340B UPDATE: PRESIDENT'S BLUEPRINT INCLUDES 340B REFORMS, THE OPPS LITIGATION CONTINUES, AND OTHER RECENT DEVELOPMENTS

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The past several weeks have featured a flurry of activity under the 340B Drug Pricing Program ("340B Program"), with recent action in all three branches of the federal government. Notably, on May 11, 2018, the Trump Administration unveiled its blueprint for lowering drug prices, which could result in significant reforms to the 340B Program among numerous other policy changes in the months ahead. The release of the blueprint came soon after the Health Resources and Services Administration ("HRSA") proposed to delay the effective date of certain final rules under the 340B Program. In addition, litigation relating to reimbursement for 340B Program drugs under the Medicare Outpatient Prospective Payment System ("OPPS") continued with oral arguments in the U.S. Court of Appeals for the D.C. Circuit earlier this month, and the Senate Committee on Health, Education, Labor and Pensions ("HELP") continued the congressional focus on the 340B Program, holding the latest in its series of hearings examining oversight issues.

As discussed below, the President's blueprint in particular provides an important opportunity for 340B Program stakeholders to submit public comments to help shape the direction of administration policy. Given the uncertainty surrounding the 340B Program's future, hospitals and other stakeholders should carefully monitor these developments and consider engaging directly with policymakers in Congress and the Administration as the debate moves forward.

PRESIDENT'S DRUG PRICING BLUEPRINT SUGGESTS REFORMS, OFFERS OPPORTUNITY FOR ENGAGEMENT

On May 11, 2018, the Trump Administration unveiled its long-anticipated drug pricing blueprint titled "American Patients First," which is aimed at reducing drug prices and out-of-pocket costs for consumers. [1] The release was accompanied by a speech at the White House in which President Trump called the plan "the most sweeping action in history to lower the price of prescription drugs for the American people." The four key strategies in the blueprint are: (1) improved competition, (2) better negotiation, (3) incentives for lower list prices, and (4) lowering out-of-pocket costs. With respect to each strategy, the blueprint outlines actions the President may take immediately, as well as actions the Department of Health and Human Services ("HHS") is considering as further opportunities.

On the 340B Program in particular, the blueprint references the proposals that were part of the President's budget request to Congress earlier this year, which included new regulatory authority for HRSA to administer and

oversee the 340B Program, a new user fee on drug purchases by covered entities, and redistribution of the savings from the OPPS reimbursement cut in a non-budget neutral manner to hospitals that provide a certain threshold of uncompensated care (see our prior alerts here and here). In addition, the blueprint discusses the recent OPPS reimbursement cut as one action already taken to reduce drug prices. Finally, it asks HHS to consider a series of questions in formulating policy under the 340B Program over the coming months.

Program Growth:

- How has the growth of the 340B Program affected list prices?
- Has it caused cross-subsidization by increasing list prices applicable in the commercial sector?
- What impact has this had on insurers and payers, including Part D plans?
- Do the Group Purchasing Organization exclusion, the Prime Vendor Program, and current inventory models increase or decrease prices?
- What are the unintended consequences of the 340B Program?
- Would explicit general regulatory authority over all elements of the 340B Program materially affect the elements of the program affecting drug pricing?

Program Eligibility:

- Would changing the definition of "patient" or changing the requirements governing covered entities contracting with pharmacies or registering offsite outpatient facilities (i.e., child sites) help refocus the 340B Program towards its intended purpose?

Duplicate Discounts:

- Are the current mechanisms for identifying and preventing duplicate discounts effective?
- Are drug companies paying additional rebates over 340B Program discounts for drugs that have been dispensed to 340B Program patients covered by commercial insurance?
- What is the impact on drug pricing given that private insurers oftentimes pay commercial rates for drugs purchased at 340B Program discounts?
- Do insurer, pharmacy, pharmacy benefit manager, or manufacturer contracts consider, address, or otherwise include language regarding drugs purchased at 340B Program discounts?
- What should be considered to improve the management and the integrity of claims for drugs provided to 340B Program patients in the overall insured market?
- What additional oversight or claims standards are necessary to prevent duplicate discounts?

