

August 5, 2020

D.C. Circuit Upholds Prior Medicare Cuts to 340B Hospitals' Drug Payments and CMS Furthers the Cuts

On July 31, 2020, the D.C. Circuit Court of Appeals overturned a 2018 D.C. district court decision and found that the U.S. Department of Health and Human Services (“HHS”) acted within its statutory authority in reducing Medicare Part B reimbursement rates by 28.5% for certain outpatient drugs to hospitals that participate in the federal 340B Drug Pricing Program. In short, this decision leaves intact, for now, HHS’s cuts to reimbursement rates made in 2018 for drugs purchased by hospitals under the 340B Drug Pricing Program. On August 4, 2020, HHS also proposed for calendar year 2021 even steeper cuts in reimbursement for hospital-purchased outpatient 340B drugs. This alert details the D.C. Circuit’s decision and its effect on Medicare covered drug reimbursement going forward, including the newly proposed reimbursement rates for 2021.

Background. The 340B Drug Pricing Program is a federal program in which pharmaceutical manufacturers provide certain outpatient drugs to eligible health care organizations—including hospitals serving a disproportionate share of low-income patients—at discounted prices.¹ The issue before the Court was whether HHS had the statutory authority to “adjust” downward Medicare reimbursement by 28.5% for drugs purchased by hospitals participating in the federal 340B Drug Pricing Program (“340B Hospitals”).

Medicare reimburses hospital purchased outpatient drugs under Medicare Part B through the Outpatient Perspective Payment System (“OPPS”) under 42 U.S.C. § 1395l(t). Certain drugs covered by Medicare Part B are known as “specified covered outpatient drugs” or “SCODs.” The OPPS sets out a specific methodology for determining payment rates for these drugs, which allows HHS to determine the reimbursement rates for SCODs in one of two ways: it may use “the average acquisition cost for the drug” obtained from hospital survey data; or, if such survey data is not available, then “the average price for the drug” may be calculated and adjusted by HHS.² Since 2006, HHS had not obtained hospital acquisition cost survey data and had used the average price of the drug to set the payment rates for SCODs. The average price of SCODs has ranged from 104% to 106% of the SCODs average sale price (“ASP”) and, prior to 2018, all hospitals, other than Critical Access Hospitals, had been paid the same rate for SCODs.³

Effective January 1, 2018, however, HHS invoked its purported authority to adjust the average price metric and reduced the SCOD reimbursement rate for 340B Hospitals from 106% ASP to ASP minus 22.5%.⁴ HHS’s stated reason for this change was to reduce the “profit” 340B Hospitals obtained through acquiring the drugs through the 340B Drug Pricing Program at a reduced price.⁵ CMS made the adjustment in a budget-neutral manner, with the anticipated savings from the 340B Hospital payment reductions redistributed to all hospitals through increased OPPS payments.⁶

Several hospitals and hospital associations (the “Hospitals”) opposed this cut, claiming, among other things, that if HHS based the reimbursement cuts off “the average acquisition cost for the drug” as opposed to “the average price for the drug,” then HHS must take into account hospital survey data, as required under 42 U.S.C. § 1395l(t)(14)(A)(iii)(I).⁷ The

¹ HRSA, *340B Drug Pricing Program*, available at: <https://www.hrsa.gov/opa/index.html>.

² 42 U.S.C. § 1395l(t)(14)(A)(iii).

³ *Am. Hosp. Ass'n v. Azar*, No. 19-5048, 2020 WL 4378021, at 5 (D.C. Cir. July 31, 2020); see also 82 Fed. Reg. 52,356, 52,494 (Nov. 13, 2017), available at: <https://www.govinfo.gov/content/pkg/FR-2017-11-13/pdf/2017-23932.pdf>.

⁴ *Am. Hosp. Ass'n v. Azar*, No. 19-5048, 2020 WL 4378021, at 6 (D.C. Cir. July 31, 2020).

⁵ 82 Fed. Reg. 52,494.

⁶ *Am. Hosp. Ass'n v. Azar*, No. 19-5048, 2020 WL 4378021, at 7 (D.C. Cir. July 31, 2020).

⁷ *Am. Hosp. Ass'n v. Azar*, No. 19-5048, 2020 WL 4378021, at 23 (D.C. Cir. July 31, 2020).

Hospitals also argued that such significant reimbursement cuts would severely affect their ability to provide critical healthcare services to their communities, including the low-income and underserved patients they treat.⁸

The Hospitals challenged the rate reduction in court. On December 27, 2018, the district court held that HHS exceeded its authority in implementing the SCODs rate cut for 340B Hospitals. However, stating it may be difficult for HHS to retroactively adjust the SCODs payments to 340B Hospitals due to HHS's distribution of the anticipated savings through increased OPPS payments, the district court remanded the matter to HHS to determine an appropriate remedy.⁹ Following further administrative proceedings, the district court ruled for the Hospitals, and HHS appealed.

