criteria for an alternative AMP calculation—known as "the 5i AMP"—that CMS created for other specialty drug products that are primarily distributed through the mail and are known as "5i" drugs because they are inhaled, infused, instilled, implanted, or injected. In the pharmaceutical industry, these oral drugs are sometimes referred to as "crack drugs" because they metaphorically "slip through the cracks" in guidance and regulation. In a Frequently Asked Questions document published on July 6, 2016, CMS instructed manufacturers that:

> ... if a specialty pharmacy meets the definition of a retail community pharmacy at section 1927(k)(10) of the [Social Security] Act, sales for [oral drugs not dispensed through retail community pharmacies] would be included in AMP. This is true even in the event there are a

[32] 42 CFR § 447.504.

> low number of AMP eligible sales. Because CMS is permitting manufacturers to use a presumed inclusion approach when calculating AMP, and to make reasonable assumptions, an AMP will likely be generated for such drugs.[33]

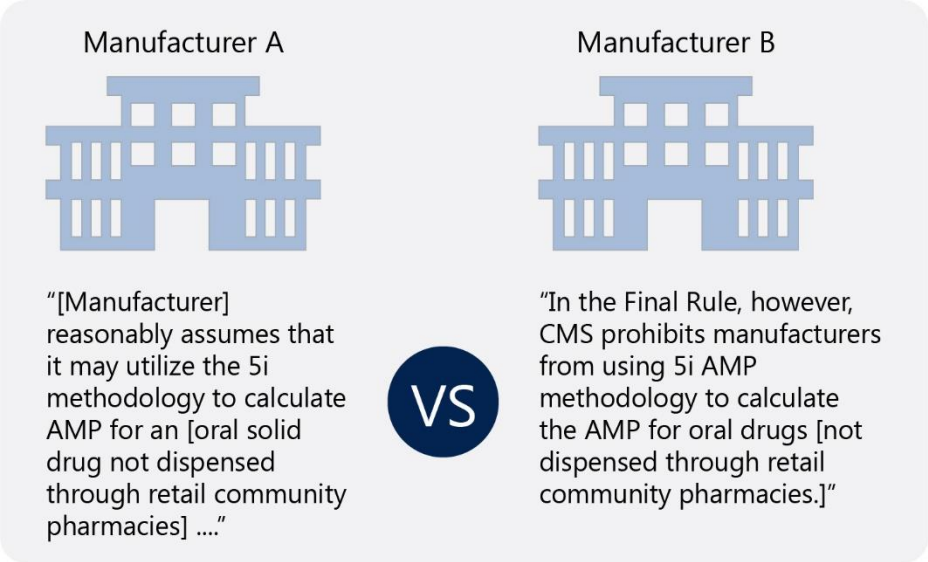
CMS also discusses these types of drugs at some length in the preamble to the MDRP final rule. However, of the 32 manufacturers that reported having (in their respective portfolios) oral drugs that are not dispensed through retail community pharmacies, 18 manufacturers (56 percent) responded that they would still like additional guidance from CMS. Another nine manufacturers[34] that do not currently produce these types of oral drugs also requested additional guidance from CMS on this issue. Manufacturers felt that current statutory, regulatory, and subregulatory policies do not adequately address how to treat oral drugs not dispensed through retail community pharmacies.

Given the lack of clarity, manufacturers applied several different approaches to calculate AMP for these drugs, all of which required assumptions. Some manufacturers reported using a 5i AMP calculation approach for so-called "crack drugs," despite the fact that the drugs do not meet the criteria to be considered 5i drugs. Other manufacturers felt CMS guidance clearly stated that using the 5i AMP calculation for such drugs would be inappropriate. Instead, these manufacturers developed assumptions that would allow for the use of the standard AMP calculation, despite these drugs' not being sold in what would typically be considered a retail community pharmacy. Exhibit 4 illustrates these differences.

[33] CMS, *Covered Outpatient Drug Final Rule with Comment (CMS-2345-FC) Frequently Asked Questions,* July 6, 2016.

[34] Of these nine manufacturers, five were smaller manufacturers and four were larger manufacturers.

Exhibit 4. Differences in manufacturers' AMP methodologies for oral drugs not dispensed through retail community pharmacies



Source: OIG analysis of responses to survey of drug manufacturers in the Medicaid Drug Rebate Program, 2018.

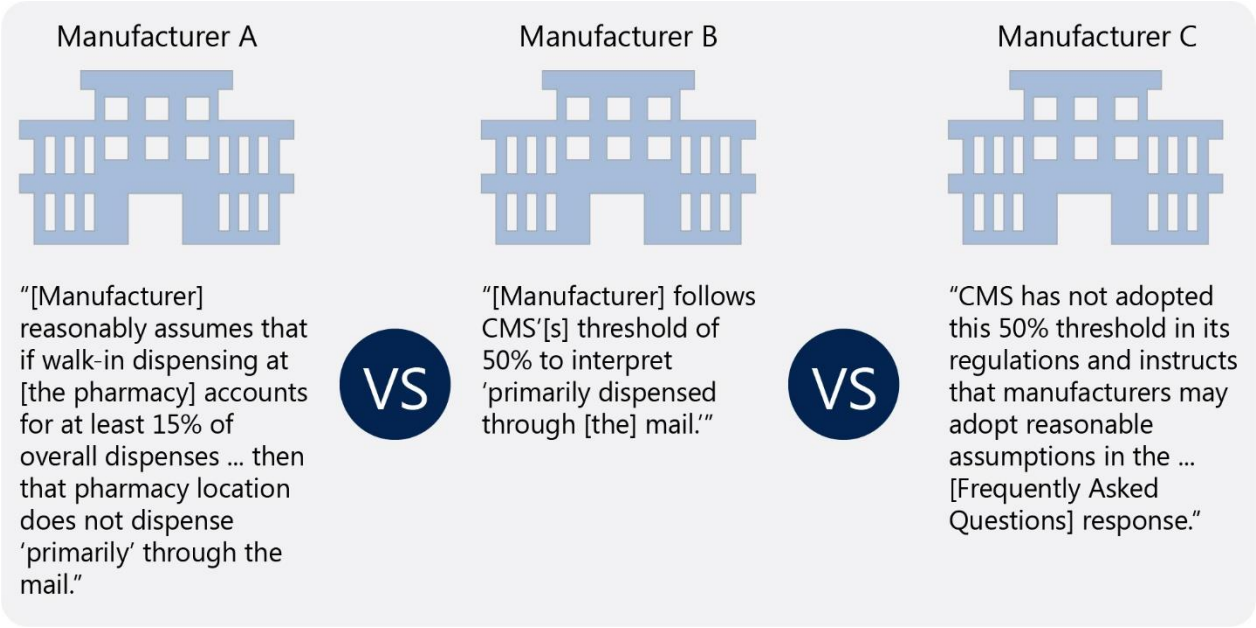
Manufacturers that did not treat oral specialty drugs as 5i drugs instead used assumptions to determine whether a drug met the criteria for being sold at a retail community pharmacy, which would allow manufacturers to use the standard calculation of AMP. These assumptions focused on the regulation stating that sales to pharmacies that dispense primarily through the mail would not be considered as sales to retail community pharmacies. However, CMS allows manufacturers to make reasonable assumptions about what constitutes "primarily," as outlined in a Frequently Asked Questions document:

> CMS declined to set a threshold in order to allow flexibility to recognize changes that take place in the pharmaceutical marketplace with regard to mail order business. CMS further noted that manufacturers may make reasonable assumptions that a pharmacy is a retail community pharmacy when the majority of the drugs are not dispensed through the mail. A "majority" is generally determined as greater than 50 percent[.]"[35]

Responding manufacturers' interpretation of this instruction has varied (see Exhibit 5), with thresholds ranging from 15 percent to 50 percent of sales to establish whether a pharmacy could be considered a retail community pharmacy. For example, to allow for an AMP to be calculated for a "crack drug," one manufacturer assumed that a pharmacy that did as much as 85 percent of its business via mail did *not* "primarily dispense through the mail," and thus qualified as a retail community pharmacy.