Although the blueprint does not impose any immediate changes, it demonstrates the Administration's clear intent to move forward developing significant reforms to the 340B Program moving forward. In addition, the Administration published the blueprint and the questions above in the *Federal Register* as part of a Request for Information ("RFI"). HHS is seeking comments from all interested parties on the questions included in the blueprint — and other questions the blueprint did not specifically address — by July 16, 2018. [2]

HRSA REQUESTS A FIFTH DELAY FOR FINAL RULE ON 340B PRICING AND MANUFACTURER PENALTIES

The release of the blueprint came shortly after HRSA formally published its proposed one-year delay of the final regulations setting drug ceiling prices and allowing HRSA to levy civil monetary penalties on drug manufacturers that knowingly overcharge covered entities for 340B Program drugs. [3] As discussed in a prior alert, HRSA submitted a request to the Office of Management and Budget in late March 2018 asking to delay the effective date until July 1, 2019, to allow for "necessary time to consider more fully the substantial questions of fact, law, and policy identified by the Department during its review of the rule pursuant to the [Trump Administration's] 'Regulatory Freeze Pending Review' memorandum." HRSA explains further, "Requiring manufacturers to make targeted and potentially costly changes to pricing systems and business procedures to comply with a rule that is under further consideration would be disruptive." HRSA also notes that it needs time to finalize additional rulemaking, noting that HHS is developing "new comprehensive policies to address the rising costs of prescription drugs . . . in government programs, such as Medicare Parts B & D, Medicaid, and the 340B discount drug program."

COURT OF APPEALS HEARS ARGUMENTS IN OPPS LITIGATION

On May 4, the U.S. Court of Appeals for the District of Columbia heard oral arguments in the litigation challenging the OPPS reimbursement cut that took effect on January 1 under the OPPS for separately payable drugs purchased under the 340B Program. As discussed in January, lead plaintiff hospitals and trade organizations appealed a U.S. District Court ruling that allowed the reimbursement cuts to take effect. However, the lower court did not address the merits of plaintiffs' arguments, but rather concluded that 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). As a result, the Court of Appeals has the first opportunity to address the substantive merits surrounding Centers for Medicare & Medicaid Services' ("CMS") authority to impose the cut. Much of the argument centered on whether the OPPS cut is reviewable at this point in time, with attorneys for HHS contending that Congress expressly precluded judicial and administrative review of adjustments to the OPPS. However, the court did not give a strong indication as to how it will decide during oral arguments. A ruling, which is expected by the end of summer 2018, could either roll back the reimbursement cut — going forward or even retroactively to January 1, 2018 — or vindicate CMS' actions to date, leaving only pending legislative fixes as hospitals last line of recourse. In this regard, Rep. David McKinley (R-WV) has introduced legislation that would prohibit the Secretary from taking any action to implement, administer, or enforce the cuts beginning on the date of enactment (H.R. 4392).

SENATE HELP COMMITTEE HOLDS HEARING ON 340B PROGRAM OVERSIGHT

Finally, the Senate HELP Committee held a second hearing on May 15, 2018, titled *Examining Oversight Reports on the 340B Drug Pricing Program*. [4] The Committee heard testimony from Ann Maxwell, Assistant Inspector General for Evaluation and Inspections at the HHS Office of the Inspector General ("OIG"), and Debra Draper, Director of the Health Care Team at the U.S. Government Accountability Office ("GAO"). The witnesses addressed a variety of issues noted in prior oversight reports issued by OIG and GAO, including a lack of clarity in the 340B Program's rules and a lack of transparency into how the 340B Program operates in practice. Ms. Draper discussed that the GAO is working on reports that will cover issues such as contract pharmacies and the extent to

which covered entities pass on 340B Program discounts to low-income patients, covered entity financial arrangements with contract pharmacies, and comparing the characteristics of 340B Program and non-340B Program hospitals.

During the question-and-answer period, key issues included what information would be most useful to gather from covered entities and manufacturers from an oversight perspective, the status of HRSA rulemakings and guidance, and the intent of the 340B Program. A representative from HRSA is expected to testify soon before the Senate HELP Committee at a hearing focused on effective administration of the 340B Program, but the date for that hearing has not yet been scheduled.

CONCLUSION

Given the potential for significant changes to the 340B Program this year, stakeholders should continue to plan for future changes that could result from new guidance or regulations in 2018 and potential legislation from Congress. Hospitals and other stakeholders may also wish to continue or begin pursuing policy advocacy. In particular, stakeholders may want to submit comments — due by July 16 — in response to the RFI issued in conjunction with the Trump Administration's drug pricing blueprint. K&L Gates' Health Care practice and Public Policy and Law practice regularly advise clients on 340B Program implementation and compliance matters and facilitate stakeholder engagement with Congress and the Administration.

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[1] U.S. Dep't of Health & Hum. Servs., *American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs* (May 2018), https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf.

[2] HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs, 83 Fed. Reg. 22,692 (May 16, 2018), https://www.gpo.gov/fdsys/pkg/FR-2018-05-16/pdf/2018-10435.pdf.

[3] 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 83 Fed. Reg. 20,008 (May 7, 2018), https://www.gpo.gov/fdsys/pkg/FR-2018-05-07/pdf/2018-09711.pdf.

[4] *Examining Oversight Reports on the 340B Drug Pricing Program,* S. Comm. on Health, Educ., Lab. and Pensions, 115th Congress (2018), https://www.help.senate.gov/hearings/examining-oversight-reports-on-the-340b-drug-pricing-program (last visited May 20, 2018).

