Supporting Statement – Part A

Hospital Survey for Specified Covered Outpatient Drugs (SCODs)
(CMS-10709; OMB 0938-New)

A. Background

In the Calendar Year (CY) 2018 Hospital Outpatient Prospective Payment and Ambulatory Surgical Center (OPPS/ASC) payment system final rule with comment period, the Centers for Medicare & Medicaid Services (CMS) finalized a policy to adjust payment for separately payable outpatient drugs acquired by eligible hospitals at discounted rates under Health Resources & Services Administration (HRSA's) 340B program from Average Sales Price (ASP) plus 6 percent to ASP minus 22.5 percent. According to 42 U.S.C. § 256b, hospitals eligible to participate in the 340B program include those with a Medicare Disproportionate Share Hospital adjustment of greater than 11.75 percent, Children's Hospitals, Critical Access Hospitals, Cancer Hospitals, Rural Referral Centers and Sole Community Hospitals. The 340B program sets a ceiling on the price that covered entities pay for outpatient drugs. The 340B ceiling price refers to the maximum amount that a manufacturer can charge a covered entity for the purchase of a 340B covered outpatient drug. The 340B ceiling price is statutorily defined as the Average Manufacturer Price (AMP) reduced by the rebate percentage, which is commonly referred to as the Unit Rebate Amount (URA).

On December 27, 2018, the United States District Court for the District of Columbia ruled that the Secretary of Health & Human Services exceeded his statutory authority to adjust payment rates under the OPPS for separately payable, 340B-acquired drugs. *See American Hospital Ass'n v. Azar*, 348 F. Supp. 3d 62, 82-83 (D.D.C. 2018), *appeal pending*, Nos. 19-5048 & 19-5198 (D.C. Cir.). The court reasoned, in part, that the Secretary had not collected the necessary data to set payment rates based on acquisition costs. The government disagrees with that ruling and has appealed. Nonetheless, in the event that the ruling is affirmed, CMS believes that it is important to begin obtaining acquisition costs for specified covered outpatient drugs to set payment rates based on cost for 340B-acquired drugs when they are furnished by covered entity hospitals.

The acquisition cost data hospitals submit in response to this survey will be used to help determine payment amounts under the OPPS 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.

B. Justification

1. Need and Legal Basis

Section 1833(t)(14)(D)(i)(I) of the Social Security Act (the Act) required the Comptroller General of the United States to conduct a survey in each of 2004 and 2005 to determine the hospital acquisition cost for each specified covered outpatient drug (SCOD) and, not later than April 1, 2005, to furnish data from such surveys to the Secretary for purposes of setting payment rates under the OPPS for SCODs for 2006. The Comptroller General was then required to make recommendations to the Secretary under section 1833(t)(14)(D)(i)(II) of the Act regarding the frequency and methodology of subsequent surveys to be conducted by the Secretary under clause (ii). Clause (ii) of section 1833(t)(14)(D) of the Act provides that the Secretary, taking into account such recommendations, shall conduct periodic subsequent surveys to determine the hospital acquisition cost for SCODs for use in setting payment rates under subparagraph (A) of section 1833(t)(14).

In response to the requirements at section 1833(t)(14)(D)(i)(I) and (II) of the Act, the Government Accountability Office (GAO) surveyed hospitals and prepared a report that included its recommendations for the Secretary regarding the frequency and methodology for subsequent surveys.[1] While GAO recognized that collecting current, accurate drug price data was important to ensure the agency does not pay too much or too little for drugs, GAO recommended that CMS conduct a streamlined survey once or twice per decade because of the significant operational difficulties and burden that such a survey would place on hospitals and CMS. *Id.* at 18.

HHS and GAO discussed whether the GAO data was useful in setting payments, particularly because GAO may have undercounted rebates. GAO included a footnote that described the exclusion of 340B discounts as part of its calculation.[2] In the CY 2006 OPPS final rule, CMS noted that the data collected by the GAO was not used to set payment rates, in part because the data did not fully account for rebates from manufacturers or payments from group purchasing organizations made to hospitals. Instead, CMS finalized changes to pay hospitals at ASP+6 percent because, at the time, we believed ASP+6 percent was a reasonable level of payment for both the hospital acquisition and pharmacy overhead cost of drugs and biologicals.