[35] CMS, *Covered Outpatient Drug Final Rule with Comment (CMS-2345-FC) Frequently Asked Questions*, July 6, 2016.

Exhibit 5. Differences in manufacturers' interpretations of guidance related to oral drugs "primarily dispensed through the mail"



Source: OIG analysis of responses to survey of drug manufacturers in the Medicaid Drug Rebate Program, 2018.

Value Based Purchasing Arrangements. Generally speaking, a value based purchasing arrangement is a contract between a drug manufacturer and a payer that ties payment for a drug to an agreed-upon measure (e.g., a manufacturer agrees not to charge for a drug when a treatment is unsuccessful).[36] Manufacturer responses pertaining to value based purchasing arrangements often expressed concerns that a lack of clarity regarding the rules may inhibit the adoption of these potentially cost-saving approaches (see Exhibit 6). Because the variety of price concessions and services that a manufacturer offers to a payer in a value based purchasing arrangement may lower the manufacturer's BP by a substantial margin, and thus greatly increase its Medicaid rebate and 340B discount obligations, manufacturers indicated that under current guidance, they might choose to forgo such arrangements.

In the MDRP final rule, CMS states:

> With the recent introduction of value based purchasing arrangements in the pharmaceutical marketplace, we recognize the value of such arrangements especially when they benefit patients. We are also interested in assuring that states and Medicaid programs have clarity as to how these arrangements might exist in Medicaid. Therefore, since these arrangements are unique, we are

[36] CMS, *CMS Approves State Proposal to Advance Specific Medicaid Value-Based Arrangements With Drug Makers*, June 27, 2018.

> considering how to provide more specific guidance on this matter, including how such arrangements affect a manufacturer's [BP].[37]

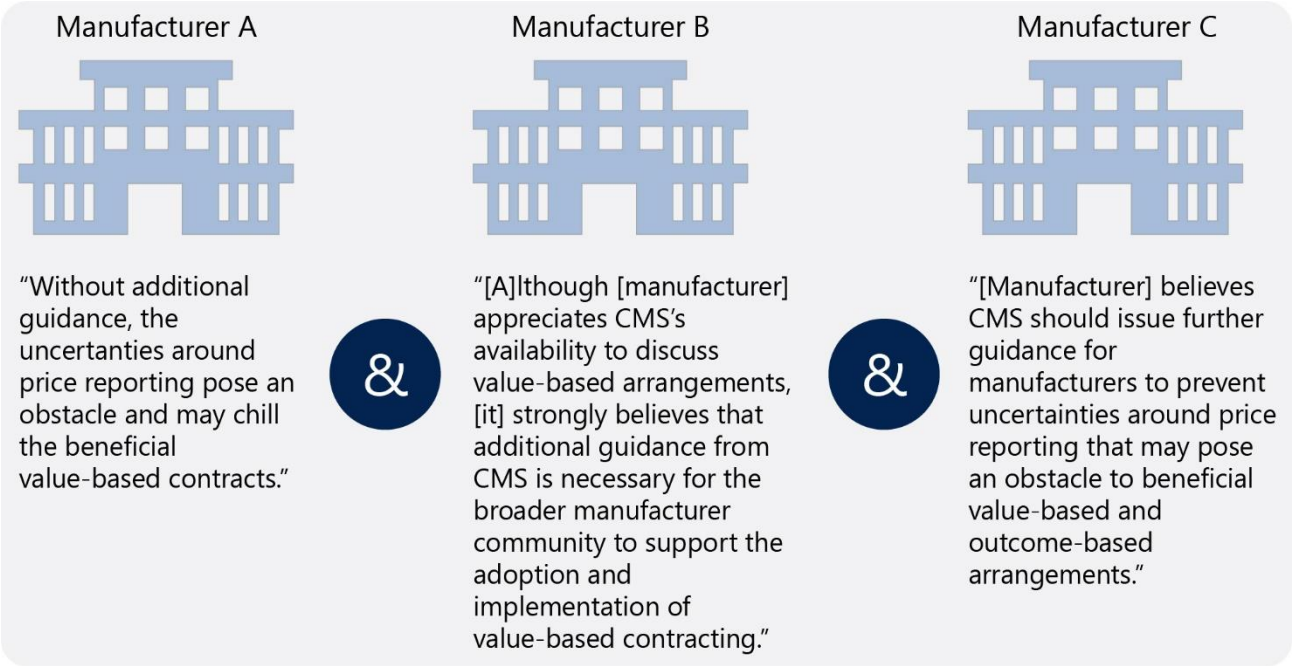
In July 2016, CMS issued such guidance in the form of a notice to manufacturers participating in the MDRP (i.e., Manufacturer Release 99), in which the agency stated that value based purchasing arrangements are an innovative approach to providing health care and encouraged manufacturers to consider entering into such arrangements with State Medicaid programs.[38] Further, CMS noted that it believes that value based purchasing arrangements are a means to address the high cost of certain drugs.[39] CMS concluded that the impact on BP will differ depending on the structure of the value based purchasing arrangement. CMS encouraged States and manufacturers to consider negotiating supplemental rebates as part of value based purchasing arrangements, as manufacturers could exclude such rebates from BP in certain cases.

In Manufacturer Release No. 99, CMS also directed manufacturers to submit any issues or questions concerning a particular value based purchasing arrangement to CMS's Division of Pharmacy. CMS stated that on the basis of such inquiries to its Division of Pharmacy, it would "seek to generalize lessons learned regarding common questions and arrangements in subsequent guidance." As of August 2019, CMS had not released any subsequent guidance related to value based purchasing arrangements. However, in discussions with OIG, CMS stated that the agency has limited ability to waive Section 1927 MDRP reporting requirements under a Section 1115A or 1115(a) waiver, potentially limiting manufacturers' ability to enter into these agreements with commercial payers.[40]

Of the 26 drug manufacturers that reported having value based purchasing arrangements in place, 14 (54 percent) responded that they would like additional guidance from CMS. An additional nine manufacturers[41] without these arrangements in their current sales practices also requested guidance from CMS. Manufacturers felt that current guidance is lacking and had concerns related to the temporal nature of these arrangements (i.e., when the sale occurs in one price reporting quarter, but the evaluation of the drug's effectiveness—and potential price-adjusting discount—occurs in a later quarter) and the potential impact on BPs.

