A Flurry of Reimbursement Wins for Hospitals . . . Decisive or Pyrrhic Victories? (Part I)

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By all accounts, 2019 has been a busy year for hospitals challenging the Medicare Program's implementation of reimbursement reductions. Courts at all levels, including the United States Supreme Court, have been called on to determine whether and to what extent agency action has violated the scope of the agency's authority under the Medicare statute and the Administrative Procedure Act ("APA").

In the next few issues of *Focus*, I will discuss the essential holdings of several important Court cases that have invalidated Medicare's rate reductions, starting with the recent decisions of Judge Rudolph Contreras, sitting on the United States District Court for the District of Columbia, in the case of *The American Hospital Association, et al. v. Alex M. Azar, II, United States Secretary of Health and Human Services, et al.*, Civil Action No. 18-2084(RC)[1].

A. Medicare OPPS, the 340B Program, and Reimbursement for 340B Drugs

Under the Department of Health and Human Services' ("HHS") Outpatient Prospective Payment System ("OPPS"), hospitals are directly reimbursed for providing outpatient services and pharmaceutical drugs to Medicare beneficiaries, which is a component of Medicare Part B reimbursement.[2] Under this system, HHS, through the Centers for Medicare and Medicaid Services ("CMS"), sets annual OPPS reimbursement rates prospectively, before the given year begins, rather than retroactively based on covered hospitals' actual costs during the year.

In 1992, Congress established what is commonly referred to as the "340B Program," which allows participating hospitals and other health care providers ("covered entities") to purchase certain drugs at steeply discounted rates, and then seek reimbursement for those purchases under Medicare Part B at the rates established by OPPS. Congress has authorized two potential methodologies for settling "specified covered outpatient drugs" ("SCODs") reimbursement rates for drugs provided by hospitals to Medicare beneficiaries. The first method looks at "hospital acquisition cost survey data" and, if available, HHS must set the reimbursement rate for each SCOD according to "the average acquisition costs for the drug for that year . . . as determined by the Secretary taking into account" the survey data.[3] The second method comes into play if the survey data are not available. In such circumstance, each SCOD's reimbursement rate must be set equal to "the average price for the drug in the year established under . . . section 1395w-3a . . . as calculated and adjusted by the Secretary as necessary for purposes of this paragraph."[4] Section 1395w-3a, in turn, provides that a given drug's default reimbursement rate is the average sales prices ("ASP") of the drug plus 6%.[5]

B. The 340B Medicare Payment Gap

Before 2018, the relevant OPPS rate for 340B drugs was ASP plus 6%[6]. This rate resulted in a significant gap between what hospitals paid for 340B drugs and what they received in Medicare reimbursements for those drugs because the 340B Program allowed participating hospitals to buy the drugs at a far lower rate than ASP plus 6%[7]. Plaintiffs[8] alleged that the revenues derived from this payment gap have helped hospitals "provide critical services to their communities, including underserved populations in those communities." Plaintiffs also alleged that the narrowing of this gap would "threaten these critical services" because the hospitals may be unable to fund the services with lower reimbursement amounts.

C. The 2018 OPPS Rule

In mid-2017, HHS proposed reducing the Medicare reimbursement rates for SCODs and other separately payable drugs acquired through the 340B Program from ASP plus 6% to ASP minus 22.5%[9]. HHS reasoned that: (1) several recent studies had confirmed the large profit margins hospitals enjoy which is created by the payment gap;[10] (2) because of this profit margin, HHS was "concerned that the current payment methodology may lead to unnecessary utilization and potential overutilization of separately payable drugs;"[11] and (3) it

was concerned "about the rising prices of certain drugs and that Medicare beneficiaries, including low-income seniors, are responsible for paying 20 percent of the Medicare payment rate for these drugs," rather than the lower 340B rate paid by the covered hospitals.[12] However, HHS did not have the data necessary to "precisely calculate the price paid by 340B hospitals for [any] particular covered outpatient drug,"[13] so HHS proposed applying the average 340B discount estimated by the Medicare Payment Advisory Commission ("MedPAC"), which was 22.5% lower than the covered drug's average sales price.[14]

