HOSPITALS ASK SUPREME COURT TO REVERSE SITE-NEUTRAL, 340B PAYMENT RULINGS

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Health Care Alert

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How far can an agency go to allow agency-developed policy objectives to supersede concerns about faithful adherence to the law? Similarly, how much should health systems and others regulated by Medicare be concerned about continued lack of reimbursement system predictability? The Supreme Court will decide, likely before the end of its term in June, whether to take action in two key cases that could give everyone some answers.

The American Hospital Association (AHA), other provider groups, and several hospitals filed petitions asking the Supreme Court to reverse two separate decisions of the U.S. Court of Appeals for the District of Columbia Circuit (D.C. Circuit) upholding significant Medicare reimbursement changes from the Centers for Medicare and Medicaid Services (CMS). The first CMS change imposed a reimbursement cut to a subset of hospital outpatient clinics for clinic evaluation and management services under the Outpatient Prospective Payment System (OPPS). The second CMS change involved a nearly 30 percent cut to drug payments under the OPPS for certain hospitals participating in the 340B Drug Pricing Program (340B Program). In both cases, CMS believes it has found what are essentially “loopholes” in the payment statutes that allow the agency to create its own payment reductions; if not for these supposed loopholes, these reductions would violate the statute.

The hospital community brought court challenges to CMS' asserted authority to impose these changes, winning both cases in the district court. However, the D.C. Circuit reversed both on appeal, reasoning in part that the agency's statutory interpretations were not “unambiguously foreclosed,” and thus could be upheld as an allowable construction of the statute. The hospital community questions whether the D.C. Circuit gave too much deference to the agency in determining statutory ambiguity, in essence, allowing the agency to rewrite the statute. Given that the predictability of the Medicare payment system hangs in the balance, the AHA appealed to the Supreme Court in both cases. The Supreme Court is not required to take up the matter, but if it does intervene, hospitals will get final judicial answers to these questions.

HOW FAR IS TOO FAR WHEN INTERPRETING A STATUTE?

The starting point for an analysis of whether an agency has properly interpreted a statute is the *Chevron*[1] case, under which the first step is always to decide whether “Congress has directly spoken to the precise question at issue.” If so, the court, like the agency, “must give effect to the unambiguously expressed intent of Congress.” Deciding how to interpret a statute requires using all of the “traditional tools” of statutory construction, thus honoring our constitutional system of the governmental branches respecting each other's authority, including the “emphatic” duty of the judicial branch to “say what the law is.” In the two cases at issue, the Supreme Court may decide that the D.C. Circuit did not actually apply all of these “traditional tools” and thus gave too much authority

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to the agency to establish the law. If so, it would send the cases back to the D.C. Circuit to determine properly how Congress intended for hospitals to get paid.

SITE-NEUTRAL PAYMENT REDUCTION

Overview

In response to an increase in the quantity of outpatient services at hospital off-campus provider-based departments (PBDs), Congress enacted Section 603 of the Bipartisan Budget Act of 2015, directing the Department of Health and Human Services (HHS) to reduce payment rates for services furnished at newly created or acquired PBDs while continuing to pay existing PBDs at the higher OPPS rates.[2]

Despite the statutory distinction in payment rates for new and current PBDs, CMS proposed to reduce rates for *all* PBDs by purporting to exercise its authority under subparagraph (2)(F) of the OPPS statute, which allows the agency to "develop a method for controlling unnecessary increases in the volume of covered [outpatient] services."[3] CMS proposed to cut reimbursement rates for evaluation and management services to all off-campus PBDs to the amount CMS pays to freestanding physician offices.[4] Although the OPPS statute generally requires annual rate adjustments to be budget-neutral, CMS indicated that it did not believe that requirement applied to methods for controlling volume under subparagraph (2)(F).

D.C. Circuit Decision and Next Steps

As discussed in our alert here, the D.C. Circuit reversed the district court's holding that HHS exceeded its statutory authority when it reduced these payments. The D.C. Circuit concluded that CMS may reduce OPPS reimbursement for a specific service, and it may implement that cut in a non-budget-neutral manner, because Congress did not "unambiguously forbid" the agency from using its authority to develop a "method" for controlling volume increases to do so.[5] The D.C. Circuit reasoned, in part, that subparagraph (2)(F) "simply says nothing about budget-neutrality" and that "[t]he text Congress enacted thus lends considerable support to the agency's reading of the statute."[6]

AHA's certiorari petition to the Supreme Court argues that the D.C. Circuit's decision violates the constitutional separation of powers, misapplies *Chevron*, and departs from proper principles of statutory interpretation.[7] Specifically, the AHA argues that by applying *Chevron* deference to CMS' interpretation of the statute, the D.C. Circuit effectively permitted the agency to set the boundary of judicial power in violation of separation of powers.[8] The AHA further argues that *Chevron* deference is not appropriate here because Congress did not delegate to the agency "the power to determine the scope of the judicial power vested by" the Medicare statute or "to determine conclusively when its dictates are satisfied."[9]

The AHA emphasizes that the question of whether to defer to an agency's interpretation of a statutory provision that determines the court's jurisdiction has great legal significance and practical impact, adding that the D.C. Circuit's decision will force many PBDs to "reduce their services or close completely" and that it could embolden CMS to make even more drastic cuts to Medicare reimbursement in the future.[10]

There is no reason to assume, in fact, that CMS will not attempt to use this same authority pertaining to applying a "method" to control volume increases to reduce payment for whichever services may be disfavored. CMS has in fact already used this authority to create a prior authorization process for targeted services.

