CMS Response to Public Comments Received for CMS-10709

The Centers for Medicare and Medicaid Services (CMS) received comments from individual hospitals, hospital associations, health systems, and individuals within the healthcare field. This is the reconciliation of the comments.

Comment on the Appropriate Payment Rate for 340B-Acquired Drug

Comment: A commenter supported the 340B drug acquisition cost survey. The commenter stated that the survey results will be important to states' Medicaid programs and supported applying this information to Medicaid programs. The commenter supported states' Medicaid programs paying for specified covered outpatient drugs (SCODs) purchased under the 340B program at amounts that approximate acquisition costs. Additionally, the commenter requested that CMS issue guidance regarding its ability to share the survey data with Medicaid programs.

Response: We thank the commenter for the support. Comments related to Medicaid and data-sharing agreements with States are outside the scope of the data collection.

Comments Related to the OPPS Payment Policy for 340B Drugs and Biologicals and Related Litigation

Comment: Several commenters stated that CMS' current policy under the OPPS of paying a reduced amount of average sales price (ASP) minus 22.5 percent for drugs and biologicals acquired under the 340B program undermines their ability to provide needed care to the low-income patients they serve. They stated that the collection of acquisition cost data from 340B hospitals for use in setting payment rates under the OPPS for 340B drugs at acquisition cost will exacerbate payment shortfalls and further limit the hospitals' ability to offer charity care to low-income patients. Finally, a few commenters opposed the information collection request, stating that CMS should not attempt to implement piecemeal responses to the court's decisions until the litigation is concluded.

Response: While outside the scope of this data collection effort, we note that CMS has seen no evidence that the current OPPS 340B drug payment policy has limited patient access to 340B drugs. Further, Medicare payments for drugs are not intended to cross-subsidize other programs. Section 1833(t)(14)(D)(ii) of the Social Security Act (the Act) provides that the Secretary shall conduct periodic subsequent surveys (following the surveys that the U.S. Government Accountability Office (GAO) was required to conduct in 2004 and 2005) to determine the hospital acquisition cost for SCODs for use in setting payment rates under subparagraph (A) of section 1833(t)(14). The survey that was included in the PRA package is consistent with this authority.

We continue to believe that ASP minus 22.5 percent for drugs acquired through the 340B Program represents the average minimum discount that 340B enrolled hospitals receive and better represents acquisition costs.

In light of the United States District Court's decision in *American Hospital Association v. Azar*, CMS continues to believe it is important to obtain and consider hospital acquisition cost survey data for SCODs in order to have the ability to establish payment rates based on acquisition cost for drugs and biologicals acquired under the 340B program for potential future payment policy as well as for a potential remedy should the Secretary not prevail in the ongoing litigation related to 2018 and 2019.

Comment: A commenter contended that CMS has prejudged the results of the survey because CMS indicated that it anticipates the results will confirm that ASP minus 22.5 percent is a conservative estimate of the amount 340B hospitals pay to acquire drugs and biologicals under the 340B program. The commenter argued that if CMS intends to establish payment based on the survey results, CMS would have to engage in notice and comment rulemaking and make the data available with the proposed rule to allow stakeholders to respond. The commenter disagreed that the data collected could be used to craft an appropriate remedy.

Response: CMS has not prejudged the results of the survey. As we stated in the CY 2018 OPPS/ASC final rule with comment period (82 FR 52494), MedPAC noted in its 2016 report to

Congress that the discounts across all 340B providers average 33.6 percent of ASP. Additionally, in GAO report GAO-15-442[1], the amount of the 340B discount ranges from an estimated 20 to 50 percent of the ASP amount. We believe the payment amount of ASP minus 22.5 percent adequately represents the average minimum discount that a 340B participating hospital receives for separately payable drugs under the OPPS. As MedPAC noted, its estimate was conservative and the actual average discount experienced by 340B hospitals is likely much higher than 22.5 percent of the ASP. To the extent that survey data are used to establish rates for a future year, we intend to propose to use such data through notice and comment rulemaking, thus allowing interested parties an opportunity to comment on any such proposal. In addition, should we not prevail on appeal of the District Court's decision, we believe that using pricing information from the survey collection to craft a remedy for 2018 and 2019 would be appropriate.