[37] 81 Fed. Reg. 5170, 5253 (Feb. 1, 2016).
[38] CMS, Medicaid Drug Rebate Program, *Manufacturer Release No. 99*, July 14, 2016.
[39] Ibid.
[40] Section 1115(a) of the Social Security Act gives the Secretary authority to approve experimental, pilot, or demonstration projects that the Secretary finds to be likely to assist in promoting the objectives of the Medicaid program. However, the Secretary is limited in the statutory requirements that may be waived.
[41] Of these nine manufacturers, seven were smaller manufacturers and two were larger manufacturers.

Exhibit 6. Manufacturers reported that lack of guidance is a barrier for adoption of value based purchasing arrangements



Source: OIG analysis of responses to survey of drug manufacturers in the Medicaid Drug Rebate Program, 2018.

Bona Fide Service Fees. CMS defines a bona fide service fee as:

> a fee paid by a manufacturer to an entity that represents 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 is 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.[42, 43]

Although CMS discusses these fees at some length in the MDRP final rule, 39 of the 74 manufacturers that reported paying these fees (53 percent) responded that they would still like additional guidance from CMS.[44] An additional seven manufacturers that do not pay bona fide service fees also requested guidance.[45]

Manufacturers reported that current guidance fails to define or provide instructions related to a key component of bona fide service fees: the determination of fair market value. In the preamble to the MDRP final rule,

[42] 42 CFR § 447.502.
[43] Bona fide service fees include—but are not limited to—distribution service fees; inventory management fees; product stocking allowances; and fees associated with administrative service agreements and patient care programs.
[44] 81 Fed. Reg. 5170, 5176 (Feb. 1, 2016).
[45] Of these seven manufacturers, five were smaller manufacturers and two were larger manufacturers.

CMS states the determination of fair market value is subjective and that "any documentation can be used, provided that it makes clear the methodologies or factors the manufacturer used in making its fair market value determination."[46] To that end, manufacturers reported a wide range of methods to assess what constitutes fair market value, ranging from a simple assumption that all fees reflect fair market value (as long as the fees are within the range of commercial standards) to hiring external consultants to establish benchmarks for fair market value. One manufacturer's response seemed to summarize industry concerns:

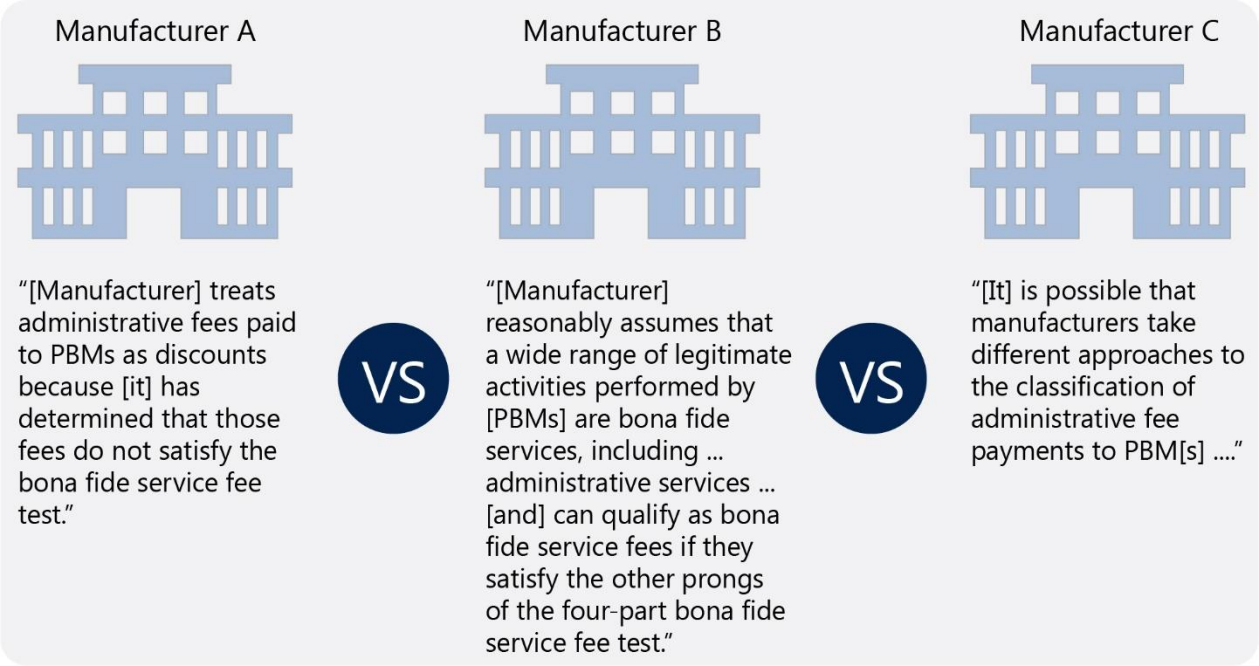
> …CMS should issue further guidance on the methodology that should be used to assess fair market value and the time period after which manufacturers should reassess the fair market value of fees. The issuance of further guidance would help to ensure consistency across the industry.

In addition, CMS also requires that bona fide service fees paid by manufacturers not be passed on to clients or customers. Current guidance allows manufacturers to presume that a fee is not passed on "in the absence of evidence or notice to the contrary."[47] However, a number of manufacturers pointed out that CMS has not defined or provided examples of what would constitute "evidence or notice to the contrary."

Finally, as illustrated in Exhibit 7, several manufacturers noted a need for greater clarity regarding certain administrative fees that they pay to PBMs, and whether those fees should be considered discounts, which would be *included* when calculating BP (thus resulting in a lower BP), or bona fide service fees, which would be *excluded* (thus resulting in a higher BP).

[46] 81 Fed. Reg. 5170, 5180 (Feb. 1, 2016).
[47] 81 Fed. Reg. 5170, 5181 (Feb. 1, 2016).

Exhibit 7. Manufacturers reported differences in how they treat certain fees paid to PBMs



Source: OIG analysis of responses to survey of drug manufacturers in the Medicaid Drug Rebate Program, 2018.

