

IMPACT ANALYSIS: FEDERAL COURT BLOCKS 2018 CUTS TO 340B DRUG DISCOUNT PROGRAM PAYMENTS

On December 27, 2018, a **federal judge ruled** in favor of hospital associations and hospitals challenging the reduction in reimbursement for drugs purchased at a discount under the 340B Program established in the 2018 Outpatient Prospective Payment System final rule ("2018 OPPS Rule"). Judge Rudolph Contreras of the United States District Court in Washington, D.C. determined that the government overstepped its statutory authority by reducing payment for drugs purchased under the 340B Program from Average Sales Price ("ASP") plus 6 percent to ASP minus 22.5 percent.

The Court granted the American Hospitals Association ("AHA") and others' motion for a permanent injunction but only for reimbursement reductions in calendar year 2018. Notably, the reimbursement reductions for 2019 remain in effect because AHA and others did not and could not bring a challenge about the 2019 OPPS final rule ("2019 OPPS Rule") for procedural reasons.

As a result, this decision has no immediate impact on the 2,000-plus hospitals, academic medical centers and other safety net providers participating in the 340B Program (collectively, "Covered Entities"). These Covered Entities should expect that the payment reductions will continue for now, and it is not certain that they will receive retroactive payments. A prospective resolution appears more likely, though Judge Contreras ordered further briefing to determine the appropriate relief. The Department of Health and Human Services ("HHS") is expected to appeal this decision. In the interim, Covered Entities should take steps to protect their appeal rights.

The Court's decision continues the saga documented in our series of articles on this topic:

- [July 2018 - 340B Program OPPS Payment Reductions and Legislative Limitation Proposals: What's Smoke and What's Fire?](#)
- [January 2018 - Medicare 340B Payment Cuts Go Live as of January 1. What's Next?](#)
- [December 2017 - Federal Judge Denies Hospitals' Motion to Enjoin Imminent 340B Program Payment Cuts](#)
- [November 2017 - Medicare's 340B Payment Cut: What Does It Mean for All Hospitals?](#)

BACKGROUND

In November 2017, the Centers for Medicare & Medicaid Services ("CMS") finalized its 2018 OPPS Rule to reduce reimbursement for separately payable, "non-pass through" drugs purchased at reduced prices under the 340B Program. The reduction, effective January 1, 2018, impacted disproportionate share hospitals, rural referral centers and sole community hospitals ("SCH"). This effectively decreased their reimbursement by nearly 30 percent, about \$1.6 billion in total for 2018.

Stakeholders sued to enjoin the policy's implementation, arguing that HHS violated its authority by changing the rates in the proposed manner. In December 2017, the Court dismissed that lawsuit on procedural grounds because the policy was not yet effective. The stakeholders appealed again once the cuts took effect, leading to the current challenge and the Court's December 2018 decision.

ANALYSIS AND IMPACT OF THE DECISION ON THE 2018 OPPS RULE 340B PAYMENT CUTS

Plaintiffs alleged that the 2018 OPPS Rule's cuts restricted hospitals' efforts to care for low-income and vulnerable patients, and they argued that HHS exceeded its statutory authority. HHS framed the cuts as part of the administration's efforts to lower prescription drug prices and reduce drug costs for Medicare patients. HHS also contended that the reductions were considered authorized "adjustments" under the OPPS payment classification system because it could make modifications by any method that rates expressed as drug prices. The Judge disagreed, stating that HHS's authority to make "adjustments" did not mean it could "fundamentally rework the statutory scheme." The Court concluded that HHS acted beyond its legal authority, referred to as *ultra vires*, with adjustments that impacted thousands of drugs and rate changes that were "not modest."

The fallout of this decision is unclear with questions about appropriate remedies and an appeal still lingering. The Judge sought input about remedies by ordering supplemental briefing from the parties. The plaintiffs hope to vacate the 2018 OPPS Rule and receive retroactive

payment increases but that outcome is uncertain due to the inherent difficulties of retroactive payment adjustments. Moreover, HHS already redistributed funds from those reductions through CMS's 3.2 percent increase in the OPPS conversion factor for all hospital outpatient services as part of its "budget neutral" policy in the 2018 OPPS Rule. In fact, the Judge called the issue of remedies "a quagmire that may be impossible to navigate considering the volume of Medicare Part B payments made in 2018." Meanwhile, HHS stated that it is reviewing its options, and an appeal appears likely.

ANALYSIS AND IMPACT OF THE 2019 OPPS RULE 340B PAYMENT CUTS

CMS finalized its 2019 OPPS Rule during the course of this litigation. The 2019 OPPS Rule expands the cuts by reducing reimbursement for separately payable 340B Program drugs provided in non-excepted (established after November 2, 2015), off-campus provider-based departments. Moreover, beginning January 1, 2019, payment for these facilities decreased from ASP plus 6 percent to ASP minus 22.5 percent, equivalent to facilities receiving 70 percent of the 2019 OPPS rate. This reduction initially applies solely to grandfathered off-campus provider-based departments during the 2019 calendar year. However, the 2019 OPPS Rule also provides for reimbursement for these facilities at a rate equivalent to 40 percent of the OPPS rate starting in 2020. For a deeper discussion of this change in the 2019 OPPS Rule, see [here](#).

The Judge explicitly stated that this December 2018 decision about the 2018 OPPS Rule does not apply to payment cuts in 2019 or subsequent years. Thus, plaintiffs will likely appeal again once 2019 claims are processed and the 2019 payment reductions will be ripe for litigation.

POLICY IMPACT

With a Democratic takeover of the House of Representatives, a major legislative initiative to reform the 340B Program is unlikely. Energy and Commerce Committee leadership signaled that 340B Program reform will no longer be a high priority for its committee. Some senators are still interested in the issue, but there is no bipartisan agreement to move legislation forward this year. The administration will likely be the thrust behind any efforts to change the 340B Program.

APPEAL RIGHTS AND NEXT STEPS

There are still questions about the mechanism for Covered Entities to preserve their appeal rights moving forward. Covered Entities should, however, work with their legal counsel to affirmatively preserve these rights. At a minimum, Covered Entities should maintain an accurate accounting of the payment reduction's impact while the parties and the Court iron out details regarding potential remedies.

Reduced payments for 340B Program drugs under the 2019 OPPS Rule will likely remain for the foreseeable future. Please note that rural SCHs, children's hospitals and PPS-exempt cancer hospitals are not currently affected by the 2018 OPPS Rule or the 2019 OPPS Rule and will continue to use the modifier -TB to report 340B Program drugs to receive ASP plus 6 percent. Covered Entities should be aware that CMS may maintain its 2019 OPPS Rule or win the current lawsuit on appeal.

Stakeholders should continue monitoring developments, including agency regulations, judicial decisions and legislation. Covered Entities and other stakeholders should also work with their advocacy teams and local legislators to demonstrate the value brought by participation in the 340B Program and advocate for the policy changes that would most benefit their patients.

We will continue to monitor developments in this area.

If you have any questions or would like additional information about this topic, please contact:

- **Todd A. Nova** at 414-721-0464 or tnova@hallrender.com;
- **John F. Williams** at 317-977-1462 or jwilliams@hallrender.com;
- **Daniel F. Miller** at 414-721-0463 or dmiller@hallrender.com;
- **Abigail L. Kaericher** at 202-780-2989 or akaericher@hallrender.com;
- **Kristen H. Chang** at 414-721-0923 or kchang@hallrender.com; or
- Your regular Hall Render attorney.