340B UPDATE: CMS SEEKS COMMENTS ON ACQUISITION COST DATA SURVEY

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U.S. Health Care Alert

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On September 30, 2019, the Centers for Medicare & Medicaid Services ("CMS") announced an opportunity for stakeholders to comment on the agency's intention to survey hospitals about their acquisition costs for specified covered outpatient drugs under the 340B Drug Discount Program ("340B Program"). [1] Comments are due by November 29, 2019. K&L Gates' Health Care practice and Public Policy and Law practice regularly advise clients on issues related to drug reimbursement, including through the development and submission of public comments.

As part of the proposed survey, 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) would supply their average acquisition cost for each specified covered outpatient drug purchased during this time. [2] The agency notes that it could be the 340B ceiling price, a sub-ceiling price, or another amount depending on the discounts the hospital received. If the acquisition price for a drug is not available, CMS intends to use the ceiling price for that drug as a proxy for the hospitals' acquisition cost for each covered drug. [3] Completed surveys would need to be submitted to corresponding Medicare Administrative Contractors by March 16, 2020. [4]

By way of background, in the Outpatient Prospective Payment System ("OPPS") final rule for CY 2018, CMS finalized a proposal to adjust payment for separately payable outpatient drugs acquired by hospitals at discounted rates under the 340B Program from Average Sales Price ("ASP") plus 6 percent to ASP minus 22.5 percent. [5] As discussed in our prior alerts (please refer to our most recent alerts on this topic here and here), the American Hospital Association, the Association of American Medical Colleges, America's Essential Hospitals, and three hospital plaintiffs filed suit challenging the authority of the Secretary of the U.S. Department of Health and Human Services ("HHS") to make such adjustment to payment rates.

In Am. Hosp. Ass'n v. Azar, a district court ruled that the Secretary of HHS exceeded his authority to adjust payment rates under the OPPS for separately payable, 340B-acquired drugs under the existing statutory framework. [6] The district court reasoned, in part, that the Secretary had not collected the necessary data to set payment rates based on acquisition costs. [7] Specifically, the court noted that the Secretary has authority to set reimbursement rates at levels consistent with hospitals' acquisition costs, but highlighted that the Secretary is required to consider certain hospital acquisition cost survey data. [8] Thus, the district court noted that "the Secretary may either collect the data necessary to set payment rates based on acquisition costs, or he may raise his disagreement with Congress, but he may not end-run Congress's clear mandate." [9]

CMS has appealed the ruling. In the event that the ruling is affirmed, CMS is proposing to survey hospitals about their acquisition costs to help determine future OPPS payment amounts for drugs purchased through the 340B Program. According to CMS, the proposed survey seeks to ensure that "the Medicare program pays for specified

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covered outpatient drugs purchased under the 340B program at amounts that approximate what hospitals actually pay to acquire the drugs." [10]

K&L Gates' Health Care practice and Public Policy and Law practice regularly advise stakeholders on issues related to drug reimbursement, including 340B Program implementation and compliance matters, and facilitate stakeholder engagement with Congress and the administration, including through the development and submission of public comments.

NOTES:

[1] *See* 84 Fed. Reg. 51,590 (Sept. 30, 2019).
[2] *See* Hospital Survey for Specified Covered Outpatient Drugs, Supporting Statement A, CENTERS FOR MEDICARE & MEDICAID SERVICES (Sept. 26, 2019), https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.
[3] *Id.*
[4] *See* Hospital Survey for Specified Covered Outpatient Drugs, Centers for Medicare and Medicaid Services Average Sales Price Survey, CENTERS FOR MEDICARE & MEDICAID SERVICES (Sept. 26, 2019), https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.
[5] *See* 82 Fed. Reg. 52,356, 52,362 (Nov. 13, 2017).
[6] *See* Am. Hosp. 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.).
[7] *Id.* at 82
[8] *Id.*
[9] *Id.*
[10] *See* 84 Fed. Reg. 51,590, 51,591 (Sept. 30, 2019).

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