

340B UPDATE: CMS OPENS ACQUISITION COST DATA SURVEY FOR 340B HOSPITALS

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U.S. Health Care Alert

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On April 24, 2020, the Centers for Medicare and Medicaid Services (“CMS”) announced that the Hospital Survey for Specified Covered Outpatient Drugs (“SCODs”) Average Acquisition Cost under the 340B Drug Pricing Program (“340B Program”) is now open. The White House Office of Management and Budget approved the survey on April 23, 2020. Despite concerns from provider groups and hospitals about the survey and the difficulty in completing the survey amid the COVID-19 pandemic, CMS is moving forward with an updated version of the survey, but appears to have sought to meet some of those concerns by offering a new “Quick Survey” option that permits hospitals to have the Health Resources and Services Administration (“HRSA”) 340B ceiling price be deemed their 340B price. 340B hospitals have until May 15, 2020, to submit completed surveys on their acquisition costs to their respective Medicare Administrative Contractors (“MACs”).

BACKGROUND

As reported in our previous alert ([here](#)), CMS announced last year its intention to require hospitals that participated in the 340B Program in the last quarter of Calendar Year (“CY”) 2018 (October 1, 2018, through December 31, 2018) and/or first quarter of 2019 (January 1, 2019, through March 31, 2019) to submit acquisition cost data for each SCOD during that period.¹ CMS indicated that it would use the data to help determine payment rates for 340B drugs in an effort to ensure that Medicare pays at amounts that “approximate what hospitals actually pay to acquire the drugs.”²

Importantly, in the Hospital Outpatient Prospective Payment System (“OPPS”) final rule for CY 2020, CMS also indicated that it would use the acquisition cost data to devise a remedy if the U.S. Court of Appeals for the District of Columbia Circuit (“D.C. Circuit”) rules against the Administration in *Am. Hosp. Ass’n v. Azar*.³ The D.C. Circuit heard oral arguments last November.

As discussed in our previous alerts ([here](#) and [here](#)), hospital groups sued the Secretary of the Department of Health and Human Services challenging CMS’ decision for CY 2018 to reduce reimbursement of 340B drugs paid under the OPPS from Average Sales Price (“ASP”) plus 6 percent to ASP minus 22.5 percent.⁴ The U.S. District Court for the District of Columbia held that the Secretary exceeded his authority in adjusting the payment, in part because the Secretary lacked the “necessary data” to support such rates.⁵ CMS appealed the District Court’s decision.

While the D.C. Circuit decision on that appeal is pending, CMS is attempting to collect through the acquisition cost data survey the “necessary data” to support such rates. CMS has sent to OMB its CY 2021 OPPS proposed rule for review, which could be published in the Federal Register in June.⁶ It has been widely speculated that CMS may use the data to support reduced rates for CY 2021.

UPDATED SURVEY

Hospital Objections to the Survey

As discussed in further detail in our previous alert ([here](#)), hospital groups and other stakeholders expressed numerous concerns with CMS' proposed survey, urging the agency to withdraw the survey. They highlighted the ambiguity in the scope of the survey and the acquisition cost data requested and described the challenges in determining the data sought, confidentiality and other concerns in sharing this information, as well as the lack of clear and detailed instructions.⁷

Although CMS clarified and revised certain aspects of the survey based on initial public comments, stakeholders submitted additional comments to OMB as it reviewed the survey. In approving the updated version of the survey, OMB is requiring CMS to prepare a report providing “a nonresponse bias and standard error analytical results and share with OMB prior to utilization of data for future publications, including rulemaking.”⁸ OMB noted that CMS must “clearly describe the scope and characteristics of the responding hospitals, as well as any limitations in the generalizability of the information collected, in any publications and documents utilizing this data.”⁹