The Medicare Payment Advisory Commission (MedPAC) has consistently stated that Medicare should institute policies that improve the program's value to beneficiaries and taxpayers. We

[1] https://www.gao.gov/new.items/d06372.pdf

[2] https://www.gao.gov/new.items/d06372.pdf (Appendix II: Purchase Price for Drug SCODs)

believe that utilizing a survey will enable CMS to gather hospital acquisition cost data, which will allow CMS to refine the payment rate for drugs acquired by 340B hospitals.

In the March 2019 Report to Congress, MedPAC noted that outpatient payments increased in part due to rapid growth in Part B drug spending.[3] CMS will use this survey to help determine payment amounts for each drug acquired through the 340B Program. As noted previously, 340B entities receive these drugs at a discount and are charged a maximum price, ceiling price, for these drugs because of their participation. We also note that these covered entities have access to certain drugs through the HRSA's Prime Vendor Program (PVP), in which the vendor can negotiate even deeper discounts. We want to ensure that the Medicare program pays for SCODs purchased under the 340B Drug Program in a manner that ensures access to care is maintained, that Medicare trust fund dollars are spent wisely, and that Medicare beneficiaries can also stretch their scarce resources. We believe that utilizing the authority under Section 1833(t)(14)(D)(ii) is a step toward increasing equity in Medicare payments and value to the program.

Hospitals that are covered entities for purposes of the HRSA's 340B Program are able to purchase drugs at the discounted 340B ceiling price, or at even lower "sub-ceiling" prices. In the CY 2018 OPPS/ASC payment system final rule with comment period, CMS exercised the Secretary's authority to adjust the applicable payment rate as necessary for separately payable drugs and biologicals (other than drugs on pass-through status and vaccines) acquired under the 340B Program from ASP+ 6 percent to ASP minus 22.5 percent. *See* 82 FR 54293. Rural sole community hospitals (SCHs), children's hospitals, and PPS-exempt cancer hospitals are excluded from this payment adjustment. Critical Access Hospitals are not paid under the OPPS, and therefore, are not subject to the payment adjustment. *Id*. at 52493-52511. In making this adjustment, CMS noted the rapid and substantial growth of Medicare spending for 340B drugs and the studies detailing that hospitals were able to purchase 340B drugs well below the statutory ceiling price. *See* 82 FR at 52494-95.

After the CY 2018 final rule was issued, three hospital associations and three member hospitals filed suit against HHS in November of 2017. On December 27, 2018, the U.S. District Court for the District of Columbia ruled that the Secretary of the Department of Health & Human Services exceeded his statutory authority by adjusting payment rates under the OPPS for 340B-acquired drugs from ASP plus 6 percent to ASP minus 22.5 percent. *See American Hospital Ass'n v. Azar*, 348 F. Supp. 3d 62, 82-83 (D.D.C. 2018).

The court reasoned in part that the Secretary had not collected the necessary data to set payment rates based on acquisition costs. *Id.* at 82-83. The agency disagrees and has appealed the decision to the D.C. Circuit. However, in light of the possibility of an adverse decision on appeal, CMS

[3] http://www.medpac.gov/docs/default-source/reports/mar19_medpac_entirereport_sec.pdf?sfvrsn=0

believes that it is important to begin obtaining hospital acquisition cost survey data for SCODs for possible use to set payment rates based on acquisition cost for drugs and biologicals acquired under the 340B program by certain hospitals.

In light of the history outlined above, and in accordance with the legal authority under section 1833(t)(14)(D), CMS is requiring all hospitals that participated in the 340B program in the last quarter of CY 2018 (October 1, 2018 through December 31, 2018) and/or first quarter of 2019 (January 1, 2019 through March 31, 2019) to supply their average acquisition cost for each SCOD purchased during this timeframe, which could be the 340B ceiling price, a 340B sub-ceiling price, or another amount, depending on the discounts the hospital received when it acquired a particular drug. In instances where the acquisition price for a particular drug is not available or submitted in response to the survey, we will use the 340B ceiling price for that drug as a proxy for the hospitals' acquisition cost for each SCOD because the price for a drug acquired under the 340B program cannot be higher than the 340B ceiling price (and, in fact, is often lower).

