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The Medicare Final Rule Regarding 340B Underpayment

Andrew Ruskin (K&L Gates LLP)

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After years of uncertainty and seemingly endless litigation, there is finally an end to one chapter of the dispute surrounding Medicare underpayments for 340B drugs, but possibly the beginning of another one, or even two. The 340B Program allows certain safety net hospitals (referred to as "covered entities") to purchase drugs from pharmaceutical manufacturers at a significant discount. In 2018, the Centers for Medicare & Medicaid Services (CMS) implemented a policy (published in 2017) that reduced payment for 340B drugs when used in the hospital outpatient department (HOD). CMS relied on statutory authorities for this policy that were highly suspect, which led the American Hospital Association (AHA) and others to challenge the policy in court. After several levels of appeal, the Supreme Court finally issued a decision in this case in June 2022. The Court unanimously held that CMS had acted *ultra vires* in promulgating its 340B policy and remanded for further action on a remedy. Seventeen months and two more court decisions later, CMS has finally agreed to make covered entities whole with a lump sum adjustment, but there is a catch. CMS had initially reallocated the drug payment cut savings to other HOD items and services, and now, claiming it is bound by budget neutrality requirements, it plans to take back these reallocated funds. That will depress HOD funding to ***all*** providers, extending out for 16 years, to the tune of **$7.8 billion**. Somewhat tangentially, CMS has also disavowed any role in connection with covered entity disputes with their Medicare Advantage (MA) plans, where covered entities are struggling to obtain "make whole" payments from them as well. In light of CMS' actions (or inactions) and as discussed below, CMS' approach means there are still to-do items on in-house counsels' checklists.

History

The genesis of this multi-pronged dispute was a CMS rulemaking from 2017. Historically, the majority of drugs that are separately payable under the outpatient prospective payment system (OPPS) are paid at a rate that is based on the manufacturer's average sales price (ASP).[1] Under OPPS, for a number of years, Medicare has paid HODs at ASP +6% for these drugs.[2] In 2017, however, without any change in the governing statute, CMS decided that drugs purchased under the 340B Program should be paid at a lower rate, on the presumption that they cost less to purchase.[3] As a result, CMS revised its payment policy for 340B drug payments, such that they began to be paid at ASP -22.5% as of January 2018.[4] Initially, CMS' policy applied only to HODs that were paid at the full OPPS rate, meaning that they had "grandfathered" status under certain payment laws.[5] However, in 2019, CMS expanded the law to apply even to those paid at a reduced rate, *i.e.*, "non-grandfathered" sites.[6] Importantly, in setting the reduced payment rate, CMS relied on informal data it had received from advisory bodies, such as MedPAC, rather than having performed any surveys of its own.[7]

This payment cut had several ripple effects. One such impact related to the payment rates associated with other HOD items and services. CMS explained in its rulemaking that it believed it necessary to effectuate these payment cuts on a budget neutral basis. Accordingly, CMS simultaneously increased funding for non-drug items and services, effectively transferring Medicare funding away from 340B safety net hospitals to other providers.[8] Moreover, MA plans took the opportunity as well to reduce their payments to providers for 340B drugs used in the

HOD, often without a clear right in their provider contracts to do so. The dual impact of payment reductions from fee for service and Medicare managed care meant that losses began to mount quickly for a number of 340B covered entities.

CMS' payment cuts were controversial from the start. Various trade associations, including AHA, were quick to try to reverse the policy through litigation. AHA achieved an early victory in the District Court for the District of Columbia. The court in that case held that CMS did not have the authority to implement the disputed payment cuts.[9] However, instead of issuing a remedy, the court in a follow-on opinion remanded to the agency to take the "first crack at crafting appropriate remedial measures."[10]

Instead of attempting to create a remedy, the agency appealed the decision to the D.C. Circuit. That court held that the governing statute did not "directly foreclose" CMS' policy, finding that the agency had the authority under the statute to make certain payment "adjustments."[11] The agency therefore left its policy in place.

