340B UPDATE: CMS ISSUES UPDATED ACQUISITION COST DATA SURVEY

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U.S. Health Care Alert

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On 7 February 2020, the Centers for Medicare & Medicaid Services (CMS) issued a notice relating to the agency's intention to survey hospitals about their acquisition costs for specified covered outpatient drugs (SCODs) under the 340B Drug Pricing Program (340B Program).[1] The notice follows last year's announcement of the agency's proposed acquisition cost data survey. As part of the notice, CMS issued an updated proposed survey based on the public comments received. While CMS clarified and revised certain aspects of the survey, there are still ambiguities that could result in operational difficulties. Stakeholders have an opportunity to submit comments on the updated survey to the White House Office of Management and Budget (OMB) by 9 March 2020.[2]

BACKGROUND

340B Acquisition Cost Data Survey

As reported in our prior alert (here), CMS announced an opportunity last year for stakeholders to comment on the agency's intention to require hospitals that participated in the 340B Program in the last quarter of Calendar Year (CY) 2018 (1 October 2018, through 31 December 2018) and/or first quarter of 2019 (1 January 2019, through 31 March 2019) to supply acquisition cost data for each SCOD during that period.[3] According to CMS, the proposed survey seeks 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."[4] CMS noted that the data would be used to help determine payment amounts for 340B drugs.

American Hospital Association v. Azar

Additionally, as part of the Hospital Outpatient Prospective Payment System (OPPS) final rule for CY 2020, CMS acknowledged that it would also use the data collected 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*.[5] As discussed in greater detail in our prior 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 certain 340B drugs paid under the OPPS from Average Sales Price (ASP) plus 6 percent to ASP minus 22.5 percent.[6]

The U.S. District Court for the District of Columbia (District Court) held that the Secretary had exceeded his authority in adjusting the payment rates.[7] The District Court reasoned, in part, that the Secretary lacked the "necessary data" to support such payment rates.[8] The D.C. Circuit heard oral arguments last year. In the

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meantime, CMS is proposing to collect hospital acquisition cost data to devise a remedy in the event that the D.C. Circuit upholds the District Court's ruling.

UPDATED SURVEY

Comments on Acquisition Cost Data Survey

Hospital groups and other stakeholders objected to CMS' proposed survey, asking the agency to withdraw the survey or, at minimum, revise it and simplify the data collection process. Stakeholders emphasized the proposed survey's potential impact on safety net hospitals.[9] They described the challenges in sharing and determining the data requested as part of the survey, as well as the various ambiguities in the survey and the lack of clear and detailed instructions.[10]

Revisions to Acquisition Cost Data Survey

CMS revised the survey based on the public comments received. In response to comments highlighting the ambiguity of the scope of the survey and acquisition cost data requested, CMS stated that "the survey shall reflect the net acquisition cost for each SCOD acquired under the 340B program (*that is, the sub-ceiling price after all applicable discounts/rebates*)."[11] In addition, CMS clarified that the acquisition cost should be reported "*regardless of whether or not the drug was dispensed at all or whether the drug was dispensed in multiple settings and regardless of how it was purchased* (such as in a replenishment model under the 340B program)."12

CMS also requested that the average acquisition cost be reported 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."[13] In this regard, CMS noted that the amount of drug represented by a single billing unit can be found in the "HCPCS Dosage" column of the National Drug Code (NDC) - HCPCS Crosswalk files that the agency publishes on its website.[14] Given the number of NDCs associated with HCPCS codes, CMS made NDC reporting optional.[15]

Additionally, in response to comments highlighting the confidentiality obligations of hospitals, CMS reiterated its intent to maintain confidentiality of individual responses "to the extent provided by law."[16] The agency noted that it may make public average acquisition prices reported for each SCOD, but it would not make confidential prices available in a hospital-identifiable manner. Lastly, although the agency updated the survey response period to 23 March - 10 April (originally 17 February - 16 March), it still gives stakeholders little time to gather the requested information.[17]

CONCLUSION

CMS has acknowledged that the data collected may have a significant impact on 340B hospitals' payments. Despite the agency's revisions, the survey contains several areas of ambiguity that could result in operational difficulties for hospitals. Stakeholders have an opportunity to submit comments to OMB by 9 March 2020. K&L Gates' health care and FDA practice and public policy and law practice regularly advise stakeholders on drug reimbursement matters, including 340B Program implementation and compliance, and facilitate stakeholder engagement with Congress and the Administration, including through the development and submission of public comments.

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FOOTNOTES

[1] *See* 85 Fed. Reg. 7306 (7 Feb. 2020).

[2] *Id.*

[3] *See* 84 Fed. Reg. 51590 (30 Sept. 2019).

[4] *Id.* at 51591.

[5] *See* 84 Fed. Reg. 61142, 61322-23 (12 Nov. 2019).

[6] *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.).

[7] *Id.* at 82-83.

[8] *Id.*

[9] *See, e.g.,* American Hospital Association, CMS–10709, *Hospital Survey for Specified Covered Outpatient Drugs; Agency Information Collection Activities: Proposed Collection; Comment Request* (27 Nov. 2019).

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

[11] *See* CMS, *Instruction Sheet for Collecting Acquisition Costs* (last accessed 10 Feb. 2020).

[12] *Id.* at 1

[13] *Id.* at 4

[14] *Id.*

[15] *Id.* at 3.

[16] *Id.* at 1.

[17] *Id.*

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