We also note that we are only requiring hospitals that acquired drugs under the 340B program in the fourth quarter of calendar year 2018 and/or the first quarter of calendar year 2019 to respond to the survey. Hospitals that did not acquire drugs under the 340B program in either of those quarters are not required to respond to the survey. We have historically found that the average sales price (ASP) is an adequate proxy for drug acquisition costs for non-340B hospitals. ASP data does not, however, include 340B drug prices. *See* CY 2011 OPPS final rule with comment period (75 FR 71800, 71960).

When GAO surveyed hospitals in 2005, it found that the survey "created a considerable burden for hospitals as the data suppliers and considerable costs for GAO as the data collector," and recommended that CMS survey hospitals only once or twice per decade to "occasionally validat[e] CMS's proxy for SCODs' average acquisition costs – the average sales price (ASP) data that manufacturers report." GAO Report to Congress: *Survey Shows Price Variation and Highlights Data Collection Lessons and Outpatient Rate-Setting Challenges for CMS,* 4 (April 2006). We have taken steps to mitigate the burden of this survey. We note that in order to participate in the 340B program, covered entities, including hospitals, must maintain accurate records to ensure that such acquired drugs are used for eligible patients. In addition, we are only asking for data on the 340B drug acquisition price at the hospital level for two quarters. We are requesting the 340B drug acquisition cost of separately payable drugs identified in Addendum B on the CMS Website. Further, for drugs for which hospitals are unable to supply the acquisition price or where a hospital does not respond to the survey, we will use the 340B ceiling price.

We believe it is necessary to survey 340B hospitals, for which ASP does not serve as a reliable proxy for their acquisition costs, but do not believe it is necessary to survey non-340B hospitals

because we already have ASP data, which are an adequate measure of the drug acquisition costs of such providers.

2. Information Users

The practical utility of the 340B drug acquisition cost survey is that CMS is exercising the explicit statutory authority to obtain drug acquisition cost per section 1833(t)(14)(D) and the agency may use the information collected to set OPPS payment rates for drugs purchased under the 340B Program.

3. Use of Information Technology

CMS intends to collect this information electronically using Excel and a secured website. Accordingly, respondents must submit the required data provided in a pre-populated Excel survey shell. In addition, respondents may refer to the CMS quarterly NDC-HCPCS Crosswalk files that are available on the CMS website. Please note that although the NDC-HCPCS Crosswalk files provide examples of commonly associated NDCs for the majority of the HCPCS codes, these files do not provide a complete and comprehensive list of all available NDCs for each HCPCS code.

CMS is working with the Medicare Administrative Contractors (MACs) to distribute and collect the surveys via a secured website to upload the survey worksheet. Hospital identity validation is required for any submission to protect the security and integrity of the data. 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.

4. Duplication of Efforts

The survey does not duplicate other efforts for CMS but to the extent that the hospital’s acquisition costs are equal to the ceiling price for a SCOD, HRSA shares such ceilings prices with eligible hospitals via a secure portal. Oftentimes, however, the actual acquisition cost to the hospital is lower than the ceiling price, thus, these efforts are not duplicated.

5. Small Businesses

This information collection may affect small entities such as small rural and urban hospitals. To minimize the burden, we have limited the specific information collected solely to the essential elements necessary to develop payment rates.

6. Less Frequent Collection

If the collection does not happen, then the agency will not have acquisition cost data for use in paying for separately covered outpatient drugs acquired under the 340B program and would be unable to pay for these drugs based on acquisition cost pursuant to section 1833(t)(14)(A)(iii)(I) of the Social Security Act. The agency believes that in order to ensure that payment for these drugs is appropriate, a data collection needs to occur.

7. Special Circumstances

This collection may apply occasionally. We are not requesting original documents of any kind. Furthermore, we are not requiring respondents to retain any records other than what hospitals already retain for pharmaceutical supplies, specifically drugs. The information collected via this survey tool is intended to be analyzed for suitability in determining payment amounts (to the extent such data are valid) for 340B-acquired drugs. This collection will not require the use of a statistical data classification or other large-scale data sorting procedures. The agency was given the authority to do this collection and collect this type of data under the law at section 1833(t)(14)(D)(ii).

