340B UPDATE: APPEALS COURT UPHOLDS 340B PAYMENT REDUCTION UNDER THE OPPS AS CMS PROPOSES FURTHER REDUCTIONS FOR CY 2021

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On 31 July 2020, the U.S. Court of Appeals for the District of Columbia Circuit (D.C. Circuit) upheld the U.S. Department of Health and Human Services' (HHS) decision to allow the Centers for Medicare and Medicaid Services (CMS) to implement a reduction of nearly 30 percent in reimbursement rates under the Medicare Outpatient Prospective Payment System (OPPS) for specified covered outpatient drugs (SCODs) for hospitals participating in the 340B Drug Pricing Program (340B Program). The decision reversed the decision of the U.S. District Court for the District of Columbia, which held the Secretary of HHS exceeded his authority in adjusting the rates. Building on the D.C. Circuit's decision, CMS has now issued the CY 2021 OPPS proposed rule, proposing for CY 2021 and subsequent years to pay for drugs acquired under the 340B Program at Average Sales Price (ASP) minus 34.7 percent, plus an add-on, for a net payment rate of ASP minus 28.7, or continue to pay ASP minus 22.5 percent.

The loss at the D.C. Circuit means that, pending a further appeal, hospitals' hopes for a retroactive remedy and/or a future change in the reimbursement cut are much less likely. As a result, this change in reimbursement for Medicare outpatient drugs purchased under the 340B Program will likely become a permanent fixture. While the 340B Program remains very much in a dynamic state at the moment, it is important to note that covered entities and now payors, such as Medicare, are reaping significant savings from the 340B Program and may be aligning on the importance of sustaining the program. This client alert provides an overview of the D.C. Circuit's decision and CY 2021 OPPS proposed rate and their potential impact on 340B hospitals.

BACKGROUND

CY 2018 OPPS Final Rule

As part of the CY 2018 OPPS final rule, HHS finalized a proposal to adjust reimbursement rates for SCODs from ASP plus 6 percent to ASP minus 22.5 percent.[1] Because the 340B Program allows hospitals to buy drugs at lower rates, there is a gap between what the hospitals pay for the drugs and what Medicare reimburses them for the drugs. While 340B hospitals generally use revenues derived from this gap to offer services to underserved populations, HHS sought to make “Medicare payment for separately payable drugs more aligned with the resources expended by hospitals to acquire such drugs” by lowering reimbursement.[2]

Because HHS did not have hospital acquisition cost data, HHS sought to “adjust the applicable payment rate as necessary” for SCODs to ASP minus 22.5 percent, stating that the adjustment was necessary because ASP minus 22.5 percent “better represents the average acquisition cost for [340B] drugs and biologicals.”[3] The rate

was based on an estimate by the Medicare Payment Advisory Committee that ASP minus 22.5 percent equaled the average minimum discount that a 340B participating hospital received when purchasing SCODs.

As discussed in our prior alerts (here and here), the American Hospital Association (AHA), the Association of American Medical Colleges (AAMC), America's Essential Hospitals (AEH), and three hospital plaintiffs brought suit challenging the authority of the Secretary of HHS to make such adjustment. They requested a permanent injunction, among other things, arguing that the reduction violates the Administrative Procedure Act and the Medicare statute because it is arbitrary and capricious, contrary to law, and in excess of the Secretary's authority.

District Court's Decision

In 2018, the U.S. District Court for the District of Columbia sided with the hospitals and granted them a permanent injunction.[4] The district court ruled that the Secretary had exceeded his authority to adjust the rates. The district court reasoned, in part, that the Secretary had not collected the necessary data to set payment rates based on acquisition costs.[5] Because the Secretary did not have that data, the district court noted that he must set reimbursement rates by reference to the drugs' average sales prices. The district court acknowledged that while the Secretary may make "adjustments," he cannot "fundamentally rework the statutory scheme."[6]

The district court noted that the Secretary was imposing a nearly 30 percent reduction impacting "not a single drug or even a handful of drugs, but rather potentially thousands of pharmaceutical products found in the 340B Program," adding that "the rate reduction's magnitude and its wide applicability inexorably lead to the conclusion that the Secretary fundamentally altered the statutory scheme established by Congress."[7] The district court noted that the Secretary may "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."[8]

D.C. CIRCUIT'S DECISION

On appeal, the D.C. Circuit reversed the district court's ruling, upholding HHS's payment reduction of nearly 30 percent for SCODs under the OPPS.[9] The D.C. Circuit found that the Secretary has broad discretion to adjust payment rates for SCODs, including an ability to adjust payment rates according to whether certain drugs are acquired at a significant discount. Specifically, the court found that, even in absence of acquisition cost data, the Medicare statute authorizes HHS to adjust average sales prices to bring payments into line with costs, noting that "HHS has long understood average price … to serve as a 'proxy for average acquisition cost'."[10]

While acknowledging the statutory requirement that the 340B drug average acquisition cost payment metric must take into account survey data, which HHS did not have, the D.C. Circuit highlighted that HHS had permissibly interpreted the statute to allow it to implement the payment reduction because it had relied on "data of undisputed reliability" and that "the agency acted on that data in a cautious way, adopting a conservative, lower-bound estimate of the 340B discount's size."[11] While noting that it would not consider "the wisdom of that decision as a policy matter," the DC Circuit found that HHS had "reasonably concluded that it need not continue subsidizing 340B providers."[12]

