PUBLICATION

CMS's Massive 340B Drug Pay Cut Policy Lands in Federal Court

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Hospitals participating in the 340B Drug Discount Program (340B Program) received distressing news on November 1, 2017, with the release of Medicare's CY 2018 drug payment policy. Under the new policy – set forth in the Hospital Outpatient Prospective Payment System (OPPS) Rule for CY 2018 (Final Rule) – 340B hospitals will see a dramatic drop in Medicare reimbursement for separately payable drugs and biologicals from Average Sales Price (ASP) plus six percent (ASP+6%) to ASP minus 22.5 percent (ASP-22.5%). CMS projects that this policy will produce a reduction of as much as $1.6 billion in OPPS payments for drugs.

According to the Final Rule, the new drug payment policy will take effect January 1, 2018. However, a lawsuit filed November 13, 2017, by and on behalf of hospitals, calls into question CMS's authority to proceed with the policy.

CMS's 340B Drug Payment Policy

CMS's 340B drug payment policy announced in the CY 2018 OPPS Final Rule applies to most 340B hospitals and most separately payable outpatient drugs and biologicals. First, certain types of 340B hospitals are not affected by the new policy and, therefore, will continue to be reimbursed at ASP+6% in CY 2018. These hospitals include: (i) rural sole community hospitals, children's hospitals and PPS-exempt cancer hospitals, for which CMS has provided an exception and (ii) critical access hospitals, which are reimbursed under OPPS. In addition, non-excepted, off-campus hospital outpatient departments will not be impacted because, with the implementation of CMS's site neutral policy under Section 603 of the Bipartisan Budget Act of 2015, these departments no longer receive payment under OPPS.

Second, hospitals affected by the policy will include those qualifying for 340B Covered Entity status as disproportionate share hospitals (DSH) and rural referral centers. These hospitals will see reduced reimbursement for most separately payable Medicare Part B drugs and biologicals purchased through the 340B Program (including those drugs purchased through the 340B Prime Vendor Program) that are dispensed or administered to hospital outpatients. The reduced payment rate will not apply to drugs with transitional "pass-through" status or to vaccines (which are not included in the 340B Program).

To implement the 340B drug payment policy, CMS will require the use of two new modifiers:

- ***JG Modifier*** (Drug or Biological Acquired with 340B Drug Pricing Program Discount): CMS will require 340B hospitals subject to the payment reduction to use Modifier JG to identify if a drug was purchased under the 340B Program. Use of the JG modifier will trigger a payment adjustment to ASP-22.5% on claims for separately payable drugs.
- ***TB Modifier*** (Drug or Biological Acquired with 340B Drug Pricing Program Discount; Reported for Informational Purposes): CMS will require 340B hospitals excepted from the payment reduction policy (i.e., rural SCHs, children's hospitals and PPS-exempt cancer hospitals) to use Modifier TB. Use of the TB modifier is intended to facilitate collection and tracking of 340B claims, but will not result in a payment reduction.

CMS has taken the position that the reduced payment rates for affected 340B hospitals will better reflect the resources those hospitals expend to acquire 340B drugs and will reduce Medicare beneficiary copayment obligations. CMS intends to implement the 340B drug payment policy in a budget neutral manner. To accomplish this, CMS will redistribute the estimated $1.6 billion in savings across all hospitals paid under OPPS by increasing the payment rates for all non-drug items and services by 3.2 percent in CY 2018.

While some stakeholders supported CMS's approach, others, including CMS's own Advisory Panel on Hospital Outpatient Payment (OPPS Advisory Panel) and both chambers of Congress, urged CMS not to implement the policy. It is notable that a total of 228 members of the House of Representatives, including 72 Republicans, signed a September 27 letter opposing the proposed rule and a total of 52 U.S. Senators, including 17 Republicans, signed a similar letter dated on October 6. Both letters expressed concerns that the proposal would likely strain already scarce resources and have little benefit to Medicare beneficiaries. Despite this significant objection from Congress and other stakeholders, CMS proceeded to issue the Final Rule with the steep cuts in reimbursement.

Hospitals Sue to Block 340B Drug Payment Cuts

Immediately following the release of the Final Rule, several hospital associations threatened litigation against the agency over the policy. Thirteen days later, the American Hospital Association, Association of American Medical Colleges, America's Essential Hospitals and several named hospitals followed through by filing a lawsuit against the Department of Health and Human Services (HHS) seeking to block implementation of the payment changes.

The plaintiffs primarily base their claims on CMS's statutory authority under the Social Security Act (SSA) for setting OPPS drug payment rates. Under the SSA, CMS may either set rates based on: (i) average acquisition costs, provided statistically sound survey data on acquisition costs are available (Reimbursement Option I); or, if such data is not available, (ii) a mandatory default rate of ASP+6%, as may be calculated and adjusted by HHS (Reimbursement Option II). CMS acknowledged in the Final Rule that it does not have hospital acquisition cost data for 340B drugs and, therefore, it would continue to set payment rates for such drugs under Reimbursement Option II (i.e., the default rate).

The crux of the plaintiffs' complaint rests on how CMS adjusted the default rate. Specifically, CMS used estimated aggregate average acquisition costs compiled by the Medicare Payment Advisory Commission (MedPAC) to arrive at the reduced rate (ASP-22.5%) for separately payable drugs acquired through the 340B Program. The plaintiffs' position is that CMS has no authority to use a proxy for 340B drug acquisition costs to adjust the statutory default drug payment rate. Instead, adjustments to the default rate must be based on ASP, not acquisition costs.

The plaintiffs also point out that Reimbursement Option I (which was not relied on by CMS) would require use of acquisition costs based on statistically sound survey data, which CMS acknowledged it does not have. In addition, the MedPAC compiled data is not based on a statistically significant survey. According to the complaint, CMS impermissibly relied on acquisition costs to adjust the default rate under Reimbursement Option II to circumvent requirements it could not meet under Reimbursement Option I with regard to statistically sound survey data.

The plaintiffs further assert that while Reimbursement Option II allows CMS to "calculate" and "adjust" the statutory default rate of ASP+6%, it does not allow CMS to implement such a drastic reduction, amounting to a nearly 30 percent decrease in Medicare reimbursement to affected hospitals. Instead, CMS's authority is limited to fine-tuning the ASP-based statutory default to reflect changes in overhead and related expenses.

The plaintiffs are seeking a declaratory judgment that the policy represents an unlawful exercise of agency authority under the SSA, along with an order directing the agency to withdraw the 340B drug payment policy. In the alternative, the plaintiffs seek a preliminary injunction to prevent the payment change from going into effect on January 1, 2018, until the case has been resolved.

Baker Donelson Comments

CMS's 340B drug payment policy for CY 2018 is a marked departure from prevailing Medicare drug reimbursement policy and now the fate of the policy will be litigated in federal court. If CMS prevails in the litigation, the policy will have a dramatic impact on many 340B participating hospitals and, in particular, those with outpatient oncology and infectious disease programs. Notwithstanding the litigation, all 340B hospitals should begin preparing for implementation of the new policy, including quantifying and evaluating the impact on current operations and on any future plans, and assessing workflow and systems processes for use of the new modifiers. It will also be important to stay abreast of sub-regulatory guidance that may be issued by CMS regarding implementation of the modifiers. We will be monitoring CMS transmittals for additional guidance on this new drug payment policy and the status of the litigation that has been filed.