8. Federal Register/Outside Consultation

The 60-day Federal Register notice published in the Federal Register on 9/30/2019 (84 FR 51590). The collection received multiple comments and CMS has provided responses to the public comments from the 60-day comment period on the 340B drug acquisition survey. Our responses can be located within the Response to Comment document, which is available on the on the OMB web site, www.reginfo.gov.

The 30-day Federal Register notice published in the Federal Register on 2/07/2020 (85 FR 7306). Our response can be located within the Response to Comment document, which is available on the OMB web site, www.reginfo.gov.

9. Payments/Gifts to Respondent

Respondents will receive no payments or gifts for their participation in this collection of information.

10. Confidentiality

CMS pledges confidentiality of individual responses regarding acquisition prices for each SCOD to the extent required by law. However, CMS may make public average acquisition prices reported for each SCOD. The website for the 340B drug acquisition cost survey is a secured website, which requires hospital identity validation.

11. Sensitive Questions

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. As noted in section 10 above, we pledge confidentiality to the extent required by law.

12. Burden Estimates (Hours & Wages)

We estimate the time associated with collecting the information for the survey and submitting the data electronically to CMS to be 6 working days (6 days x 8 hours = 48 hours). We believe this is reasonable, as the information submitted by the hospital is typical information that the hospital already has for the drugs it purchases. Thus, the hospital should be able to query its inventory to get pricing information along with any discounts provided by manufacturers and the like. Accordingly, this is a required collection. We estimate 67,584 total hours for submitting the survey (that is 1,408 surveys x 48 hours). When computed, we assumed a current salary of $37.89 per hour (based on data from the Bureau of Labor and Statistics website at **https://www.bls.gov/oes/current/oes132011.htm** for the position of Accountants and Auditors) plus 100 percent for fringe benefits. We believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method ($37.89 + $37.89). The estimated cost of burden for this survey is $3,637.44 per hospital ($75.78 per hour x 48 hours per hospital). The total maximum cost burden to respondents or record-keepers resulting from the collection of this information is $5,121,515.52 ($3,637.44 x 1,408 hospitals).

We note that there will be not be any additional non-labor expenses such as postage or copying as this survey shall be submitted electronically.

13. Capital Costs

There are no capital costs.

14. Cost to Federal Government

The cost to process the information submitted is estimated as follows based on review by analysts, supervisory staff, and contractor support. This review includes analysts reviewing calculations and possibly reaching back out to hospitals whose surveys contain missing information. We estimate the total time to process, evaluate, and develop final estimates is a total of 800 hours and we used this figure to derive the following estimate.

$60.48 (average salary GS 12-15 and estimated contractor wages) X 800 hours = $48,384.

15. Changes to Burden

None. CMS revised the 340B drug acquisition cost survey based on comments received, to reduce the burden imposed on hospitals. Although the original burden estimate remains unchanged, we believe the changes made in response to comments are now in line with the 48 hours of burden estimated for each respondent hospital should the institution select to conduct the detailed survey. The burden estimate would be lower if the 340B hospitals elects to use the ceiling price data described below. We have made the following revisions:

- Eliminated the request for information at the hospital off-campus provider-based department (PBD) level, permitting hospitals to respond at the hospital level;
- Set up a Web portal to streamline survey submission
- Created a “Quick Survey” option that a hospital can select if it chooses not to submit individual drug data and instead elects to have CMS apply the ceiling price data for the hospital because such data reflects its acquisitions costs (note that hospitals that take no action to respond will have ceiling price data applied to them).

We believe these changes are responsive to the burden that concerned many commenters, while allowing CMS to capture the appropriate data for future use, and is consistent with the original burden we estimated for the survey.

16. Publication/Tabulation Dates

In accordance with section 1833(t)(14)(A)(iii)(I), the agency plans to use the data collected to determine acquisition costs for SCODs, to the extent the submitted data is valid. Following the

collection of data and its analysis, the results of the survey will be used to formulate proposed payment rates, which would be subject to notice and comment rulemaking.

17. Expiration Date

CMS will display the expiration date and OMB control number on the CMS website at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html. There is a placeholder in the footer of the instruction document as well as in the PRA Disclosure Statement. On the instrument, there is a placeholder on the PRA Disclosure Statement on the cover tab in the Excel workbook.

18. Certification Statement

There are no exceptions to the certification statement.