Rebates Offered to Pharmacy Benefit Managers. The MDRP final rule requires (at 42 CFR § 447.505(c)(17)) that when manufacturers calculate BP, they must include PBM rebates, discounts, or other financial transactions (1) related to purchases for their mail order pharmacies or (2) where such rebates, discounts, or price concessions are designed to adjust prices at the retail or provider level.[48]

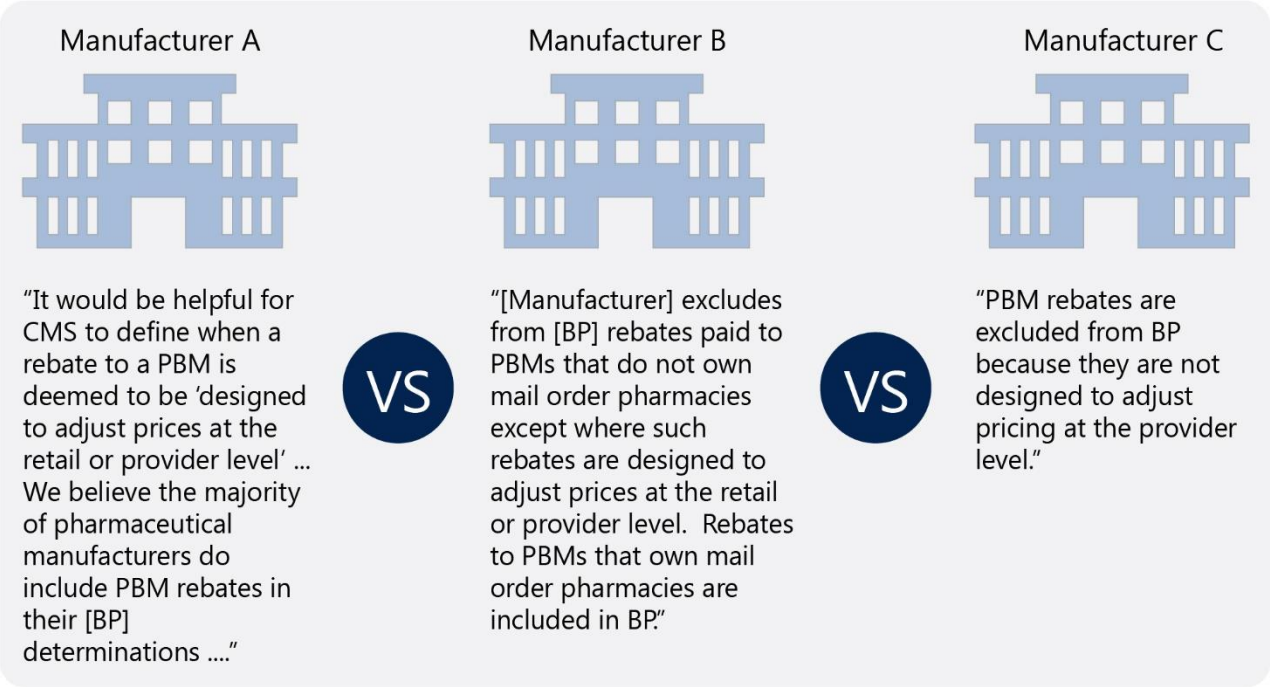
Of the 48 manufacturers that sell drugs through PBMs, 21 (44 percent) responded that they would like additional guidance from CMS. An additional three manufacturers[49] that do not have sales through PBMs also requested guidance. Specifically, manufacturers wanted additional clarity regarding how to determine whether or not a rebate is "designed to adjust prices at the retail or provider level."

Responding manufacturers noted that they have little insight into how PBMs use rebates and questioned whether such rebates are "designed to adjust prices" if manufacturer contracts do not direct how rebates are to be used. Despite these questions, most manufacturers reported that to be conservative, they assumed that all PBM rebates reduce retail/provider prices, and thus they include them when calculating BP. However, one manufacturer stated the exact opposite, and another described a process that included some PBM rebates and excluded others (see Exhibit 8).

[48] 81 Fed. Reg. 5170, 5351-5352 (Feb. 1, 2016).

[49] Of these three manufacturers, two were smaller manufacturers and one was a larger manufacturer.

Exhibit 8. Manufacturers reported differences in how they treat rebates that they offer to PBMs



Source: OIG analysis of responses to survey of drug manufacturers in the Medicaid Drug Rebate Program, 2018.

CMS provides little formalized oversight of the reasonable assumptions process; the agency believes that its statutory authority in this area is limited

CMS Does Not Collect or Regularly Review Reasonable Assumptions

As this report noted earlier, given the hundreds of manufacturers that participate in the MDRP, CMS specifically instructs manufacturers not to submit their assumptions to the agency, and states that if a manufacturer does so, CMS will not review the assumptions. Although CMS stated in writing that it has limited authority to assess the assumptions of manufacturers, the agency exercises this authority on a case-by-case basis to support formal oversight inquiries, manufacturer recalculations, and requests for technical assistance. In a limited number of specific cases, CMS has notified a manufacturer that an assumption is not consistent with the regulation and statute. If the manufacturer was reporting AMP and/or BP based on those assumptions, CMS asked that it recalculate and restate its AMP and/or BP. However, CMS believes its authority does not extend to enforcement—such as suspending a particular drug or manufacturer—when an assumption is not consistent with the regulation and statute.

According to CMS, the agency is not the official repository for assumptions and does not have a system in place to track them. Rather, in accordance with 42 CFR § 447.510, manufacturers must maintain records of the assumptions they make when calculating AMP and BP. To ensure that manufacturers maintain records that are compliant with the recordkeeping requirements specified in 42 CFR § 447.510(f), CMS has issued releases and

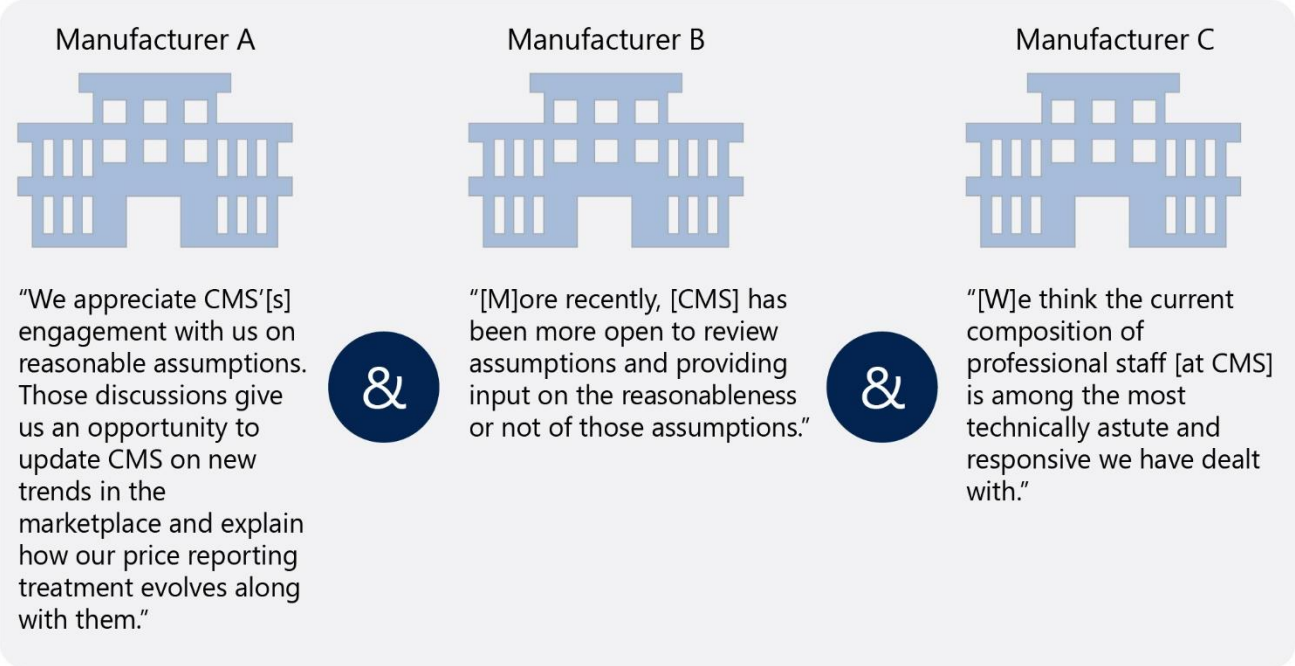
reiterated these requirements in the updated National Drug Rebate Agreement published March 23, 2018. [50, 51]

In an October 2017 MDRP Drug Labeler Release, CMS requested that manufacturers submit inquiries about their AMP and BP calculations in writing to the rxdrugpolicy@cms.hhs.gov resource mailbox or to the Division of Pharmacy Director.[52] The agency reported to OIG that it has recently begun receiving more technical assistance requests from manufacturers. CMS believes that since issuing the MDRP final rule, it is able to more easily reference the rule in response to manufacturers' inquiries.