Comments Related to the Statutory Authority

Comment: Commenters claimed that CMS' plan to collect acquisition cost data from 340B hospitals only, and not from other hospitals, is contrary to law. Commenters agreed that the Medicare statute allows for a survey of hospitals on drug acquisitions costs, but stated that the statute does not allow CMS to target a single group of hospitals, such as 340B hospitals, for the survey under the statute at section 1833(t)(14)(D)(iii). The commenters argued that section 1833(t)(14)(A)(iii)(I) provides that hospital group is defined based on the volume of covered OPD services or other relevant characteristics. They argued 340B covered entity status is not a relevant characteristic and utilizing it to target the survey is akin to differentiating between hospitals based on relative effectiveness of a hospital's group purchasing agreement or drug wholesaler. They argued that if a survey is administered, it must either apply to all hospitals or a representative sample of providers, consistent with how they read the specific statutory authority to conduct such survey.

[1] GAO-15-442: Published: Jun 5, 2015. Publicly Released: Jul 6, 2015. https://www.gao.gov/products/GAO-15-442

Response: CMS disagrees with the commenters' assertion that collection of drug and biological acquisition cost data from 340B hospitals is contrary to law. There is no requirement in the section 1833(t)(14)(D)(ii) or (iii) that the survey of hospital acquisition costs for SCODs must be administered to all hospitals or all hospital types. CMS also disagrees with the commenters' interpretation of the term "relevant characteristic" in the statute at section 1833(t)(14)(A)(iii)(I) as we believe that the significant drug acquisition discounts that 340B participating hospitals receive may vary significantly from those received by hospitals not participating in the 340B program; accordingly 340B enrollment status is a relevant characteristic for drug acquisition costs. This provision explicitly states that the average acquisition cost for a drug for a year "at the option of the Secretary, may vary by hospital group (as defined by the Secretary based on volume of covered OPD services or other relevant characteristics)." We believe it is within the Secretary's discretion under section 1833(t)(14)(A)(iii)(I) to choose to distinguish between hospital groups based on whether or not they are covered entities eligible to receive drugs and biologicals at discounted rates under the 340B program. We also note that section 1833(t)(14)(D)(ii) refers to use of the hospital acquisition costs for SCODs in setting payment rates under subparagraph (A), and therefore, we believe it is appropriate to read the two provisions together to permit the Secretary to survey 340B hospitals only.

Comment: A commenter stated that while CMS appropriately limited the survey to data on SCODs because of a lack of authority to collect cost data for non-SCODs, collecting data on non-SCODs (such as acetaminophen) would provide a more robust set of drug acquisition costs and would avoid the use of acquisition costs for SCODs while using an ASP methodology for non-SCODs. In order to avoid a two-tiered payment system that uses the acquisition cost data to set payment rates for SCODs and an ASP methodology to set payment rates for non-SCODs, the commenter suggested that the survey be expanded to apply to non-SCODs.

Response: Under our statutory authority at section 1833(t)(14)(D)(ii), we are required to conduct surveys to determine the hospital acquisition cost for each SCOD for use in setting payment rates under subparagraph (A). We note that in the CY 2013 final rule with comment

period (77 F 38277), we stated that drugs, biologicals, or diagnostic radiopharmaceuticals for which we have not established a separate APC and, therefore, for which payment would be packaged rather than separately provided under the OPPS are not considered to be SCODs. Accordingly, the payment for these non-SCODs are not based on the current ASP methodology; therefore, we do not believe that collecting data on non-SCODs would be useful. We remind commenters that any potential changes in payment policy based on the collected data would first be proposed through notice and comment rulemaking.

Comment: A commenter contended that while CMS is statutorily authorized to adjust drug payments, CMS must take into account "overhead and related expenses, such as pharmacy services and handling costs" under section 1833(t)(14)(E)(ii) of the Act.