In reaching this conclusion, the D.C. Circuit rejected arguments that the payment reduction of almost 30 percent is "simply too large and sweeping to qualify as an adjustment."[13] In this regard, the court highlighted the ambiguity of the term, noting that, even if there are limits to what HHS could permissibly consider an adjustment, that line had not been crossed here, "where the agency acted on a conservative estimate drawn from data of undisputed

reliability."[14] Finally, the D.C. Circuit found that the statute does not preclude HHS from adjusting rates in a targeted manner to address problems with reimbursement rates applicable only to certain types of hospitals.[15]

In a statement, the AHA, AAMC, and AEH said that 340B hospitals and the millions of patients they serve will suffer lasting consequences from the DC Circuit's decision.[16] They emphasized that "hospitals that rely on the savings from the 340B drug pricing program are also on the front-lines of the COVID-19 pandemic," adding that "the [D.C. Circuit's] decision will result in the continued loss of resources at the worst possible time."[17] They said they would continue to call on HHS to reverse this policy to ensure hospitals can continue to provide needed services.[18]

CY 2021 OPPS PROPOSED RULE

Only a few days after the D.C. Circuit upheld HHS's payment reduction for SCODs under the OPPS, CMS issued the CY 2021 OPPS proposed rule, proposing for CY 2021 and subsequent years to pay for drugs acquired under the 340B Program at ASP minus 34.7 percent, plus an add-on of 6 percent of the product's ASP, for a net payment rate of ASP minus 28.7.[19] In the alternative, CMS proposed to continue to pay ASP minus 22.5 percent for 340B drugs.[20]

CMS noted that the proposed payment rate is based on the results of the Hospital Acquisition Cost Survey for 340B-Acquired Specified Covered Drugs.[21] As discussed in our prior alerts (here, here, and here), earlier this year, CMS surveyed 340B hospitals regarding their acquisition costs for SCODs.[22] CMS indicated that the acquisition cost data would help ensure Medicare pays at amounts that "approximate what hospitals actually pay to acquire the drugs."[23]

As part of the OPPS final rule for CY 2020, CMS indicated that it would use the acquisition cost data to devise a remedy if the D.C. Circuit upheld the district court's ruling.[24] CMS noted that it anticipated the data would confirm that the ASP minus 22.5 percent rate is "a conservative amount that overcompensates covered entity hospitals."[25] Based on the data, CMS estimated that the typical acquisition cost for 340B drugs for hospitals paid is ASP minus 34.7 percent.[26]

CMS, however, noted that only seven percent of surveyed hospitals provided acquisition cost data, with 55 percent responding that they preferred to have CMS utilize the 340B ceiling prices obtained from the HRSA as reflective of their acquisition costs and the remaining 38 percent not responding.[27] Based on the recent D.C. Circuit's decision, CMS proposed in the alternative to continue to pay ASP minus 22.5 percent for CY 2021 and subsequent years.[28]

CONCLUSION

In one month, the D.C. Circuit has now upheld two significant changes in Medicare hospital outpatient reimbursement that have and will continue to significantly negatively impact hospitals. As discussed in our alert here, the D.C. Circuit also recently upheld HHS' decision to implement a service-specific, non-budget-neutral reimbursement cut for clinic visits under the OPPS. As providers continue to respond to COVID-19, these changes - now in effect for several years - appear to be on a path to being made permanent with a closing window on any opportunity to challenge the cuts through litigation. These decisions may further embolden the current administration, and future administrations, to make decisions about payment that do not fit within the carefully crafted payment model that Congress envisioned, but may serve more expedient policy objectives. K&L

Gates will continue to monitor future developments. K&L Gates' health care and FDA practice regularly advise stakeholders on 340B Program and Medicare reimbursement matters and is available to provide guidance to stakeholders in this regard.

FOOTNOTES

[1] 82 Fed. Reg. 52,356, 52,362 (Nov. 13, 2017).

[2] 82 Fed. Reg. 33,558, 33,633 (Jul. 20, 2017).

[3] 82 Fed. Reg. at 33,634.

[4] Am. Hosp. Ass'n v. Azar, 348 F. Supp. 3d 62 (D.D.C. 2018).

[5] *Id.* at 82.

[6] *Id.*

[7] *Id.*

[8] *Id.*

[9] Am. Hosp. Ass'n v. Azar, No. 19-5048 (D.C. Cir. July 31, 2020).

[10] *Id.* at 21.

[11] *Id.* at 28.

[12] *Id.*

[13] *Id.*

[14] *Id.*

[15] *Id.*

[16] *See* Press Release, Am. Hosp. Ass'n, Appeals court upholds payment cut for 340B hospitals (July 31, 2020).

[17] *Id.*

[18] *Id.*

[19] Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; New Categories for Hospital Outpatient Department Prior Authorization Process; Clinical Laboratory Fee Schedule: Laboratory Date of Service Policy; Overall Hospital Quality Star Rating Methodology; and Physician-owned Hospitals [CY 2021 OPPS Proposed Rule]. The OPPS Proposed Rule is scheduled to be published in the Federal Register on 12 August 2020.

[20] *Id.* at 323.

[21] *Id.* at 296.

[22] *See* CMS, Hospital Survey for Specified Covered Outpatient Drugs.

[23] *See* 84 Fed. Reg. 51590, 51591 (Sept. 30, 2019).

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

[25] CY 2021 OPPS Proposed Rule at 301.

[26] *Id.* at 310.

[27] *Id.* at 307-308.

[28] *Id.* at 323.

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