Manufacturers Reported Mixed Experiences in Working With CMS on Assumptions-Related Issues

Of the manufacturers in our sample, 36 (35 percent) reported that they have contacted CMS for assistance regarding a scenario in which guidance on price calculations may be lacking. Half of these manufacturers stated that they were satisfied with the assistance they received (see Exhibit 9). Respondents praised CMS's engagement and the expertise of its staff.

Exhibit 9. Manufacturers described their satisfaction with CMS technical assistance



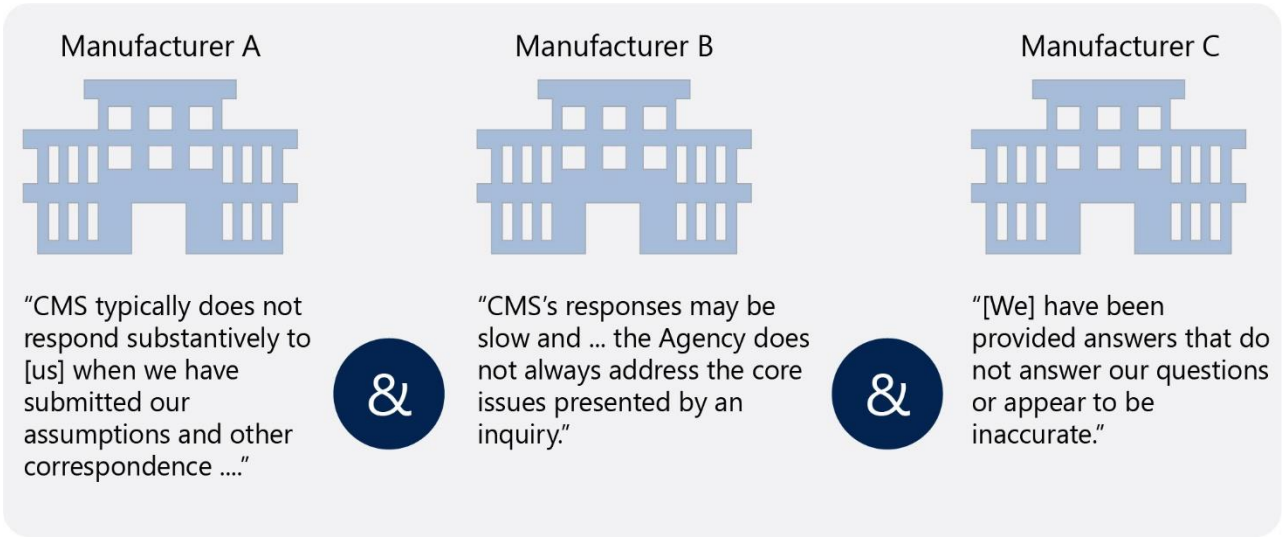
Source: OIG analysis of responses to survey of drug manufacturers in the Medicaid Drug Rebate Program, 2018.

In contrast, 11 manufacturers reported not being satisfied and 5 manufacturers said that CMS never responded to their inquiries. The remaining two manufacturers did not indicate whether or not they were

[50] CMS, Medicaid Drug Rebate Program, *Drug Labeler Release No. 78*, June 26, 2007.
[51] 83 Fed. Reg. 12770 (March 23, 2018).
[52] CMS, Medicaid Drug Rebate Program, *Drug Labeler Release No. 107*, October 30, 2017.

satisfied. The manufacturers that expressed dissatisfaction with CMS's responses primarily said that they were dissatisfied because CMS failed to substantively respond to their inquiries (see Exhibit 10). In these cases, manufacturers felt CMS's responses did not answer their questions and simply reiterated the language of current guidance or allowance of reasonable assumptions.

Exhibit 10. Manufacturers described their dissatisfaction with CMS technical assistance



Source: OIG analysis of responses to survey of drug manufacturers in the Medicaid Drug Rebate Program, 2018.

Manufacturers Recognized the Barriers That CMS Faces in Providing Oversight, and They Suggested Several Options to Improve the Reasonable Assumptions Process

Recognizing the sheer volume of documentation maintained by the hundreds of companies participating in the MDRP, less than 20 percent of responding manufacturers thought that CMS should regularly review records of their assumptions. Instead, manufacturers suggested that CMS use certain factors (e.g., complexity of the subject area, manufacturer feedback, potential fiscal impact to the program) to determine which assumptions merit an in-depth review by CMS. Other manufacturers said they believed that a periodic auditing of a sample of manufacturers could be a practical approach.

When we asked manufacturers how CMS could improve its process for providing assistance, the most common answer related to timeliness. Manufacturers felt that CMS does not always reply in a timely manner, which could result in the manufacturer's submitting AMPs and/or BPs without the clarity it had requested.

Further, a number of manufacturers felt that CMS should publish its individual responses to all assumptions-related inquiries so that CMS's

instructions would be available to—and benefit—the greatest number of manufacturers. Publishing these responses would require removing any proprietary information, but it would ensure that each manufacturer has access to the same information from CMS, thereby facilitating consistency and fairness in the program.

CONCLUSION AND RECOMMENDATIONS

Ensuring the accuracy of manufacturer-reported AMPs and BPs is vital given that these prices are the primary benchmarks that the Federal Government uses in efforts to reduce drug costs for Medicaid and certain safety-net providers. Recognizing the complexities of pharmaceutical industry sales practices and—in certain scenarios—the absence of comprehensive Federal guidance, CMS allows drug manufacturers to make "reasonable assumptions" regarding their AMPs and BPs that are consistent with statutory and regulatory requirements.

Our findings show that the use of reasonable assumptions when calculating AMPs and BPs is common practice among manufacturers. However, we also note that the "reasonableness" of most assumptions being made by manufacturers is never assessed. CMS believes its statutory authority in this area is limited, and the agency specifically instructs manufacturers not to submit their assumptions. As a result, CMS reviews assumptions only on a limited, case-by-case basis.

