340B Hospitals File Suit in Wake of Hospital Outpatient Cuts

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On November 13, 2017, a group of hospital trade associations (the American Hospital Association, the Association of American Medical Colleges, and America's Essential Hospitals), along with two health system providers, filed suit against the Department of Health and Human Services (HHS) in the U.S. District Court for the District of Columbia. In the lawsuit, the associations and hospitals allege that a portion of HHS's outpatient prospective payment (OPPS) rule is invalid. The challenged portion of the rule cuts payment rates to 340B-eligible hospitals for most outpatient drugs used by these hospitals by 27%. This policy, according to the lawsuit, is inconsistent with both the Social Security and Public Health Services Acts, and, as such, triggers a violation of the Administrative Procedure Act (APA), in turn giving the providers the right to sue HHS. In addition to asking that the proposal be overturned, the plaintiffs have requested the Court issue a preliminary injunction blocking the payment cuts pending a decision on the merits.

The 2018 OPPS rule being challenged in the lawsuit finalized a 27% reduction in the payment for Medicare Part B separately payable, nonpass-through drugs and biologicals (other than vaccines) purchased by hospitals through the 340B Program. HHS' decision to cut payment rates for these drugs was based on a series of recent findings by MedPAC indicating:

1. There is a significant profit factor associated with drugs purchased at a significant discount under the 340B program (often 20-50% of a drug's average sales price (ASP)) and then reimbursed at ASP + 6%
2. As a result, Part B drug spending by 340B hospitals often greatly exceeds spending by non-340B hospitals.

Under the finalized proposal, HHS estimates that Medicare would spend $1.6 billion less under OPPS in reduced drug payments. The final rule redistributes those savings in an equal offsetting amount to all hospitals paid under the OPPS through increased payment rates for non-drug items and services.

In general, the complaint alleges two violations:

1. **A violation of the Secretary's statutory authority to reimburse hospitals for outpatient drugs according to a specific statutory formula**
2. **A violation of the Secretary's authority under the 340B program to allow eligible hospital to "stretch scarce Federal resources."**

As a result of these violations, the hospitals argue that HHS has violated its duties under the APA by enacting a policy that is either arbitrary or capricious, or in excess of the statutory jurisdiction of the Secretary. The plaintiff hospitals argue that they are entitled to declaratory and injunctive relief under the APA because they would suffer significant and immediate harm from imposition of the lower reimbursement rates.

Violation of OPPS Payment Formula

The plaintiff hospital's first argument – that the Secretary has violated his obligations under the Social Security Act by veering from the statutory obligation to pay for Part B drugs according to a statutorily-specified formula – is based upon a particular interpretation of the Part B payment formula located at section 1833(t)(14) of the Social Security Act. Although the hospitals' complaint repeatedly incorrectly cites the applicable statutory provision, this provision provides that payment for outpatient drugs in any year after 2005 must be made under one of the following two options:

- Option (I) “To the average acquisition cost for the drug for that year (which, at the option of the Secretary, may vary by hospital group (as defined by the Secretary based on volume of covered OPD services or other relevant characteristics)), as determined by the Secretary taking into account the hospital acquisition cost survey data under subparagraph (D);" or
- Option (II) "If hospital acquisition cost data are not available, the average price for the drug in the year established under section 1842(o), section 1847A, or section 1847B, as the case may be, as calculated and adjusted by the Secretary as necessary for purposes of this paragraph.”

HHS has long taken the position that it was unable to obtain the average acquisition cost of separately-payable drugs used in the outpatient setting, thereby foreclosing its ability to use “Option (I)” in setting payment rates for these drugs. Therefore, the agency has used its more general grant of authority under “Option (II)” to set payment rates for separately-payable drugs at ASP+6%. This is clearly a policy decision made by the Secretary and one that is authorized by Option (II) (“as calculated … by the Secretary”).

In the final OPPS rule, HHS explained that it was relying upon Option (II) as a basis for reducing payment to hospitals for 340B-purchased Part B drugs. In particular, the agency stated that because acquisition cost data for 340B drugs was unavailable (thus eliminating the ability to use the formula in Option (I)) the agency would instead pay using the Average Sales Price formula in Option (II). That amount (ASP + 6%) would, under the final rule, be further “adjusted by the Secretary” (as authorized by the statute) by applying a reduction of 22.5%.

In the complaint, the plaintiff hospitals argue that, despite the agency’s statement in the final rule, HHS was effectively applying Option (I) in setting rates for separately-payable drugs for 340B hospitals. Under the hospitals’ theory, HHS was relying on the MedPAC studies cited above and has effectively obtained acquisition cost data and was using that data to set rates of payment for these drugs. The plaintiffs argue that because HHS has long announced that it would determine rates of payment for separately-payable drugs used in the outpatient setting by utilizing Option (II), that it cannot now switch to Option (I); according to the hospitals, the ASP methodology *only* permits the Secretary to calculate the ASP as set forth in statute (and fine tune it to reflect changes in overhead and related expenses), and thus HHS cannot apply its acquisition cost findings (i.e. that the average acquisition cost of 340B acquired drugs is generally 30% less than for non-340B acquired drugs) to the formula in Option (II).

In addition, the plaintiffs argue that the acquisition cost data itself is flawed, because it is based not on “hospital acquisition cost survey data,” as prescribed in statute, but instead by cost data compiled by MedPAC. Moreover, the OPPS Advisory Panel which was required to review the 340B payment proposal, did so only after the proposed rule was published, and actually voted against adopting the proposal.

Violation of the Intent of the 340B Program

In addition to violating the OPPS payment formula requirements, the plaintiff hospitals argue that the 340B payment proposal exceeds the Secretary’s authority because it undermines the 340B program by depriving 340B hospitals of the discounts intended under the program, threatening 340B-hospitals’ ability to provide essential healthcare services to their communities. Because many hospitals currently rely on the savings generated under the 340B program to fund these services for the underserved, the hospitals argue that these programs will be threatened, in direct contravention of the intent and design of the 340B program itself. In the preamble to the final rule, HHS did address this concern noting: “While we recognize the intent of the 340B Program, we believe it is inappropriate for Medicare to subsidize other activities through Medicare payments for separately payable drugs.”

Conclusion

Based on these two counts, the plaintiff hospitals have asked the D.C. District Court to: (1) declare unlawful the cuts to the 340B payment rates and reinstate the 340B payment rates used in CY 2017; or (2) issue a preliminary injunction suspending the effective date of the rule (January 1, 2018) until the case can be heard on the merits.

We note that HHS did address many of these legal concerns raised by the plaintiff hospitals already in the preamble to its final rule – indicating that HHS was well aware of the potential for a legal challenge.

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