The AHA plaintiffs then appealed the matter to the Supreme Court. In a unanimous decision, the Court held that the statute expressly requires that CMS conduct a valid survey as a predicate to any payment changes for HOD drugs.[12] Therefore, it would "make no sense" for the statute to also allow CMS to make payment reductions through "adjustments," thereby circumventing the survey requirement altogether.[13] The Court thus reaffirmed the District Court's decision that CMS had acted *ultra vires* (and overturned the Circuit Court decision).[14] Yet, like the District Court, the Supreme Court as well refrained from imposing a specific remedy on the agency, and it also nodded to the fact that CMS had raised budget neutrality concerns.[15] The Supreme Court thus remanded the case to the lower courts for further proceedings.

On remand, the District Court issued two decisions, one relating to the prospective period, and one relating to the retrospective period. The first decision that the District Court ordered on remand related to the *prospective* period, *i.e.*, the portion of 2022 still remaining. As to that period, the court held that, no matter what CMS' concerns are with respect to budget neutrality, nothing can excuse continued noncompliance with the statute.[16] CMS shortly thereafter began paying for 340B drugs at ASP + 6%. As to the prior period, however, the court, in a separate decision, was not nearly as inflexible as to CMS' options. Rather, the court, again nodding to CMS' claims of a need to apply a budget neutrality factor (but without endorsing them), stated that the agency was entitled to fashion its own remedy in the first instance.[17] CMS was therefore given liberty to promulgate its proposed remedy through rulemaking.

Final Rule

After a proposed rule was published in July 2023, the final rule came out on November 2 in the display copy and published in the *Federal Register* on November 8.[18] In large part, the final rule tracked the policy proposals in the proposed rule. The primary objective of the rule is to rectify the underpayments on 340B drugs, which is to be accomplished through a lump sum payment process that is to occur likely in the first quarter of 2024.[19] CMS has published the amounts going to each covered entity, which appear in an Addendum AAA accessible on CMS' website.[20] Though it is unclear if there are appeal rights in court, CMS will entertain limited disputes with its calculations if a covered entity notifies it at outpatientpps340b@cms.hhs.gov, by November 30, 2023.[21] CMS' data appears to be largely accurate, as there have not been widespread reports of any systemic inaccuracies.

The more controversial aspect of CMS' rule relates to a purported "budget neutrality" adjustment. CMS contends that it has "overpaid" providers (all of them, not just covered entities) for their non-drug items and services over the past four years.[22] Accordingly, it's going to claw back those amounts gradually, with an 0.5% reduction in payments per year, spanning up to 16 years, depending on how long it takes for CMS to decide it has been "made whole."[23] That amount will total approximately $7.8 billion.[24] When first published in the proposed rule, this policy evoked much criticism from the health care industry.

CMS readily acknowledges that there is no precedent for this measure.[25] However, it nevertheless contends that it has the statutory authority to move forward with this policy. CMS cites two statutory provisions in particular as support for its actions, specifically Sections 1395*l*(t)(2)(E) and 1395*l*(t)(14)(H) of title 42 of the U.S. Code.[26] However, the author of this article has described at length in a comment letter submitted in connection with the proposed rule that those provisions are inapposite for the purposes CMS is using them for now.[27] CMS also seeks to invoke several other authorities to support its actions, including the ability to engage in retroactive rulemaking in extraordinary circumstances, as well as a general right to recoupment.[28] While CMS' legal right to impose this payment cut is questionable, it is nevertheless clear that CMS is determined to implement it, absent litigation or an act of Congress.

Finally, almost as an aside, CMS also acknowledged that it was not interfering in the relationships that covered entities have with their MA plans.[29] In other words, a covered entity with substantial revenues associated with Medicare managed care (which is the majority of covered entities) needs to decide how they want to approach their plans to discuss. In the author's experience, the MA plans are taking a wide variety of approaches to covered entity inquiries. Some are amenable to an amicable resolution of 340B underpayments, while others have equivocated or even expressly stated that their payments are not being revised (at least not without arbitration). The time limitations for bringing an action vary from contract to contract, and from state to state. Counsel within covered entities who intend to recapture these lost revenues may deem it prudent to look at their contracts at this juncture.

Does CMS Have the Authority to Apply the Budget Neutrality Adjustment

Given the controversy surrounding CMS' clawback of funds, questions arise as to whether CMS' action is lawful, and if not, is there anything that can be done about it? For the reasons stated below, the answer to the first question is no, and the answer to the second is yes, but perhaps not immediately.