OIG recognizes that with hundreds of manufacturers, thousands of drugs, and a myriad of complex practices for pricing and sales, CMS is not in a position to review all assumptions on a regular basis. Many manufacturers also acknowledged the difficulty of such a task. However, given the fact that these assumptions can have large financial ramifications on the cost of prescription drugs to Medicaid and safety-net providers, OIG believes that—with the goal of ensuring compliance and consistency in the industry—CMS could take additional steps to improve its oversight in the area. Therefore, we recommend that CMS:

Issue guidance related to the areas identified in this report, specifically value based purchasing arrangements

OIG noted four specific areas that may need additional guidance from CMS: oral specialty drugs, bona fide service fees, PBM rebates, and value based purchasing arrangements.

According to responding manufacturers, the lack of guidance related to value based purchasing arrangements could actually be inhibiting innovative payment practices. Given that CMS has encouraged manufacturers to consider entering into such arrangements with State Medicaid programs, the agency should address manufacturers' concerns by issuing guidance to the extent permitted in law.

Assess the costs and benefits of implementing a targeted process to review certain assumptions

To strengthen oversight of the assumptions being made by drug manufacturers participating in the MDRP, CMS should assess whether it

would be cost-effective to develop a targeted process to collect and review manufacturer records related to certain practices. CMS should explore (1) using a set of factors (e.g., the complexity of the subject area, feedback from manufacturers, and potential fiscal impact to the program) to prioritize areas in which it would review manufacturer assumptions, or (2) reviewing assumptions from a sample of manufacturers. CMS could use the information from these reviews to inform its future published guidance and instruction.

Implement a system to share responses to manufacturer inquiries for technical assistance

To increase transparency and to facilitate consistency and fairness in the MDRP, CMS should implement a system to share its responses to manufacturer inquiries for technical assistance, protecting proprietary and confidential information as appropriate. CMS's response to a single manufacturer's inquiry has the potential to benefit other manufacturers in the program. However, CMS should ensure that such sharing of responses with multiple manufacturers does not affect the timeliness of its response to the requesting manufacturer and thereby delay that manufacturer in submitting accurate AMPs and/or BPs. CMS should also use this system to ensure that no manufacturer requests go unanswered.

AGENCY COMMENTS AND OIG RESPONSE

In its response to our draft report, CMS reaffirmed its commitment to ensuring the integrity of the MDRP so that prescription drugs are affordable for States and accessible for Medicaid beneficiaries.

CMS concurred with each of our three recommendations. In response to our recommendation to issue specific guidance related to value based purchasing arrangements, CMS stated that it will work to provide additional clarity regarding these arrangements.

In response to our recommendation to assess the costs and benefits of implementing a targeted process to review certain assumptions, CMS stated that it will determine whether the benefits outweigh the costs of implementing a targeted process to review certain manufacturer reasonable assumptions.

Finally, in response to our recommendation to implement a system to share responses to manufacturer inquiries for technical assistance, CMS stated that it currently publishes guidance related to common issues or questions that manufacturers may have regarding a specific Medicaid drug rebate program topic. However, CMS said that it will examine ways to improve and promote this process to ensure that its technical assistance can be used across the industry.

The full text of CMS's comments can be found in Appendix F.

APPENDIX A: Detailed Methodology

Identification of Reasonable Assumption Areas. We worked with CMS and industry stakeholders to develop a list of 15 common areas in which manufacturers have been making assumptions subsequent to the final rule of February 1, 2016. To supplement OIG's own analysis of relevant literature to identify industry trends, we also sought the assistance of stakeholder groups—the Pharmaceutical Research and Manufacturers of America (PhRMA), the Biotechnology Innovation Organization (BIO), and the Association for Accessible Medicines (AAM)—in developing a list of common assumption areas. PhRMA staff consulted with its members and provided OIG with a list. BIO and AAM declined to collaborate with OIG on this matter. We asked CMS staff to review the list and provide feedback, which we took into account for the manufacturer survey.

Sample Selection. OIG obtained 2016 data on Medicaid drug expenditures and utilization from CMS's State Drug Utilization Data file.[53] We summarized this data by the labeler code that the Food and Drug Administration assigns to a manufacturer. The State Drug Utilization Data file contained 618 labeler codes with reimbursement greater than $0.00. Because a single manufacturer may be associated with multiple labeler codes, we used CMS's Drug Manufacturer Contact Information file to combine all spending and utilization among all labeler codes with the same physical address to create a unique list of spending and utilization by manufacturer.[54] This resulted in 362 manufacturers from which we drew our sample.

We selected a stratified sample of manufacturers participating in the MDRP. The first stratum in our sample, which we refer to as "larger manufacturers," consists of drug manufacturers that meet at least one of the following two criteria:

(1) total amount reimbursed by Medicaid is greater than or equal to $500 million; or

(2) total units reimbursed by Medicaid are greater than or equal to 100 million units.

[53] The data include State, drug name, National Drug Code, number of prescriptions, and dollars reimbursed by Medicaid. CMS, *Medicaid Drug Rebate Program*. Accessed at https://www.medicaid.gov/medicaid/prescription-drugs/state-drug-utilization-data/index.html on June 13, 2017.

[54] The file Drug Manufacturer Contact Information contains the optional effective date; the termination date (if applicable); and legal, invoice, and technical contact information for each drug company participating in the Medicaid Drug Rebate Program. CMS, *Medicaid Drug Rebate Program*. Accessed at https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/index.html on June 14, 2017.

Combining both criteria ensured that we would reach not only manufacturers associated with high total expenditures, but also those with high sales volumes of lower-cost products (i.e., manufacturers of generic drugs). We included all 71 larger manufacturers in our sample. The 71 larger manufacturers represent 89 percent of all spending in the Medicaid program in 2016.

The second stratum, to which we refer as "smaller manufacturers," includes all other manufacturers that do not meet the criteria for the first stratum (i.e., less than $500 million reimbursed by Medicaid or less than 100 million units reimbursed by Medicaid). We randomly selected 100 of these 291 smaller manufacturers for our sample.

