340B UPDATE: TRUMP ADMINISTRATION'S 2019 BUDGET AND WHITE HOUSE COUNCIL OF ECONOMIC ADVISORS SIGNAL FURTHER CHANGES TO 340B PROGRAM

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On February 12, 2018, the Trump Administration released its fiscal year ("FY") 2019 budget request to Congress outlining several proposals related to the 340B Drug Pricing Program (the "340B Program") including a modification on the use of funds generated through the Medicare Part B reimbursement cut for certain 340B Program drugs that took effect on January 1, 2018, the imposition of new user fees for 340B Program covered entities, and legislation to provide the Health Resources and Services Administration ("HRSA") with additional regulatory authority over the 340B Program. In addition, the White House Council of Economic Advisors (the "Council") recently released a report commenting on the 340B Program and recommending policy changes on issues such as eligibility criteria and charity care metrics. Hospitals and other 340B Program stakeholders should carefully monitor these developments and consider engaging directly with policymakers in Congress and the Administration as the debate over the 340B Program moves forward.

BACKGROUND

As discussed in our prior alert, on November 1, 2017, the Centers for Medicare and Medicaid Services ("CMS") finalized a policy that reduced Part B reimbursement for 340B Program drugs to certain hospitals receiving payments under the outpatient prospective payment system ("OPPS") from the average sales price ("ASP") plus six percent to ASP minus 22.5 percent, effective January 1, 2018 (the "Final Rule").[1] With this change, CMS sought to reduce Medicare beneficiaries' co-insurance obligations for drugs and recognize the lower acquisition cost for drugs that hospitals purchase through the 340B Program. In the Final Rule, CMS indicated it would redistribute the savings in a budget neutral manner by increasing non-drug OPPS payments to both 340B Program and non-340B Program hospitals.

In a separate prior alert, we highlighted the industry's swift response to the Final Rule and the arguments hospital organizations advanced as part of a lawsuit challenging CMS's authority to make such a change. Specifically, the hospital organizations filed a lawsuit asserting that CMS lacked statutory authority to implement the change, given the statutory limitations on varying payments by "hospital group" under Part B. CMS, for its part, has argued that Congress delegated broad statutory authority to the agency to adjust payments for drugs, including drugs acquired at a discount through the 340B Program. The hospital organizations are currently appealing dismissal of the lawsuit to the U.S. Court of Appeals for the District of Columbia Circuit, and arguments are expected to begin

after the April 2 briefing deadline.[2] Despite the ongoing litigation, the Administration's proposed changes for 2019 suggest a new approach to use of the savings generated by the Part B reimbursement cut.

BUDGET CALLS FOR ADDITIONAL CHANGES TO THE 340B PROGRAM

The President's FY 2019 budget request calls for a series of policy changes aimed at reducing the cost of prescription drugs across a number of federal programs — for example, by creating a pilot program allowing states to determine which drugs would appear on their Medicaid drug formulary and requiring Medicare Part D plan sponsors to pass through at least one-third of the total rebates and price concessions they receive from drug manufacturers to beneficiaries at the point of sale. With regard to the 340B Program, the budget request proposes further modifications to CMS's current Medicare Part B reimbursement policy. The budget proposes redistributing some of the savings generated by lower Part B payments for 340B Program drugs in a non-budget neutral manner, based on the amount of uncompensated care that 340B Program hospitals provide.[3] In particular, CMS would calculate the savings to Medicare from hospitals that provide uncompensated care equal to at least one percent of their total patient care costs, then redistribute those savings based on such hospitals' share of aggregate uncompensated care. Additional details on how CMS would make uncompensated care calculations and how the redistribution would operate are not included in any of the budget documents released to date. However, hospitals not satisfying the one percent threshold would not be eligible for the redistribution, and any remaining savings from the payment reduction would be returned to the Medicare trust fund. Since the Social Security Act requires adjustments to the OPPS to be budget neutral, the Administration notes that this proposal would require legislation from Congress.[4]

The budget request also calls for new regulatory authority for HRSA to administer and oversee the 340B Program, with support from a new user fee on drug purchases by covered entities. Similar to the Administration's FY 2018 budget request, the FY 2019 budget proposes that Congress grant HRSA broad regulatory authority to set enforceable standards of participation and require all covered entities to report on the use of 340B Program savings. HRSA's enhanced oversight efforts would be financed, in part, by the new user fee on covered entities that is estimated to generate $16 million in FY 2019, which would be added to the $10 million the Administration is requesting for the 340B Program in FY 2019 under its discretionary budget authority. Additional details from the Administration, including the specific rate of the proposed user fee, are not available at the time of this writing.

WHITE HOUSE ECONOMIC ADVISORS RECOMMEND CHANGES TO THE 340B PROGRAM

In addition to the budget request, on February 9, 2018, the Council issued a report, titled "Reforming Biopharmaceutical Pricing at Home and Abroad," which outlined a number of policy proposals that the Council believes might help reduce U.S. drug prices while promoting innovation.[5] With regard to the 340B Program, the Council found that "imprecise eligibility criteria" and the ability for providers to "earn significant profits" to "fund other forms of care or shareholders' dividends rather than provide care for low-income patients" had resulted in a program that provides "guaranteed profits" to covered entities with "little to no benefit" for low-income patients.[6] Given 340B Program participation is limited to not for profit providers that do not have shareholders, the Council's

reference to shareholder profits presumably refers to arrangements that covered entities are permitted to maintain with commercial contract pharmacies.