Response: This comment is outside the scope of this information collection request. The information collection does not purport to change any payment methodology for SCODs under the OPPS. Should CMS wish to propose changes to the current methodology, it would propose to do so through notice and comment rulemaking. Nonetheless, we note that section 1833(t)(14)(E)(i) of the Act required MedPAC to submit to the Secretary, not later than July 1, 2005, a report on adjustment of payment for ambulatory payment classifications (APCs) for SCODs to take into account overhead and related expenses, such as pharmacy services and handling costs. The report was required to include, among other things, a recommendation regarding the methodology for making such an adjustment if MedPAC determined that such an adjustment should be made. Section 1833(t)(14)(E)(ii) provides that the Secretary may adjust the weights for APCs for SCODs to take into account MedPAC's recommendations.

As we stated in the CY 2018 OPPS/ASC final rule with comment period (82 FR 52494), MedPAC noted in its 2016 report to Congress that the discounts across all 340B providers average 33.6 percent of ASP. The current 340B drug payment policy of ASP minus 22.5 percent is more than 11 percent greater than the 340B discount calculated by MedPAC of ASP minus 33.6 percent. We consider the difference between the MedPAC calculated average discount and

the current Medicare 340B drug payment policy to adequately cover the overhead and related expenses for pharmacy services and handling costs.

Comments Related to the Survey Burden

Comment: Commenters stated the survey would represent considerable burden for hospitals already operating on thin margins and the survey burden may be insurmountable. Specifically, commenters stated that the draft survey is overly burdensome, predominantly citing that surveying each hospital off-campus provider-based department (PBD) would be extremely time-intensive, explaining that many hospitals do not track drug utilization by specific department location and that the location of any particular PBD for a hospital does not change the 340B acquisition cost. These commenters alleged that the survey would drastically exceed the 48 hours of time to complete that CMS estimated. Further, commenters alleged that the survey constituted a Paperwork Reduction Act (PRA) violation, in part because CMS did not explain the purpose of collecting data or how CMS intends to use this information. Commenters alleged that the survey did not meet the "practical utility" standard required by the PRA, noting that there are over 1,100 NDCs mapped to the approximate 400 SCODs that would be subject to the information collection request. Commenters contended that the burden on hospitals would be inconsistent with the Patients over Paperwork initiative and would take valuable time away from patient care.

Response: CMS believes the estimated 6 working days or 48 hours is reasonable given that the information should be readily available to hospitals for their institutional accounting purposes. Based on commenters' feedback, we have revised the survey to eliminate the request for information on a hospital PBD-level basis. Instead, the survey will permit hospitals to respond at the hospital level. We believe this will ease the reporting burden that concerned many commenters while allowing CMS to capture the appropriate data for future use.

In addition, the PRA seeks to:

- Minimize the paperwork burden on the public and other entities.

- Ensure the greatest possible public benefit from and maximize the utility of information created, collected, maintained, used, shared, and disseminated by or for the Federal Government.
- Improve the quality and use of Federal information to strengthen decision making, accountability, and openness in Government and society.
- Minimize the cost to the Federal Government of creating, collecting, maintaining, using, disseminating, and disposing of information.
- Ensure the integrity, quality, and utility of the Federal statistical system.[2]

This information collection is in accordance with the authority granted to the Secretary under section 1833(t)(14)(D) of the Act and may be used to inform payment rates under the Medicare program for drugs purchased under the 340B program. The practical utility of this information is that we are exercising explicit statutory authority to collect information regarding hospital acquisition costs for drugs. The agency may use the information collected to set payment rates for drugs purchased under the 340B Program. The acquisition cost data hospitals submit in response to this survey will be used to help determine payment amounts for drugs acquired under the 340B program. We want to ensure that the Medicare program pays for specified covered outpatient drugs purchased under the 340B program at amounts that approximate what hospitals actually pay to acquire the drugs. This will ensure that the Medicare program uses Medicare trust fund dollars prudently while maintaining beneficiary access to these drugs and allowing beneficiary cost-sharing to be based on the amounts hospitals actually pay to acquire the drugs.