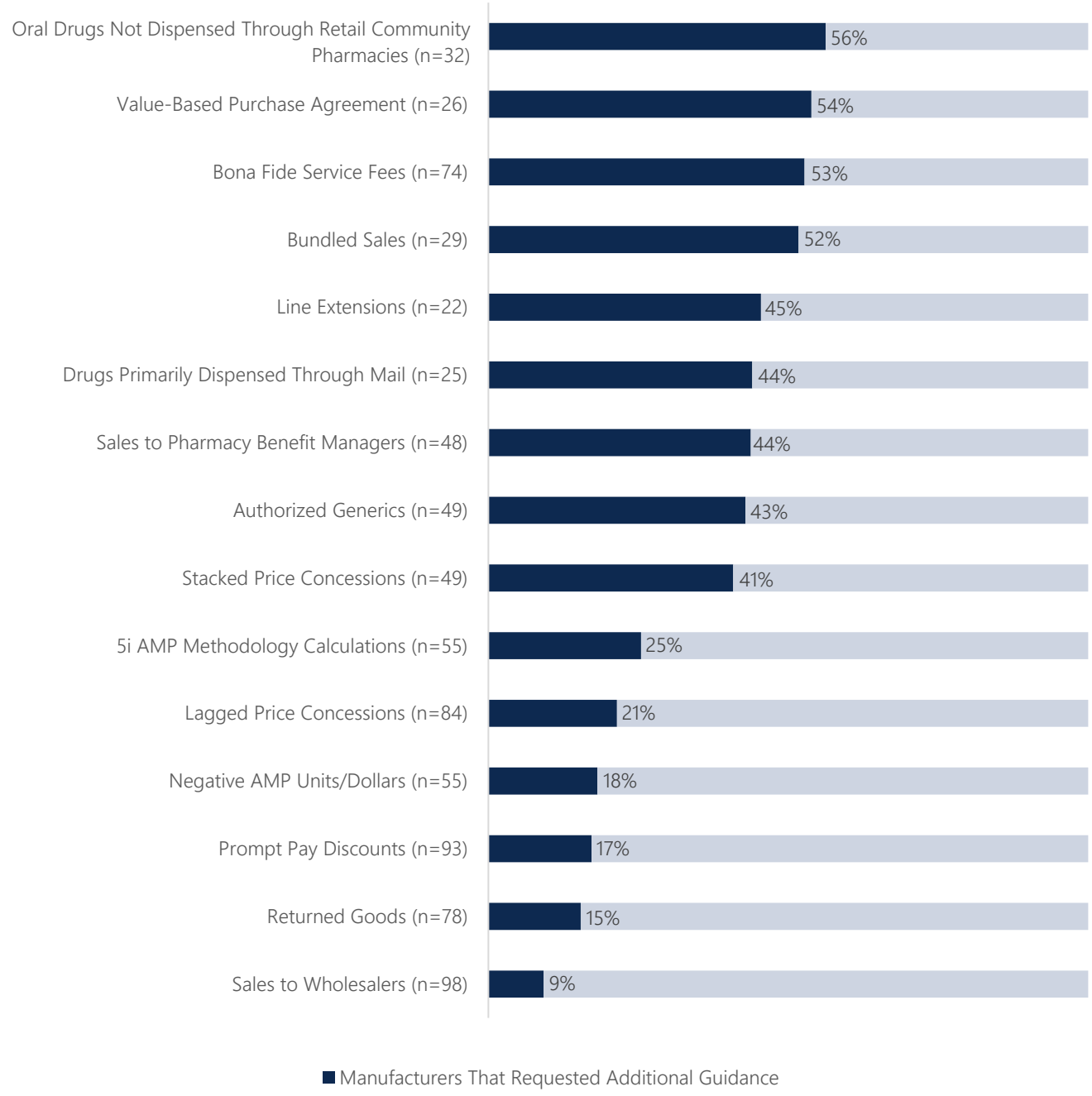
Exhibit 11: Stratified sample of drug manufacturers

Description	Number of Manufacturers	Total Amount Reimbursed	Percentage of Spending	Sample Size	Responses	Response Rate
Larger Manufacturers Manufacturers with greater than or equal to $500 million in total Medicaid amount reimbursed OR with greater than or equal to 100 million units reimbursed	71	$55,862,322,387	89%	71	46	65%
Smaller Manufacturers Manufacturers with less than $500 million in total Medicaid amount reimbursed OR less than 100 million units reimbursed	291	$7,208,684,768	11%	100	57	57%
TOTAL	**362**	**$63,071,007,154**	**100%**	**171**	**103**	**60%**

Source: OIG analysis of 2016 State drug utilization data, 2018.
Note: We calculated the total amount reimbursed and percentage of spending for 2016 using the State Drug Utilization Data file[55] and the Drug Manufacturer Contact file.[56] Because of rounding, the total amount reimbursed does not equal the sum of individual numbers.

[55] We downloaded State Drug Utilization Data for 2016 on June 13, 2017, from https://www.medicaid.gov/medicaid/prescription-drugs/state-drug-utilization-data/index.html.
[56] We downloaded the Drug Manufacturer Contact Information file on June 14, 2017, from https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/index.html.

APPENDIX B: Percentage of Manufacturers That Reported Wanting Additional Guidance From CMS Regarding Calculations of AMP and BP in Each Area



Source: OIG analysis of responses to survey of drug manufacturers in the Medicaid Drug Rebate Program, 2018.
Note: The simple sample percentages of manufacturers reported in Appendix B are only for manufacturers in our sample that reported having the underlying product types, sales practices, and/or sales calculations.

APPENDIX C: What Manufacturers Feel Is Lacking From Current Guidance in the Five Additional Areas In Which More Than 40 Percent of Manufacturers Requested Guidance

Authorized Generics. In general, an authorized generic is a brand-name drug that the brand manufacturer permits a secondary manufacturer (or a subsidiary) to sell as a generic. Of the 49 manufacturers with authorized generics, 21 (43 percent) responded that they would like additional guidance from CMS. An additional seven manufacturers[57] that did not have any authorized generics also requested guidance. Specifically, manufacturers wanted additional clarity regarding scenarios in which the primary manufacturer and the manufacturer of the authorized generic are affiliated in some way (e.g., a subsidiary that typically produces generic drugs). Another common request was for CMS to address what it means for a secondary manufacturer to "act as a wholesaler" in the context of authorized generics.

Line Extensions. Generally, a line extension is a new formulation of an existing brand-name drug (e.g., an extended-release version of the product). Of the 22 manufacturers with line extensions, 10 (45 percent) responded that they would like additional guidance from CMS. An additional 13 manufacturers[58] that did not have line extensions also requested guidance. Manufacturers cited the lack of a definition of line extension. In the MDRP final rule, CMS requested additional comments on the definition of line extension drug and the identification of new formulations that the Agency may consider addressing in future rulemaking.[59] As of August 2019, CMS had not issued any further guidance on this issue.

Drugs Primarily Dispensed Through the Mail. There are certain drugs that are primarily dispensed through the mail rather than by retail community pharmacies. Of the 25 manufacturers with drug products that are primarily dispensed through the mail, 11 (44 percent) responded that they would like additional guidance from CMS. An additional four manufacturers[60] that did not produce drugs primarily dispensed through the

[57] Of these seven manufacturers, four were smaller manufacturers and three were larger manufacturers.
[58] Of these 13 manufacturers, six were smaller manufacturers and seven were larger manufacturers.
[59] 81 Fed. Reg. 5170, 5265 (Feb. 1, 2016).
[60] Of these four manufacturers, three were smaller manufacturers and one was a larger manufacturer.

mail also requested guidance. As this report's second finding discusses, and as Exhibit 5 displays, CMS has not provided a specific definition of "primarily dispensed through the mail," resulting in manufacturers' adopting a variety of thresholds related to certain oral drugs that are dispensed primarily through specialty mail-order pharmacies.

Stacked Price Concessions. When calculating BPs, manufacturers may "stack"—i.e., aggregate—in their price concessions the discounts that they offer to customers. For example, a manufacturer may offer a prompt-pay discount to a wholesaler and a separate back-end rebate to a pharmacy for the same drug purchase. Of the 49 manufacturers that offered stacked price concessions, 20 (41 percent) responded that they would like additional guidance from CMS, most commonly in regard to when it is and is not appropriate to stack price concessions in determining BP. An additional five manufacturers[61] that did not engage in "stacking" also requested guidance. In the MDRP final rule, CMS states: "We do not believe it is necessary to specify the degree of the relationship between two separate but related entities since the manufacturer's price concessions or discounts that are passed on to BP-eligible entities are not predicated upon a relationship existing between the two entities." However, manufacturers reported that they need further guidance explaining how corporate affiliations affect stacked price concessions.