Revisions to the Acquisition Cost Data Survey

As part of the updated survey, CMS is now offering hospitals the option to complete a “Detailed Survey” or a “Quick Survey.” As part of the Detailed Survey, hospitals must provide their acquisition costs for each individual SCOD.¹⁰ As part of the Quick Survey, hospitals have the option to not complete the Detailed Survey and have CMS utilize the 340B ceiling prices obtained from the HRSA as reflective of their acquisition costs.¹¹

CMS also simplified certain aspects of completing the survey. CMS made the survey available for download at a 340B Survey Gateway ([here](#)) instead of asking hospitals to download the survey from their MACs websites as initially proposed.¹² Completed surveys must still be submitted to corresponding MACs by May 15, 2020. In addition, CMS pre-populated the payment rates from the OPPS Addendum B, instead of asking hospitals to retrieve them from there.¹³ CMS is no longer asking hospitals to report National Drug Codes (NDCs), which had been optional.

In regard to the acquisition cost data requested, CMS clarified that “acquisition cost” refers to “the price that hospitals pay upon receiving the product (that is, the sub-ceiling price after all applicable discounts).”¹⁴ CMS notes that this includes, but is not limited to, “340B drugs purchased via a replenishment model under the 340B program, or under penny pricing.”¹⁵ CMS further explained that “applicable discounts are any discounts below the discounted ceiling price.”¹⁶

In reporting this data, hospitals must enter the average acquisition cost for each SCOD as identified by the Healthcare Common Procedure Coding System (HCPCS) code for the amount corresponding to a single billing unit of the corresponding HCPCS billing code. CMS explained that, “while a single billing unit of a HCPCS code is equivalent to the HCPCS code dosage, it is not equivalent to the dose received by the patient.”¹⁷ CMS also noted that, “to the extent the hospital purchased a drug with multiple NDCs that map to a single HCPCS code but the NDC pricing varies, the average acquisition cost submitted at the HCPCS level should reflect the volume weighted average acquisition cost.”¹⁸ CMS provided calculation examples in Appendix B.

CONCLUSION

Hospitals must submit completed surveys to their respective MACs by Friday, May 15, 2020. This includes Detailed Surveys, as well as the Quick Surveys. K&L Gates' Health Care and FDA practice regularly advise stakeholders on drug reimbursement matters, including 340B Program implementation and compliance, and can assist hospitals through the submission process. K&L Gates will be reporting on the outcome of the pending 340B appeal and the potential use of the survey data in the CY 2021 OPSS proposed rule now at OMB that is likely to be released in June.

FOOTNOTES

¹ See 84 Fed. Reg. 51,590 (Sept. 30, 2019).

² *Id.* at 51,591.

³ See 84 Fed. Reg. 61142, 61322-23 (Nov. 12, 2019).

⁴ See *Am. Hosp. Ass'n v. Azar*, 348 F. Supp. 3d 62 (D.D.C. 2018), appeal pending, Nos. 19–5048 & 19–5198 (D.C. Cir.).

⁵ *Id.* at 82-83.

⁶ See Office of Information and Regulatory Affairs, CY 2021 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates (CMS-1736-P).

⁷ See, e.g., 340B Health, Comments on CMS Proposed Collection of Information, Hospital Survey for Specified Covered Outpatient Drugs (CMS-10709) (Nov. 27, 2019).

⁸ See Office of Information and Regulatory Affairs, Hospital Survey for Specified Covered Outpatient Drugs (CMS-10709) (Date Received: 02/11/2020; Conclusion Date: 04/23/2020; Action: Approved with Change).

⁹ *Id.*

¹⁰ See CMS, [Hospital Survey for Specified Covered Outpatient Drugs](#), [hereinafter “Hospital Survey Instruction Sheet”].

¹¹ *Id.*

¹² *Id.*

¹³ See CMS, [Hospital Survey for Specified Covered Outpatient Drugs Worksheet](#).

¹⁴ See Hospital Survey Instruction Sheet.

¹⁵ *Id.*

¹⁶ *Id.*

¹⁷ *Id.*

¹⁸ *Id.*

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