As stated above, CMS heavily relies on two provisions of the OPPS statute for its imposition of a so-called "budget neutrality adjustment." CMS refers to the first of these as its "equitable adjustment authority," namely Section 1833(t)(2)(E) of the Social Security Act. That section states that "the Secretary shall establish, in a budget neutral manner, outlier adjustments . . . and transitional pass–through payments . . . and other adjustments as determined to be necessary to ensure equitable payments, such as adjustments for certain classes of hospitals." As the author pointed out in his comment letter, however, the text's plain meaning is to allow CMS to create new types of payment mechanisms, so long as they are implemented in a budget neutral fashion. It is not to correct the wrongdoings of unlawful agency action. In response, CMS acknowledged the author's comment, but focused on the word "equitable" in that provision, without context, and crafted its own meaning for that word so that it could serve as the linchpin for its actions here.[30]

The second authority CMS has called on for its policy relates to changes that CMS can make to its drug payment policies, but only under certain conditions, not applicable here. Specifically, CMS is allowed by statute to revise its drug payment provisions after performing certain surveys of drug acquisition costs, where such surveys meet the statutory requirements.[31] CMS is also allowed under certain circumstances to make payment adjustments to reflect a more accurate assessment of overhead costs.[32] If either of these adjustments resulted in an overall payment increase, then there is a budget neutrality provision in Section 1833(t)(9)(B) of the Act that would be triggered. Neither of those provisions are applicable, however, to paying for drugs at ASP + 6%, which is the default rate under the statute. Thus, the budget neutrality provision is not triggered either. Here again, CMS acknowledged the comment, but did not counter with a different reading of the statute.

As shown by the *AHA* case at the Supreme Court, CMS will be held to task for applying the statute in accordance with its plain meaning. It will not be given deference, simply because it has a "unique situation" to address, as it

refers to this matter in the final rule.[33] CMS' silence in terms of offering a different plain meaning acts as a tacit admission that in fact it *is not* showing fidelity to the actual purpose of the statute, rendering its impending payment cuts unlawful.

CMS' arguments regarding its ability to engage in retrospective rulemaking are also discordant with existing law. In particular, CMS routinely relies on a regulation that states as follows:[34]

> A change of legal interpretation or policy by CMS in a regulation, CMS ruling, or other interpretive rules, general statements of policy, and rules of agency organization, procedure, or practice established by CMS, whether made in response to judicial precedent or otherwise, is not a basis for reopening a CMS or contractor determination, a contractor hearing decision, a CMS reviewing official decision, a Board decision, or an Administrator decision, under this section.

CMS uses this provision as a shield against reopening claims and cost reports after it loses in court. However, here it is disregarding this provision (indeed, it is not discussed at all in the final rule). CMS instead gives tremendous weight to a case where a court stated that CMS can, in some cases, apply a remedy prospectively, instead of making retrospective adjustments.[35] However, the authority to make a prospective adjustment for underpayments or overpayments from prior periods can *only* apply if those prior periods are still subject to reopening and recalculation. In other words, CMS needs *authority* to make an adjustment before it can decide *how* that adjustment will be made.

Finally, CMS' purported common law right to recoupment also reflects an attempt by the agency to grasp at any concept that it can to bolster its policy that is so highly susceptible to challenge. CMS itself quotes a case supposedly supporting this right, and noting that it applies to "monies wrongfully paid."[36] Yet nowhere does CMS claim that providers who received these funds did anything wrongful. They filed accurate claims and got paid accurately. CMS would face significant difficulty convincing a court that those other cases support it here.

In short, CMS did not hold up clearly relevant provisions and/or legal concepts to support its actions. They are therefore susceptible to successful challenge. The timing of such challenge is somewhat of a question. The policy may be final 60 days after publication, but there is case law that supports that claims must be paid incorrectly before agency action is ripe for review. That will not occur until 2026. In the meantime, in-house counsel should support and encourage their trade associations to prepare for action, so as to avoid the loss of $7.8 billion spanning into the foreseeable future.