Bundled Sales. In general, a bundled sale refers to an arrangement under which a price concession for a drug is contingent upon the purchase of another product, a certain volume of the same product, or some other performance requirement. Of the 29 manufacturers that had bundled sales, 15 (52 percent) responded that they would like additional guidance from CMS. An additional five manufacturers[62] that do not offer bundled sales to customers also requested guidance. Manufacturers specifically requested that CMS provide additional guidance on temporal bundles (when sales and discounts occur in different quarters) and performance requirements (e.g., achieving of a certain market share or formulary placement.).

[61] Of these five manufacturers, three were smaller manufacturers and two were larger manufacturers.

[62] Of these five manufacturers, two were smaller manufacturers and three were larger manufacturers.

APPENDIX D: Sample Percentages and Key Statistics for Manufacturers That Make Reasonable Assumptions

	Manufacturers with the sales product, practice, and/or calculation			Manufacturers with the sales product, practice, and/or calculation—making assumptions		
	n	smaller (n)	larger (n)	smaller (n)	larger (n)	sample percentage
Bona Fide Service Fees	74	36	38	32	35	91%
Bundled Sales	29	4	25	3	23	90%
Stacked Price Concessions	49	12	37	7	32	80%
5i AMP Methodology Calculations	55	22	33	15	28	78%
Drugs Primarily Dispensed Through the Mail	25	7	18	5	14	76%
Prompt Pay Discounts	93	49	44	33	38	76%
Lagged Price Concessions	84	40	44	26	37	75%
Negative AMP Units/Dollars	55	21	34	14	26	73%
Sales to Wholesalers	98	52	46	34	37	72%
Oral Drugs Not Dispensed Through Retail Community Pharmacies	32	13	19	8	15	72%
Authorized Generics	49	15	34	6	28	69%
Sales to Pharmacy Benefit Managers	48	15	33	8	24	67%
Value Based Purchasing Arrangements	26	4	22	0	17	65%
Returned Goods	78	41	37	17	29	59%
Line Extensions	22	4	18	2	8	45%

Source: OIG analysis of responses to survey of drug manufacturers in the Medicaid Drug Rebate Program, 2018.

APPENDIX E: Sample Percentages and Key Statistics for Manufacturers That Request Guidance

	Manufacturers with the sales product, practice, and/or calculation			Manufacturers with the sales product, practice, and/or calculation - requesting guidance		
	n	smaller (n)	larger (n)	smaller (n)	larger (n)	sample percentage
Oral Drugs Not Dispensed Through Retail Community Pharmacies	32	13	19	6	12	56%
Value Based Purchasing Arrangements	26	4	22	1	13	54%
Bona Fide Service Fees	74	36	38	16	23	53%
Bundled Sales	29	4	25	0	15	52%
Line Extensions	22	4	18	3	7	45%
Drugs Primarily Dispensed Through the Mail	25	7	18	2	9	44%
Sales to Pharmacy Benefit Managers	48	15	33	3	18	44%
Authorized Generics	49	15	34	5	16	43%
Stacked Price Concessions	49	12	37	1	19	41%
5i AMP Methodology Calculations	55	22	33	4	10	25%
Lagged Price Concessions	84	40	44	7	11	21%
Negative AMP Units/Dollars	55	21	34	3	7	18%
Prompt Pay Discounts	93	49	44	7	9	17%
Returned Goods	78	41	37	6	6	15%
Sales to Wholesalers	98	52	46	3	6	9%

Source: OIG analysis of responses to survey of drug manufacturers in the Medicaid Drug Rebate Program, 2018.

APPENDIX F: Agency Comments

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: AUG 14 2019

TO: Joanne Chiedi
Acting Inspector General

FROM: Seema Verma
Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: Reasonable Assumptions in Manufacturer AMP Reporting (OEI-12-17-00130)

The Center for Medicare & Medicaid Services (CMS) appreciates the opportunity to review and comment on this draft report. CMS is committed to ensuring the integrity of the Medicaid drug rebate program so that prescription drugs are affordable for states and accessible for Medicaid beneficiaries.

The Medicaid Drug Rebate Program is a partnership between CMS, State Medicaid Agencies, and participating drug manufacturers that helps to offset the federal and state costs of most outpatient prescription drugs dispensed to Medicaid patients. The program requires a drug manufacturer to enter into, and have in effect, a National Drug Rebate Agreement with the Secretary of the Department of Health and Human Services in exchange for state Medicaid coverage of most of the manufacturer's drugs. Manufacturers are required to report all of their covered outpatient drugs to the Medicaid Drug Rebate Program. Manufacturers are then responsible for paying a rebate on those drugs for which payment was made under the state plan. These rebates are paid by drug manufacturers on a quarterly basis to states and are shared between the states and the Federal government.

The rebate amount owed for each drug is based on the average manufacturer price (AMP), and in certain circumstances, the best price (BP) reported by manufacturers. In the absence of specific guidance, the manufacturer may make reasonable assumptions in its calculation of AMP and BP, consistent with the general requirements and intent of section 1927 of the Social Security Act, Federal regulations and the National Drug Rebate Agreement. In accordance with the requirements of the National Drug Rebate Agreement, each manufacturer must maintain adequate documentation supporting its assumptions. CMS guidance also states that manufacturers are not required to submit their assumptions and their receipt is not considered acquiescence by CMS.[1] However, CMS has the ability to request manufacturers' records of reasonable assumptions for purposes including formal oversight inquiries, manufacturer recalculations, and technical assistance.

[1] Manufacturer Release No. 78

CMS also communicates regularly with manufacturers and provides technical assistance related to assumptions used in calculations. In addition, to increase transparency and efficiency, CMS also publishes guidance when we identify common issues or questions manufacturers may have regarding a specific Medicaid drug rebate topic, and ensures that the entire sector has access to this information.[2]

OIG's recommendations and HHS's responses are below.

OIG Recommendation
Issue guidance related to the areas identified in this report, specifically value-based purchasing arrangements.

CMS Response
CMS concurs with this recommendation. CMS will work to provide additional clarity regarding value-based purchasing arrangements to manufacturers.

OIG Recommendation
Assess the costs and benefits of implementing a targeted process to review certain assumptions.

CMS Response
CMS concurs with this recommendation. CMS will determine whether the benefits of implementing a targeted process to review certain manufacturer reasonable assumptions outweigh the costs.

OIG Recommendation
Implement a system to share responses to manufacturer inquiries for technical assistance.

CMS Response
CMS concurs with this recommendation. As noted above, CMS publishes guidance as a result of receipt of common issues or questions manufacturers may have regarding a specific Medicaid drug rebate program topic. CMS will examine ways to improve and promote this process to ensure our technical assistance can be used across the industry.

[2] https://www.medicaid.gov/medicaid/prescription-drugs/program-releases/index.html

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