Moreover, because HHS did not have hospital acquisition cost data for 340B drugs, it could not invoke its express authority under 42 *U.S.C.* § 1395l(t)(14)(A)(iii)(I) to set rates according to the drugs' average acquisition costs. Instead, HHS invoked its authority under § 1395l(t)(14)(A)(iii)(II), "which states that if hospital acquisition cost data are not available, the payment for an applicable drug shall be the average price for the drug . . . as calculated *and adjusted* by the Secretary as necessary."[15] Consequently, HHS "adjust[ed] the applicable payment rate as necessary" for separately payable drugs acquired under the 340B Program "to ASP minus 22.5[%]."[16] HHS further stated that the adjustment was necessary because ASP minus 22.5% "better represents the average acquisition cost for 340B drugs and biologicals."[17]

While Plaintiffs strongly opposed the proposed 2018 340B reimbursement rates during the comment period, in November 2017, HHS, nonetheless, adopted the 340B reimbursement rate reduction.[18]

D. The Parties' Arguments

Plaintiffs argued that the Secretary acted *ultra vires*, or in other words, outside the scope of his authority, in "adjusting" the 340B drug reimbursement rates from ASP plus 6% to ASP minus 22.5%. In response, HHS argued that the Secretary's authority under § 1395l(t)(14)(A)(iii)(II) to "calculate and adjust" drug payments "as necessary for purposes of this paragraph" gave the Secretary broad discretion, including discretion to adjust Medicare payment rates according to whether or not certain drugs were acquired at a significant discount.[19] Thus, the case turned on the scope of the Secretary's discretion under this statutory section to alter statutory benchmark drug reimbursement rates.

E. The United States District Court's Decision

The Court framed the issue as "whether the Secretary acted within his authority to 'calculate [ ] and adjust [ ]' the statutory benchmark rate of ASP plus 6% when he reduced that rate to ASP minus 22.5% based on his estimation of 340B hospitals' drug acquisition costs, rather than the drugs' average sales prices." The Court emphatically held that the Secretary did not.

In striking down the Secretary's action, the Court first found that Congress did not intend for the term "adjust" in 42 *U.S.C.* § 1395l(t)(14)(A)(iii)(II) to confer unbridled authority on the Secretary. Rather, the Court stated, that statutory provision commands that SCOD reimbursement rates "shall" be set "equal" to a rate specified in certain other statutory provisions – here each drug's average sales price plus 6% and this clear directive is qualified only by the Secretary's modest authority to "adjust" those rates. Thus, the Court concluded that the language and structure of subsection (t)(14)(A)(iii)(II) make clear that the Secretary may not make "basic and fundamental changes" to the 340B SCOD reimbursement rates under the purported auspices of making mere "adjustments" to the rates statutorily imposed by that subsection.

Applying the facts to the Secretary's actions, the Court observed that the Secretary's purported rate "adjustment" did not affect only a single drug or even a handful of drugs, but rather potentially thousands of pharmaceutical products found in the 340B Program, amounting to a nearly 30% reduction from the formula Congress set forth in the statute. When viewed together, the Court stated, 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 for determining SCOD reimbursement rates, thereby exceeding the Secretary's authority to "adjust" SCOD rates under section (t)(14)(A)(iii)(II). Finally, the Court admonished, "[t]o the extent the Secretary disagrees on policy grounds with Congress's decision . . . the Secretary may either collect the data necessary to set payment rates based on acquisition costs [under subsection (t)(14)(A)(iii)(I)], or he may raise his disagreement with Congress, but he may not end-run Congress's clear mandate."

So far, so good . . .

Not so fast . . .

F. The Court Decided to Give the Secretary "First Crack" at Fashioning a Remedy

On the question of what the appropriate remedy would be, the Court did not make its decision at the same time it held that the Secretary's actions were unlawful. Rather, it ordered additional briefing from the parties to address the question. When the parties submitted their supplemental briefs, the Plaintiffs also filed a supplement complaint alleging that the Secretary implemented the same 340B reimbursement rate for 2019 that the Court held was unlawfully implemented in 2018.

In their remedies brief, Plaintiffs asked the Court to: (1) order the Secretary to pay them the difference between the amount they received under the 2018 and 2019 OPPS rules and the amount to which they are entitled based on the ASP plus 6% methodology, and (2) order the Plaintiffs that have not yet received reimbursement for 340B drugs prescribed in 2018 and 2019 to be paid the amount they would have received under the 2017 OPPS rule.

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The Secretary, on the other hand, asked the Court to remand both the 2018 and 2019 OPPS rules back to the HHS, without vacating the rules or imposing specific duties on the agency.