Next Steps for In-House Counsel

Although the provider community rightfully should celebrate that CMS has finally acquiesced in the view that providers have held all along, *i.e.*, its 340B underpayments were unlawful, that is unfortunately not the end of the story. In-house counsel should educate others in their organization regarding the vulnerability of CMS' purported budget neutrality adjustments, and then work with their trade associations to prepare for litigation. Indeed, some larger organizations may even want to file protective suits on their own, after determining what administrative formalities should precede such a suit. Additionally, in-house counsel in many organizations may be expected to lead efforts at determining their rights under their MA plan contracts, and determine how to secure compensation consistent with the terms of those contracts.

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[1] 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II) (cross-referencing the ASP concept found within 42 U.S.C. § 1395w-3a(b)(1)(A)-(B).

[2] *See*, *e.g.*, 77 Fed. Reg. 68210, 68387 (Nov. 15, 2012) (CMS' adoption of a reimbursement rate of ASP plus 6% for covered drugs in light of the "continuing uncertainty about the full cost of pharmacy overhead and acquisition cost" and the concern that deviating from the default rate "may not appropriately account for average acquisition and pharmacy overhead cost ....").
[3] 82 Fed. Reg. 33558, 33633 (Jul. 20, 2017).
[4] 82 Fed. Reg. 59216, 59369 (Dec. 14, 2017).
[5] *Id*. at 59367.
[6] 83 Fed. Reg. 58818, 59021 (Nov. 21, 2018).
[7] 82 Fed. Reg. at 59356.
[8] *Id*. at 59369-70.
[9] *Am. Hosp. Ass'n v. Azar*, 348 F. Supp. 3d 62, 67–72 (D.D.C. 2018) *reversed Am. Hosp. Ass'n v. Azar* (*AHA II*), 385 F. Supp. 3d 1, 3–4 (D.D.C. 2019), *reversed and remanded American Hospital Assoc. v. Becerra*, 596 US 724, 142 S.Ct. 1896 (2022).
[10] *Am. Hosp. Ass'n v. Azar*, 385 F. Supp. 3d 1, 3–4 (D.D.C. 2019).
[11] *American Hospital Assoc. v. Azar*, 967 F.3d 818, at 828, 834 (2020), *reversed and remanded American Hospital Assoc. v. Becerra*, 596 US 724, 142 S.Ct. 1896 (2022).
[12] *American Hospital Assoc. v. Becerra*, 596 US 724, 142 S.Ct. 1896 (2022).
[13] *Id*. at 736.
[14] *Id*. at 739.
[15] *Id*. at 734.
[16] *Am. Hosp. Ass'n v. Becerra*, No. 18-cv-2084-RC, 2022 WL 4534617, at *5 (D.D.C. Sept. 28, 2022).
[17] *Am. Hospital Ass'n v. Becerra*, 1:18–cv–2084–RC, 2023 WL 143337, at *3.
[18] 88 Fed. Reg. 77150 (Nov. 8, 2023).
[19] *Id*. at 77161, 77167.
[20] *Id*. at 77185.
[21] *Id*. at 77166.
[22] *Id*. at 77154 (referring to these payments as a "windfall").
[23] *Id*. at 77181.
[24] *Id*.
[25] *Id*. at 77159.
[26] *Id*. at 77152.
[27] *See* comment letter, https://www.regulations.gov/comment/CMS-2023-0115-0043.
[28] 88 Fed. Reg. at 77152 and 77154.
[29] *Id*. at 77184.
[30] *Id*. at 77158.
[31] Social Security Act § 1833(t)(14)(D).
[32] *Id*. at § 1833(t)(14)(E).
[33] 88 Fed. Reg. at 77159.
[34] 42 C.F.R. § 405.1885(c)(2).
[35] 88 Fed. Reg. at 77154 (quoting *Mount Sinai Hosp. of Greater Miami, Inc. v. Weinberger*, 517 F.2d 329, 345 (5th Cir.), *modified*, 522 F.2d 179 (5th Cir. 1975).
[36] 88 Fed. Reg. at 77172 (quoting *Shands Jacksonville Med. Ctr., Inc. v. Azar*, 959 F.3d 1113, 1118 (D.C. Cir. 2020).

