340B UPDATE: HOSPITALS APPEAL RULING ON OPPS REIMBURSEMENT CUT; HOUSE COMMITTEE ISSUES REPORT RECOMMENDING CHANGES TO 340B PROGRAM

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U.S. Health Care Alert

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The beginning of 2018 has brought significant developments relating to the federal 340B Drug Pricing Program ("340B Program"). On January 1, reimbursement under the Medicare Part B hospital Outpatient Prospective Payment System ("OPPS") dropped substantially, from the drug's average sales price ("ASP") plus 6% to ASP minus 22.5%. Shortly thereafter, hospitals filed notice that they intend to appeal a lower court's ruling that allowed the cuts to take effect. In addition, the House Energy and Commerce Committee has released a new report examining a variety of 340B Program-related issues, including a series of recommended policy changes to the 340B Program that lawmakers could advance in the early months of 2018. Looking ahead, stakeholders should be proactively engaging with policymakers who will shape the outcome of any future legislation to ensure their views are heard.

HOSPITAL GROUPS APPEAL DISTRICT COURT RULING ALLOWING OPPS CUTS TO TAKE EFFECT

On December 29, 2017, Judge Rudolph Contreras allowed the OPPS reimbursement cuts to take effect on January 1, 2018 (see our prior alerts on the reimbursement cut here and here). On January 9, 2018, lead plaintiff hospitals and trade organizations appealed Judge Contreras's decision dismissing their lawsuit. In particular, the American Hospital Association, Association of American Medical Colleges, America's Essential Hospitals, and several hospitals across the country filed notice with the U.S. District Court for the District of Columbia that they intend to appeal the D.C. district court's ruling that granted the government's motion to dismiss and denied the plaintiffs' motion for a preliminary injunction as moot. [1]

In his order granting the government's motion to dismiss and denying the plaintiffs' motion for a preliminary injunction, Judge Contreras did not address the merits of plaintiffs' arguments but rather concluded that under 42 U.S.C. § 405(g), the court lacked jurisdiction prior to the presentment of a claim by the plaintiff hospitals, as well as the exhaustion of the agency appeals process (a requirement the court may waive). [2] As a result, the substantive merits surrounding Centers for Medicare & Medicaid Services authority to impose the reimbursement change have not yet been addressed and/or rejected. The U.S. Court of Appeals for the District of Columbia will now consider the lawsuit, which could have a significant financial impact on hospitals across the country.

HOUSE LAWMAKERS CALL FOR SIGNIFICANT CHANGES TO 340B PROGRAM

Separately, on January 10, 2018, the House Energy and Commerce Committee released a report on the 340B Program. A link to the press release and report can be found here. The Committee's report is the product of a two-year investigation into the 340B Program, which included several hearings and requests for information addressing covered entities' use of the 340B Program and oversight by the Health Resources and Services Administration ("HRSA"). While emphasizing strong bipartisan support for the 340B Program, the Committee argued that the program has several shortcomings, which it attributes to a lack of clear statutory parameters and insufficient regulatory authority for HRSA to conduct oversight.

The report makes 12 policy recommendations, ranging from more immediate administrative action by HRSA to enactment of new legislation by Congress. With respect to administrative action, the Committee recommended that HRSA use its existing regulatory authority over certain aspects of the 340B Program to issue and begin enforcing final regulations where it has statutory authority. Such authority includes administration of the 340B Program's alternative dispute resolution process, imposition of civil monetary penalties against drug manufacturers for knowingly and intentionally overcharging covered entities, and the calculation of drug ceiling prices. [3]

A majority of the Committee's recommendations focus on statutory changes to provide HRSA with additional regulatory authority and resources to administer and oversee the 340B Program. HRSA's expanded authority under the Committee's recommendations would allow it to issue regulations to clarify various requirements, monitor and track 340B Program use, and verify that low-income and uninsured patients benefit from the 340B Program. To achieve these ends, the report specifically recommends legislation to:

- Clarify the intent of the 340B Program to account for developments in the health care sector that have affected the structure and goals of the program over time.
- Require covered entities to disclose information about annual 340B Program savings and/or revenue and ensure covered entities and other stakeholders have access to ceiling prices.
- Establish a common definition for charity care and a mechanism to monitor the level of charity care covered entities provide.
- Address duplicate discounts for drugs paid under Medicaid-managed care.

The report also recommends legislative changes to require certain covered entities to conduct independent audits of 340B Program compliance and further recommends that all covered entities be required to perform independent audits of their contract pharmacies at regular intervals. Although the report does not formally recommend changing the current 340B Program eligibility criterion that uses a hospital's disproportionate share adjustment percentage, the report recommends reassessing whether it is the most appropriate measure and considers alternatives based on outpatient population.

Following the release of the report, Energy and Commerce Committee Chairman Greg Walden (R-OR) noted that one of his top priorities in the first few months of 2018 is to advance legislation addressing the recommendations in the report. Notably, Chairman Walden indicated that the Committee would consider the Medicare payment reductions discussed above as part of their discussions.

CONCLUSION

Legislative and regulatory developments over the last several months demonstrate continued interest among policymakers in addressing the growth of the 340B Program. Looking ahead, stakeholders should assess their compliance with existing 340B Program requirements and continue to plan for future changes to the 340B Program that could result from the OPPS litigation and potential legislation from Congress. Hospitals and other stakeholders may wish to continue or begin pursuing policy advocacy in Washington, D.C., to inform future actions by Congress and the administration. K&L Gates' Health Care practice and Public Policy and Law practice can assist stakeholders in each of these areas. K&L Gates regularly advises clients on 340B Program implementation and compliance matters, engages in high-stakes litigation with payors and federal agencies, and facilitates stakeholder engagement with Congress and the administration.

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[1] American Hospital Ass'n v. Hargan, No. 17-2447 (RC) (D.D.C. Jan. 9, 2018), ECF No. 25.

[2] *See* American Hospital Ass'n v. Hargan, No. 17-2447 (RC) (D.D.C. Dec. 29, 2017), ECF No. 24.

[3] Since President Trump took office, HRSA has delayed on several occasions a rule addressing 340B Program ceiling prices and manufacturer civil monetary penalties. Most recently, on September 29, 2017, HRSA delayed the final rules until July 1, 2018, and reiterated its intent to engage in further rulemaking. 82 Fed. Reg. 45,511 (Sept. 29, 2017). The White House Office of Management and Budget ("OMB") received a proposed rule from HRSA on October 6, 2017, and was initially expected to publish the rule before the end of 2017. OMB has not yet completed its review and has not indicated when the proposed rule will be released for public comment.