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340B PAYMENT REDUCTION

Overview

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 determines how much Medicare will pay hospitals for specified covered outpatient drugs (SCODs). Under what is commonly referred to as "subclause (I)," reimbursement rates are determined based on each drug's average acquisition cost.[11] Under subclause (II), reimbursement rates are determined according to a statutorily defined default rate based on each drug's average sales price (ASP), namely ASP+6 percent.[12] Notably, CMS may only determine rates based on average acquisition cost if it has hospital acquisition cost survey data.[13]

As part of the calendar year 2018 OPPS final rule, CMS finalized a proposal to adjust reimbursement rates for SCODs from ASP+6 percent to ASP-22.5 percent in an effort to make "payment for separately payable drugs more aligned with the resources expended by hospitals to acquire such drugs."[14] Because CMS did not have hospital acquisition cost data, the agency adjusted the rate to ASP-22.5 percent, reasoning that the adjustment was necessary because ASP-22.5 percent "better represents the average acquisition cost for [340B] drugs and biologicals."[15]

D.C. Circuit Decision and Next Steps

As described in our alert here, the D.C. Circuit reversed the district court's finding that CMS exceeded its statutory authority when it reduced these payments. The lower court had reasoned, in part, that the secretary had not collected the necessary data to set payment rates based on acquisition costs, adding 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' clear mandate."[16]

The D.C. Circuit upheld CMS' payment reduction of nearly 30 percent for SCODs, finding 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. While acknowledging the statutory requirement that the 340B drug average acquisition cost payment metric must take into account survey data, the D.C. Circuit considered CMS to have permissibly interpreted the statute to allow it to implement the payment reduction because it had relied on "data of undisputed reliability."[17]

As with the site-neutral payment reduction, the AHA argues to the Supreme Court that the D.C. Circuit misapplied *Chevron* deference, permitting the agency to set the boundary of judicial power in violation of separation of powers.[18] The AHA notes that problem is particularly acute here, given the breadth of agency authority to "adjust" statutory requirements in the U.S. Code. The AHA argues that "under the decision below, those provisions are a license for agencies to achieve almost any policy end they desire, rather than an appropriately limited grant of residual discretion."[19]

The AHA again argues that the case presents a question of enormous importance for the Medicare program generally and the 340B Program in particular. It states that the case will determine "whether HHS has the vast power to set reimbursement rates however it sees fit (subject only to arbitrary-and-capricious review), or whether HHS is instead restrained by the statutory scheme that Congress designed."[20]

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CONCLUSION

The D.C. Circuit's decisions regarding the site-neutral and 340B payment reductions have—and will continue to have—a significant negative impact on hospitals. Unless the Supreme Court intervenes, hospitals will have exhausted their opportunities to challenge these cuts through litigation. Congress could potentially foreclose these types of adjustments by CMS in the future legislatively. However, absent Supreme Court or Congressional intervention, these decisions may embolden current and future administrations to further policy objectives through payment changes in a manner that may be at odds with the fundamental methodologies on which reimbursement statutes are based.

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] Chevron U.S.A., Inc. v. Nat. Res. Def. Council, Inc., 467 U.S. 837 (1984).

[2] Bipartisan Budget Act of 2015, Pub. L. No. 114-74, 129 Stat. 584, 597–98 (codified at 42 U.S.C. § 1395l(t)(21)).

[3] 42 U.S.C. § 1395l(t)(2)(F).

[4] 83 Fed. Reg. 37,046, 37,142 (July 31, 2018).

[5] Am. Hosp. Ass'n v. Azar, 410 F. Supp. 3d 142, 157–58 (D.D.C. 2019), *rev'd*, No.19-5352 (D.C. Cir. July 17, 2020).

[6] *Id*.

[7] *See* Petition for Writ of Certiorari, Am. Hosp. Ass'n v. HHS, at 20, here.

[8] *Id.*

[9] *Id*. at 22.

[10] *Id*. at 25.

[11] 42 U.S.C. 1395l(t)(14)(A)(iii)(I).

[12] 42 U.S.C. 1395l(t)(14)(A)(iii)(II).

[13] 42 U.S.C. 1395l(t)(14)(A)(iii)(I).

[14] 82 Fed. Reg. 52,356, 52,362 (Nov. 13, 2017); 82 Fed. Reg. 33,558, 33,634 (July 20, 2017).

[15] 82 Fed. Reg. 33,634.

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

[17] Am. Hosp. Ass'n v. Azar, 967 F.3d 818 (D.C. Cir. 2020).

[18] *See* Petition for Writ of Certiorari, Am. Hosp. Ass'n v. HHS, at 26, here.

[19] *Id*. at 27.

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[20] *Id*. at 28.

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