Comment: A commenter argued that the survey is extremely burdensome given that not all drugs are purchased from their designated wholesaler, and that some may be purchased from secondary or tertiary suppliers. The commenter also alleged CMS lacked research and preparation in creating the acquisition cost survey and CMS did not work with any stakeholders to gauge the true cost and burden involved in providing this data. The commenter cited the GAO

[2] https://www.opm.gov/about-us/open-government/digital-government-strategy/fitara/paperwork-reduction-act-guide.pdf

report that expressed reservations about surveying hospitals due to burden on staff/hospitals. Additionally, commenters questioned whether a smaller, statistically valid, sample of hospitals would be sufficient to reflect accurate drug costs for two quarters since prices for 340B drugs are largely consistent across 340B covered entities per statutory pricing requirements.

Response: CMS appreciates these comments related to the burden hospitals expect to be associated with this data collection. CMS designed the survey with the goal of minimizing the burden on hospitals to respond. We have used the public comments we received during the initial public comment period to inform appropriate changes to the survey design which we are now including as part of the OMB approval process and the 30-day comment period. We are revising the survey instructions to provide further clarity for ease of reporting. CMS designed the survey to collect the data from the universe of 340B covered entities in order to work with a full dataset and to avoid problems that can accompany sampling. In addition, we are receiving stakeholder input on the information collection request via the PRA process.

Comment: Some commenters questioned why the survey applies to hospitals exempted from the 340B Medicare payment policy and noted that the survey is especially burdensome for those provider types: rural sole community hospitals (SCHs), PPS-exempt cancer hospitals and children's hospitals. These commenters suggested that it is unclear why these types of hospitals should incur any burden associated with filling out a survey when the current payment policy for 340B drugs does not apply to them.

Response: While current 340B payment policy exempts rural SCHs, PPS-exempt cancer hospitals and children's hospitals from the current 340B drug payment reduction, CMS is seeking to acquire data from all 340B participating entities so we may appropriately capture acquisition costs from all providers participating in the 340B program regardless of how they are currently paid for 340B drugs under the OPPS.

Comments Related to the Survey Methods and Non-Disclosure Provision

Comment: Some commenters expressed concerns with the use of a one-time data collection to set 340B prices moving forward. The commenter stated that drug prices are dynamic and suggested that CMS either establish a regular data collection schedule in an effort to better reflect prescription drug costs or apply an inflation index to drugs with relatively stable pricing over time.

Response: CMS thanks the commenter for the comments. CMS intends to consider all available options to most accurately set payment rates for 340B drugs and biologicals. This data collection is intended to be a one-time data collection.

Comment: A commenter suggested that rather than conduct a survey of actual acquisition costs, CMS should instead use the ceiling prices for the 340B acquired drugs as this information is readily available to CMS and thus would not necessitate a reporting burden placed on hospitals.

Response: In accordance with section 1833(t)(14)(D)(ii) of the Act and in light of the District Court decision, CMS believes it is important to obtain and consider hospital acquisition cost survey data for SCODs in order to set possible payment rates for drugs and biologicals acquired under the 340B program by hospitals. As discussed in Support Statement – Part A, where the acquisition cost for any individual drug is unknown or left blank or where the hospital fails to respond timely to the survey entirely, CMS will use the 340B ceiling prices as proxies for the acquisition costs for the drugs for which acquisition cost data is not submitted.

Comment: A commenter contended that the 340B price for a drug is a manufacturer's defined "best price" and there is a different relationship between Average Sales Price (ASP) and best price by NDC code (by drug, by manufacturer). The commenter further stated that "an overall average reduction from ASP assumes that all 340B-eligible hospitals have a similar mix of drug utilization, which ignores differences in service mix, clinical protocols used, and wholesalers' drug access. Hospitals with large oncology practices use a significantly different mix of drugs

than hospitals with large cardiology or surgical programs. Their average 340B discounts will vary significantly."

Response: The survey is intended to capture drug acquisition cost for each SCOD acquired under the 340B program. Once the survey data are obtained, we will have the ability to analyze variations in acquisition cost not only for different classes of drugs but for individual HCPCS codes. While CMS has not yet proposed how such information may be used to inform future rate setting, we note that any such use of the data collected in response to the survey would be proposed in notice and comment rulemaking prior to being used to establish payment rates.