For the same reasons it held the 2018 rates were unlawful, the Court also held that the HHS's 2019 340B reimbursement rates were likewise unlawful. However, the Court agreed with the Secretary on the remedy and remanded both rules back to the HHS, giving HHS the "first crack at crafting appropriate remedial measures." In taking this approach, the Court observed, "there are multiple ways for HHS to remediate its underpayments, some more complicated than others." For instance, HHS could implement the Plaintiffs' proposed mechanism. It could adjust reimbursement rates in future years to make up for its underpayments in 2018 and 2019. Or, HHS could amend the 2018 and 2019 OPPS rules and issue retroactive payments accordingly. Even the Plaintiffs conceded there were recent examples of cases in which the HHS paid hospitals for past underpayments and, in each of those cases, the agency reached its own decision on remand without the Court directing the HHS on how to do it. Finally, the Court cautioned against its imposition of a remedy, noting the potential dilemma that HHS's actions be budget neutral and conceding that the "path forward is not sufficiently clear cut that this [C]ourt should chart it in the first instance."

On the question of whether the 2018 and 2019 rules should be vacated in their entirety, the Court stated its decision weighs "ever so slightly, against vacatur." While the Secretary's deficiencies were substantial (that is, the Secretary patently violated the Medicare Act's text), the Court believed that "no amount of reasoning on remand will allow the Secretary to re-implement the 340B rates in the same manner." Rather, it explained, "the Secretary would need to justify those rates under a different statutory provision – a nearly impossible task, given the Secretary's lack of relevant data."

In addition, the Court recognized that vacating the 2018 and 2019 OPPS rules and reinstating the 2017 OPPS rule would be highly disruptive. First, OPPS payments must remain budget neutral, which could throttle the Secretary's ability to retroactively adjust reimbursement rates. Thus, if the Secretary were to be required to retroactively raise the 2018 and 2019 340B rates, budget neutrality would require him to retroactively lower the 2018 and 2019 rates for other Medicare Part B products and services. And, because HHS has already processed claims under previous rates, the Secretary would potentially be required to recoup certain payments made to providers, an expensive and time-consuming project which could cost between $25 and $30 million and take up to one year to accomplish.

The Court also warned that the presumption against retroactive rulemaking would complicate vacatur, as it would force the Secretary to retroactively issue rules for 2018 and 2019.

On whole, the Court believed that remanding the rules back to the HHS will allow the agency more flexibility to determine the least disruptive means of correcting its underpayments to the hospitals, including possibly making remedial payments in a non-budget neutral manner. Finally, a remand to the HHS to fashion a remedy without vacating the rules could permit the agency to avoid the budget neutrality issue altogether by, perhaps, raising 340B rates in future years to compensate for the 2018 and 2019 underpayments.

In sum, the Court concluded that given the "complex prospective payment system . . . vacating the 2018 and 2019 OPPS Rules would do more harm than good, despite the fatal flaws in the Secretary's 340B rate adjustments."

G. Appeal to the D.C. Circuit Court

On July 11, 2019, the Secretary appealed Judge Contreras' decisions to the United States Court of Appeals for the District of Columbia Circuit. Oral argument was held on November 8, 2019 and a decision from the Court of Appeals is expected shortly – perhaps even by the time this article is published.

H. Observations About the Court's Decision

For someone who spends much time and effort challenging agency decision-making on Medicare and Medicaid reimbursement, I find the United States District Court decision to be frustrating and even naïve. On the one hand, the Court inexorably declared the Secretary's actions in reducing 340B drug reimbursement by 30% to be an egregious violation of the Medicare statute. On the other hand, the Court was persuaded by the Secretary to remand the case back to the HHS, the same agency that behaved badly in the first place, to give it an opportunity to fix its indiscretions. I do not believe this remedy is sufficient.

Yes, Medicare reimbursement is complex. Yes, agencies have the expertise to determine prospective reimbursement rates. But, in this case, the HHS had its chance to do the right thing and failed miserably. Why does the Court now believe that HHS will do it correctly on remand? The Court assures us that the Secretary could not possibly re-implement the 340B rates in the same manner as he did previously because he would need to justify the rates under a different statutory provision – "a nearly impossible task," the Court declares.