D.C. Circuit's Reversal and Implications. On July 31, 2020, a split panel of the D.C. Circuit Court of Appeals overturned the district court decision, ruling that HHS acted within its statutory authority under 42 U.S.C. § 1395l(t)(14)(A)(iii)(II) in reducing the Medicare SCODs reimbursement for hospitals that purchased drugs at 340B prices. After first agreeing with the district court that paragraph 1395l(t)(12) of the OPPS statute does not preclude judicial review of the SCODs rate adjustment,¹⁰ the Court of Appeals applied *Chevron* deference to conclude that the plain language did not preclude the agency's interpretation, which it upheld as a reasonable interpretation of the statute.¹¹ The Court explained that under the statute, "Congress's primary goal is to reimburse providers for their acquisition costs," and that when hospital acquisition cost survey data is unavailable, "Congress signaled that average price functions as a stand-in for costs."¹² The dissenting judge disagreed, reasoning that the relevant statute precluded HHS's interpretation, and that additional hospital survey data was necessary to initiate the rate adjustments.¹³

Meanwhile, not only had the SCODs rate reduction gone into effect as of January 1, 2018 for drugs furnished to patients in 340B Hospital outpatient departments paid under the OPPS, but also, effective January 1, 2019, HHS extended the rate cut to drugs acquired under the 340B Drug Pricing Program and furnished in off-campus provider-based departments paid under the physician fee schedule.¹⁴ And despite the lower court's decision in December 2018, with final judgment entered in July 2019, HHS continued to include the SCODs reimbursement cuts for 340B Hospitals in the 2020 OPPS rates published in 2019.¹⁵ In the same 2019 OPPS rule, the agency also announced its intention to collect 2018 and 2019 SCODs acquisition cost data from 340B Hospitals, which the agency said could be used to determine future SCODs reimbursement rates under 42 U.S.C. § 1395l(t)(14)(A)(iii)(I).¹⁶

On August 4, 2020, HHS released its proposed OPPS reimbursement rates for CY 2021, which included even steeper cuts to SCODs reimbursement rates for 340B Hospitals (ASP minus 28.7%) than previously used in CY 2018-2020 (ASP minus 22.5%).¹⁷ HHS justified these proposed additional cuts by citing the 2018 and 2019 SCODs acquisition cost data collected earlier in the year from 340B Hospitals.¹⁸ HHS also proposed, in the alternative, to maintain the SCODs reimbursement rate for 340B Hospitals at ASP minus 22.5%, noting that the process for determining the rate was recently upheld by the D.C. Circuit, and that HHS continues to believe it is an appropriate payment rate.¹⁹ The 2021

⁸ Am. Hosp. Ass'n v. Azar, 348 F. Supp. 3d 62, 71 (D.D.C. 2018), rev'd, No. 19-5048, 2020 WL 4378021 (D.C. Cir. July 31, 2020).

⁹ Am. Hosp. Ass'n v. Azar, 385 F. Supp. 3d 1, 15 (D.D.C. 2019), judgment entered, No. CV 18-2084 (RC), 2019 WL 3037306 (D.D.C. July 10, 2019), rev'd, No. 19-5048, 2020 WL 4378021 (D.C. Cir. July 31, 2020).

¹⁰ Am. Hosp. Ass'n v. Azar, No. 19-5048, 2020 WL 4378021, at 9 (D.C. Cir. July 31, 2020).

¹¹ *Id.* at 19.

¹² *Id.* at 21.

¹³ *Id.* at 31.

¹⁴ 83 Fed. Reg. 58,818, 59,022 (Nov. 21, 2018), available at: <https://www.govinfo.gov/content/pkg/FR-2018-11-21/pdf/2018-24243.pdf>.

¹⁵ Fed. Reg. 61,142, 61,321 (Nov. 12, 2019), available at: <https://www.govinfo.gov/content/pkg/FR-2019-11-12/pdf/2019-24138.pdf>.

¹⁶ *Id.* at 61,322.

¹⁷ FR Document: 2020-17086, at 322, available at: <https://s3.amazonaws.com/public-inspection.federalregister.gov/2020-17086.pdf>

¹⁸ *Id.* at 300.

¹⁹ *Id.* at 322.

proposal does not address the effect on SCODs reimbursement rates for 340B drugs furnished in off-campus provider-based departments paid under the Medicare physician fee schedule rather than the OPFS. In any event, it appears that SCODs reimbursement cuts for 340B Hospitals, both on- and off-campus, could be here to stay unless challenged further for later years.