Comment: Some commenters stated that information regarding acquisition costs for specific drugs is protected and also cited a non-disclosure provision in their wholesale agreements that precludes them from disclosing proprietary drug pricing information.

Response: CMS thanks the commenters for their comments. CMS does not intend to release an individual facility's SCOD acquisition cost data to the public. CMS reiterates our pledge to maintain the confidentiality of individual responses that include acquisition prices for each SCOD to the extent required by law. However, CMS may make public average acquisition prices reported for each SCOD. To the extent that acquisition prices for certain SCODs are deemed sensitive and/or confidential, we do not intend to make such prices available in an individually identifiable manner.

Comments Related to the Survey Instructions

Comment: Several commenters requested that CMS rescind the survey and stated that if CMS does not withdraw the 340B acquisition survey, CMS should reissue it with more detailed instructions to meet the requirements of the PRA and to allow commenters to submit meaningful comments on the burden. Additionally, commenters stated there are inconsistencies in the survey supporting documents that have resulted in general confusion.

Response: CMS has amended the survey instructions and supporting documents, as appropriate to improve clarity and to reduce burden. We believe that we did provide sufficient information in the initial information collection request to allow for meaningful comment and, in fact, received many comments related to issues that commenters identified as areas for improvement. We believe that changes we have made in response to the initial public comments received provide additional clarity. We also note that the Medicare Administrative Contractors (MACs) will be available to answer survey respondent questions to facilitate the implementation of the data collection.

Comment: Commenters cited ambiguous survey instructions and that it is unclear if the average acquisition cost CMS is seeking refers to the weighted price. Commenters also stated that it is unclear whether CMS is requesting the 340B ceiling price, sub-ceiling price, or the price received by the hospital after applicable wholesaler discounts.

Response: CMS thanks the commenter for the comments. CMS is revising the instructions for completing the survey. CMS is not surveying for the weighted average acquisition cost of 340B drugs. CMS is surveying for the 340B drug acquisition cost, including the sub-ceiling price after all applicable wholesaler discounts. The survey instructions will clarify the definition of 340B acquisition costs, remove the requirement to report drug information at the PBD level, and provide information on NDC-HCPCS crosswalk files.

Comment: Some commenters argued that survey data will be inconsistent and incorrect due to issues surrounding the existence of multiple NDCs for a particular HCPCS code. Commenters noted that while the information collection request appears to be asking hospitals to calculate average 340B prices for all NDCs paid under a given HCPCS code, the survey instructions also ask hospitals to provide the drug name that corresponds to the HCPCS code and the NDC, and noted a lack of clarity about whether CMS expected hospitals to provide the average price per NDC or per HCPCS code. These commenters contended they were unable to identify NDCs for particular HCPCS codes and that HCPCS units may change on a quarterly basis.

Additionally, commenters stated that since there are potentially thousands of NDCs correlated to the HCPCS codes for which we requested data, this will inevitably lead to human error and inaccuracy in the survey responses. The commenters suggested CMS provide NDC templates mapped to HCPCS codes. The commenters expressed concern that drugs purchased in a particular quarter may be administered in subsequent quarters that will lead to inevitable period mismatching between purchases and administrations. Some commenters were confused by the term "dose descriptor" and what they should report for acquisition cost per dose descriptor.

Response: To clarify, we are requesting the average acquisition price for each HCPCS code associated with a separately payable SCOD. To the extent that commenters need an NDC crosswalk to identify drug acquisition costs, we note that CMS publishes quarterly NDC-HCPCS Crosswalk files that are available on the CMS website at the following link: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index. The survey instructions will identify the quarterly releases of the NDC-HCPCS Crosswalk files that correspond to the Q4 2018 and Q1 2019 survey period. We note that the HCPCS units do not frequently change and we do not believe that any future code descriptor changes that involve a unit change will affect this survey since CMS is specifically surveying for the acquisition cost of drugs that are found on the October 2018 and January 2019 Addenda B. However, once we analyze the data from the initial data collection under this PRA package, we intend to continue to consider the concerns raised by these commenters when assessing whether additional surveys may be necessary.