Really?!? Does this Court not think that if the Secretary is determined to substantially reduce 340B drug rates, it couldn't find an alternative statutory provision under which to do so? Let's not be naïve to think that the Secretary will do the right thing the second time around.

There is a maxim in the law known as *ubi jus ibi remedium*, which means "for every wrong the law provides a remedy." Under the District Court's analysis, it cannot be argued that the Secretary did not commit a wrong, which negatively impacted the Plaintiffs and requires a remedy to correct. But does the Court's remand back to HHS to fix its unlawful act provide an adequate remedy? Given the flagrant nature of the Secretary's conduct, I believe it simply does not. Instead, the Court could and should have enjoined the enforcement of HHS's 2018 and 2019 OPPS rules and ordered the Secretary to implement the previous OPPS reimbursement rates in effect in 2017. Remanding the whole matter back to HHS to fix the errors is a little like letting the fox back in the hen house to return the stolen chicken.

About the author

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Footnotes

[1]Judge Contreras has issued several decisions which, together, comprise of the holdings which will be discussed in this article. They are: (1) Memorandum Opinion dated December 27, 2018 Denying Defendants' Motion to Dismiss; Granting Plaintiffs' Motion for a Permanent Injunction; Denying as Moot Plaintiffs' Motion for a Preliminary Injunction; (2) Memorandum Opinion dated May 6, 2019 Granting in part Plaintiffs' Motion for a Permanent Injunction; Remanding the 2018 and 2019 OPPS Rules to HHS; and (3) Memorandum Opinion dated July 10, 2019 Granting Defendants' Motion for Entry of Final Judgment; Denying as Moot Plaintiffs' Motion for a Firm Date.
[2]See 42 *U.S.C.* § 1395l(t).
[3]42 *U.S.C.* § 1395l(t)(14)(A)(iii)(I).
[4]42 *U.S.C.* § 1395l(t)(14)(A)(iii)(II).
[5]42 *U.S.C.* § 1395w-3a(b)(1)(A)-(B).
[6]*See, e.g., 77 Fed. Reg.* at 68, 387.
[7]*See 82 Fed. Reg.* at 52, 495 (citing an Office of Inspector General report finding that this margin "allowed covered entities to retain approximately $1.3 billion in 2013").
[8]The Plaintiffs in the case are the American Hospital Association, the Association of American Medical Colleges, America's Essential Hospitals, Henry Ford Health System, Northern Light Health (formerly Eastern Maine Healthcare Systems), and Fletcher Hospital, Inc. d/b/a Park Ridge Health.
[9]82 *Fed. Reg.* 33, 558, 33, 634 (July 20, 2017).
[10]*Id.* at 33, 632-33.
[11]*Id.* at 33, 633.
[12]*Id.*
[13]*Id.* at 33, 634.
[14]*See* id.
[15]82 Fed. Reg. at 33, 634.
[16]*Id.*
[17]*Id.*
[18]82 *Fed. Reg.* at 52, 362.
[19]*Id.* at 52, 499.

•Certification Corner•

The 43rd Annual Institute is behind us, and it was a great success! This year, the Institute provided a jam-packed agenda with valuable educational content focusing on many important aspects of healthcare. Among many educational events offered, it was not always easy to choose which one to attend.

The Certification Lunch and Learn session on HFMA certification options was very well attended. Our trainer, Rachelle Fletcher, MSHSA, FHFMA, reviewed HFMA certification options, prerequisites, and maintenance requirements. HFMA now offers eight different certification options:

- Certified Healthcare Financial Professional (CHFP)
- Certified Specialist Accounting and Finance (CSAF)
- Certified Revenue Cycle Representative (CRCR)
- Certified Specialist Business Intelligence (CSBI)
- Certified Specialist Managed Care (CSMC)
- Certified Specialist Physician Practice Management (CSPPM)
- Certified Inpatient Coding Auditor (CICA)
- Fellow of HFMA (FHFMA)

While membership in HFMA is not required for these certifications, except for Certified Healthcare Finance Professional, members can earn as many certifications as they like – they are all included with member dues.

The Certification Committee is working with regional counterparts on organizing a webinar later this year for those who were not able to attend the Lunch and Learn session at Borgata. Please be on the lookout for an email with more information.

If you have any questions about certifications, would like to become certified or learn about certification maintenance, please contact Amina Razanica, CHFM, CSBI at arazanica@njha.com.

We hope you had a wonderful holiday season and 2020 will be your best year yet!