The Council highlighted the OPPS reimbursement cut that began on January 1, 2018 as an administrative action that it believes will address overutilization of the 340B Program and save Medicare beneficiaries an estimated $3.2 billion in coinsurance liability over the next 10 years.[7] The Council recommended further changes to 340B Program eligibility criteria to better identify hospitals serving significant low-income populations through charity care.[8] The Council was critical of the disproportionate share hospital ("DSH") measure as a proxy for evaluating a hospital's charity care, and also questioned the automatic inclusion of critical access hospitals in the 340B Program without scrutinizing their level of charity care. Beyond enacting more precise eligibility criteria to meet what the Council argued were the original goals of the 340B Program, the Council proposed having a single agency set prices at which eligible providers can buy drugs and equipping that agency with guidance to establish eligibility requirements and reduce alleged "profiteering."[9] In this regard, the Council report echoes a recent letter from Senate Finance Committee Chairman Orrin Hatch (R-UT) to Secretary Azar, which stated that the 340B Program has outgrown the jurisdiction of HRSA and asked Secretary Azar to consider placing it under the purview of CMS.[10]

IMPLICATIONS FOR PROVIDER STAKEHOLDERS

While presidential budget requests are widely considered aspirational documents that function primarily to communicate an administration's policy and fiscal priorities, the budget and Council report are both noteworthy because of the commonalities they share with recent congressional proposals. As we noted in our recent alert, Congress is considering legislation to modify the 340B Program and is expected to take action this spring. In January, the House Committee on Energy and Commerce released a report that proposed administrative actions by HRSA and legislative changes by Congress that aim to curtail growth and any misuse of the 340B Program.[11] The Committee has not yet endorsed specific legislation, but Chairman Greg Walden (R-OR) has expressed a desire to consider legislation within the first few months of 2018 that could include some of policies proposed in the budget and Council report. In light of this ongoing activity, it is notable that the fourth quarter of 2017 saw the most 340B Program lobbying on record, according to Senate filings.[12]

There has generally been bipartisan support for legislative changes to the 340B Program focused on increased transparency and establishing clearer standards to address hospitals' obligation to provide uncompensated care. By contrast, proposals to significantly modify 340B Program eligibility criteria have historically triggered partisan disagreements that could complicate efforts to enact legislation this year. This remains especially true in the Senate, where Republicans maintain a narrow margin of control. The dynamic in Congress suggests that any legislative changes to the 340B Program enacted in 2018 will be narrow and include only those proposals that can attract fairly strong bipartisan support in the Senate.

Given the potential for significant changes to the 340B Program this year, provider stakeholders should closely monitor developments on Capitol Hill and at HHS and be prepared to offer feedback. Likewise, stakeholders should assess their compliance with existing 340B Program requirements and 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 Washington, D.C. to mitigate

risks and capitalize on opportunities presented by new policy. K&L Gates' Health Care practice and Public Policy and Law practice can assist stakeholders in each of these areas. We regularly advise clients on 340B Program implementation and compliance matters and facilitate stakeholder engagement with Congress and the Administration.

Notes:

[1] 82 Fed. Reg. 52,356 (Nov. 13, 2017).

[2] *See* Per Curiam Order, American Hospital Association et al. v. Azar, No. 18-5004 (D.C. Cir. Jan. 30, 2018) (setting briefing schedule); *see also* Paige Minemyer, *Court Grants Hospital Groups' Request for Expedited Brief in 340B Case Appeal*, FIERCE HEALTHCARE (Feb. 5, 2018, 1:15 PM), https://www.fiercehealthcare.com/finance/american-hospital-association-340b-cuts-lawsuit-expedited-brief-appeal.

[3] U.S. DEPT. OF HEALTH AND HUMAN SERVS., FISCAL YEAR 2019 BUDGET IN BRIEF, https://www.hhs.gov/sites/default/files/fy-2019-budget-in-brief.pdf.

[4] CMS considered various approaches for redistributing savings in the Final Rule and left open the possibility of adopting an approach similar to that proposed in the budget request. In response to comments expressing concern that the savings from the payment reduction for 340B Program drugs would be shared with both 340B Program and non-340B Program hospitals, CMS noted that it "continue[s] to be interested in exploring ways that funds from a subsequent proposal could be targeted in future years to hospitals that serve a high share of low-income or uninsured patients." 82 Fed. Reg. at 52,624.

[5] WHITE HOUSE COUNCIL OF ECONOMIC ADVISORS, REFORMING BIOPHARMACEUTICAL PRICING AT HOME AND ABROAD (2018), https://www.whitehouse.gov/wp-content/uploads/2017/11/CEA-Rx-White-Paper-Final2.pdf.

[6] Id. at 15.

[7] Id. at 17.

[8] Id. at 16.

[9] Id. at 17.

[10] *See* Susannah Luthi, MODERN HEALTHCARE, *Hatch Asks Azar to Shift 340B Oversight to CMS*, Feb. 6, 2018, http://www.modernhealthcare.com/article/20180206/NEWS/180209941.

[11] HOUSE COMM. ON ENERGY AND COMMERCE, REVIEW OF THE 340B DRUG PRICING PROGRAM (2018), https://energycommerce.house.gov/wp-content/uploads/2018/01/20180110Review_of_the_340B_Drug_Pricing_Program.pdf.

[12] See Llewellyn Hinkes-Jones, BLOOMBERG BNA HEALTH LAW REPORTER, *Safety-Net Hospital Lobbying Surges as Medicare Slashes Payments*, Feb. 15, 2018.