Hospitals should respond to the survey with past acquisition cost data using the HCPCS code at the time of acquisition (not the administration) and the amount of drug in a single billing unit of the corresponding HCPCS billing code. The amount of a drug represented by a single billing unit of a HCPCS code, also referred to as the HCPCS code dosage, can be found in the "HCPCS Dosage" column of the NDC-HCPCS Crosswalk files links that appear earlier in this response. For example, the acquisition cost for daptomycin injection, which is billed by outpatient hospitals using HCPCS code J0878, (Injection, daptomycin, per 1 mg), would be reported per 1 mg of daptomycin.

For greater clarity, we are providing some examples of the relationship between acquisition costs at the product level and the acquisition cost at the HCPCS code level below.

- Drug products billed under J0885 (Injection, epoetin alfa, (for non-esrd use), 1000 units) include products sold under the brand names Epogen and Procrit. The drug products are sold in a variety of amounts, including vials and syringes that contain between 2000 units and 40,000 units of epoetin packaged in amounts that vary from 4 to 25 vials. On the CMS NDC-HCPCS Crosswalk files, the "HCPCS Dosage" column indicates that CMS payment of J0885 to outpatient hospitals (and other providers billing Part B by HCPCS codes) is based on 1,000 units of epoetin. For the survey, CMS is seeking the 340B average acquisition cost of J0885 per 1,000 units. Therefore, if the acquisition cost of a package of ten 20,000 unit epoetin vials is $1800, the acquisition cost of each 20,000 unit epoetin vial in the 10 vial package is $180. For reporting, the acquisition cost per 1,000 units of epoetin (corresponding to the amount in the HCPCS dosage as well as the HCPCS code dose descriptor) would be $180 divided by 20, or $9.00.
- Similarly, daptomycin is billed using HCPCS code J0878 (Injection, daptomycin, 1mg). Daptomycin is commonly sold in 350 mg or 500 mg vials packed in quantities ranging from 1 to 10 vials. The survey is seeking the acquisition cost of daptomycin based on 1 mg of the drug. If a package of ten 350 mg vial is acquired for $1400, then the acquisition cost a single 350 mg vial from the package is $140. The acquisition cost per 1 mg of daptomycin in the HCPCS dosage or dose descriptor, 1 mg, is $0.40.

Comment: One commenter asked for several additional clarifications regarding the information requested in the survey. They requested information on which drugs were to be included in the survey, and whether the survey only includes drugs paid for under the OPPS. Additionally, the commenter sought clarification regarding the inclusion of commercial outpatient claims, drugs dispensed in multiple settings, drugs purchased at WAC, and first time drug purchases as part of a replenishment model. They also asked CMS to clarify if the reported 340B price should include discounts.

Response: CMS reiterates that only the net acquisition costs for each SCOD acquired under the 340B program should be submitted in response to the survey. For purposes of the survey, CMS is not concerned with whether or not the drug was dispensed or whether the drug was dispensed in multiple settings. Similarly, CMS is surveying for the 340B drug program acquisition cost of all SCODs purchased under the 340B program, including drugs purchased at WAC or drugs purchased in a replenishment model under the 340B program. We are only requesting the acquisition cost of the drugs under the 340B program during the specified timeframe for each hospital surveyed. We are not surveying for commercial outpatient claims. Drug costs for drugs purchased outside of the 340B program should not be included in response to the survey.

Comment Out Of Scope

Comment: One commenter asserted that ASP pricing is not a fair or relevant benchmark to determine payment rates. This commenter asserted that ASP has the similar flaws as AWP, which preceded ASP. The commenter pointed to the industry self-reporting of drug prices as being leveraged to increase profit margins in the United States. This commenter suggested overall changes are needed for drug payment policy.

Response: We thank the commenter for their comment, and while it generally is outside the scope of this data collection, we will take the provided feedback into advisement for potential future policy decisions.