JONES DAY

COMMENTARY

NOVEMBER 2017

Legislation, Lawsuit Cloud Future of 340B Program Payment Rate Reductions

IN SHORT

The Situation: A Final Rule published by the Centers for Medicare & Medicaid Services carries a provision that reduces reimbursement for most 340B Program drugs dispensed by disproportionate share hospitals and rural referral center hospitals.

The Reaction: Bipartisan legislation was introduced that would reverse the payment cuts. Separately, suit was filed against the Department of Health and Human Services alleging violations of the Administrative Procedures Act by CMS.

Looking Ahead: The impact of the Final Rule on suppliers and other stakeholders is potentially very significant. CMS will accept comments on the Final Rule until December 31, 2017.

SKIP TO THE FULL VERSION

On November 1, 2017, the Centers for Medicare & Medicaid Services ("CMS") published the Hospital Outpatient Prospective Payment System ("OPPS") and Ambulatory Surgical Center Payment ("ASC") Payment System Final Rule ("Final Rule"), which includes a controversial provision that significantly reduces reimbursement for most 340B Program drugs dispensed by disproportionate share hospitals ("DSH") and rural referral center ("RRC") hospitals beginning January 1, 2018.

On November 15, Representatives David B. McKinley (R-WV) and Mike Thompson (D-CA) introduced H.R. 4392 ("House Bill"), which, if passed, would reverse the 340B payment cuts contemplated in the Final Rule. The House Bill came just two days after industry stakeholders filed suit against the Department of Health and Human Services ("HHS") and Acting Secretary of Health and Human Services, Eric Hargan, alleging that CMS violated the Administrative Procedures Act when it published portions of the Final Rule.

Policy Discussions Influencing CMS' 340B Changes in Final Rule

The 340B Program, which enables certain eligible health providers to purchase drugs at reduced prices in support of outpatient programs, has been the topic of much debate in recent years. The changes to the 340B Program made in the Final Rule are not surprising to some, given significant media coverage and high-profile commentary often casting a negative perception on a health provider's ability to "profit" from a discounted drug that is reimbursed at standard rates.

However, Health Resources & Services Administration ("HRSA"), the agency responsible for the implementation and maintenance of the 340B Program, consistently stresses the important role of the 340B Program to address public health concerns and services for indigent, uninsured, and underinsured patients.

Overview of 340B Program Changes in Final Rule

In the Final Rule, CMS cut the applicable payment rate for separately payable, non-pass-through drugs (excluding vaccines) purchased through the 340B Program by DSHs and RRCs from the average sales price ("ASP") plus 6 percent to ASP minus 22.5 percent (collectively, the "Payment Reduction"). For 340B providers affected by the Payment Reduction, a drug with an ASP of $1,000 would be reimbursed at $775 compared to the current reimbursement of $1,060.

Policy Implications: Are the 340B Changes Beyond CMS' Authority?

CMS has suggested that implementation of the Payment Reduction in a budget-neutral manner would generate an anticipated $1.6 billion in savings to the Medicare program to be reallocated equally among all hospitals paid under the OPPS. CMS identifies the two primary concerns the Payment Reduction was intended to address.

First, CMS was concerned that prior reimbursement rates did not adequately reflect the 340B hospital's lower acquisition cost for the drug, which CMS believed could be leading to increased drug spending at 340B facilities.

Second, CMS echoed earlier beliefs and concerns that seniors and other Medicare beneficiaries are paying a greater than necessary share of overall drug costs. Medicare beneficiaries are responsible for a copayment that is equal to 20 percent of the

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OPPS payment rate, but according to OIG findings in some instances, the beneficiary's copayment alone was greater than the amount the covered entity paid for the drug.

CMS' concerns and the implementation of the Payment Reductions come on the heels of a June 2015 Government Accountability Office (GAO) report entitled "Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals" ("GAO Report") and amid recent hearings on the 340B Program held by the House Energy and Commerce Committee Subcommittee on Oversight and Investigations in July and October of this year.

The GAO Report raised concerns that generally track the overarching concerns stated by CMS. Specifically, the Report indicated that 340B hospitals, and particularly 340B DSHs, were being incentivized to maximize Medicare revenue by prescribing more or more expensive drugs. As support for the impact of this incentive, the GAO Report noted that 340B DSH hospitals had substantially higher per beneficiary spending on Medicare Part B drugs than non-340B hospitals, which "could not be explained by factors outside of the 340B Program, such as hospital teaching status or patient health status."

Most importantly, the GAO Report itself noted that CMS did not have the statutory authority to reduce hospitals' Medicare Part B reimbursement for 340B discounted drugs. The American Hospital Association and others immediately called the question of whether the Payment Reduction exceeds CMS' statutory authority following release of the Final Rule.

Potential Impact of the Final Rule

For those 340B Program providers impacted by the Final Rule and its Payment Reduction, the implementation of compliance and operational elements may prove challenging given CMS' suggestion that it will use subregulatory and informal processes outside of formal rulemaking for information on modifiers and other key components to the new requirements.

Opportunity for Additional Industry Comment

CMS will be accepting comments regarding the Final Rule through December 31, 2017. As such, stakeholders are best served to engage in a careful and meaningful review of the Final Rule and Payment Reduction and pursue opportunities to submit comments to CMS.

Given the uncertainty surrounding the Payment Reduction in the Final Rule, 340B covered entities also should monitor closely: (i) whether the House Bill gains traction, (ii) developments in the pending litigation challenging CMS' authority to implement the Payment Reduction, and (iii) any further guidance from CMS, along with activities of other stakeholders in their discussions about the Final Rule.

FOUR KEY TAKEAWAYS

1. In the Final Rule, the applicable payment rate for separately payable, nonpass-through drugs (excluding vaccines) purchased through the 340B Program by DSHs and RRCs is reduced from the average sales price plus 6 percent to average sales price minus 22.5 percent. This change is anticipated to result in $1.6 billion in savings to Medicare.
2. On November 13, a number of industry stakeholders filed suit against HHS and Acting Secretary of HHS, Eric Hargan. These industry stakeholders allege that CMS violated the Administrative Procedures Act when it published portions of the Final Rule.
3. On November 15, Representatives David B. McKinley (R-WV) and Mike Thompson (D-CA) introduced H.R. 4392, which, if passed, would reverse the 340B payment cuts contemplated in the Final Rule.
4. Providers impacted by the Payment Reduction need to be prepared to deal with the operational challenges of implementing the payment modifiers and other requirements in the Final Rule if the pending litigation and legislation do not bring relief before it otherwise becomes effective on January 1, 2018.

WANT TO KNOW MORE?
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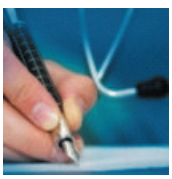
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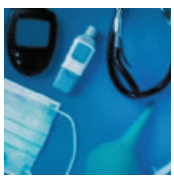
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