340B MOVING FORWARD: LEGISLATIVE AND EXECUTIVE BRANCH 340B PRIORITIES FOR 2019-2020

We continue to receive questions regarding the future of the 340B drug discount program ("340B Program") now that its mid-term longevity is no longer in doubt. These include whether Congress will continue to focus on limiting the 340B Program's scope as well as what effect, if any, broader efforts to reduce drug costs might have. In our previous article, we analyzed the impact of the Health Resources & Services Administration Office of Pharmacy Affairs' ("OPA") implementation of the long-awaited 340B covered outpatient drugs ("340B Drugs") ceiling price access website. In this article, we discuss the scope and potential implications of legislative and executive branch actions as they related to 340B Program access.

In contrast to Congressional scrutiny of the 340B Program the past few years, changes in the current political climate have shifted legislative and executive branch priorities as they relate to the 340B Program. As a result, members of Congress have issued fewer calls for 340B Program reform, focusing instead on prescription drug pricing, with 340B Program pricing but one variable in the calculation.

However, although key congressional leaders distanced themselves from 340B Program reform, the executive branch continues signaling its interest in affecting change with the program. These efforts include elements of the president's 2020 budget request that was released to Congress on March 11. The proposed budget includes several policies that would impact certain characteristics of the 340B Program even though the underlying structure and purpose of the 340B Program remain fundamentally unchanged.

From congressional hearings mentioning the 340B Program, to budget proposals that expressly include further Medicare Part B 340B Program payment reductions, the health care debate continues in all branches of the federal government even as these developments suggest a more favorable outlook for the 340B Program's viability than in recent years. In light of this atmosphere, this article provides 340B Program covered entities ("Covered Entities") and other stakeholders with an overview and framework for long-term planning and advocacy. These stakeholders can use the information in their decision-making about how to advocate for their positions and where to focus scarce resources to make the most impact.

HOUSE ENERGY & COMMERCE SUBCOMMITTEE PASSES ON 340B PROGRAM OVERSIGHT HEARINGS

The political climate surrounding the 340B Program has changed with the new Congress, and the 340B Program's viability appears to be less in question than in the past few years. Indeed, House Energy and Commerce Oversight and Investigations Subcommittee Chair Diana DeGette (D-CO) recently stated that she has no plans to hold oversight hearings on the 340B Program. This echoes Energy and Commerce Health Subcommittee Chair Anna Eshoo's (D-CA) sentiment that the committee intends to review other health care priorities before changes to the 340B Program.

DeGette noted that "the Dem[ocratic] majority in the House, and frankly I think a lot of the Republicans, too, realize the importance and the usefulness of the 340B drug program… I don't have any plans right now to do oversight over that." This is a stark contrast from last Congress when there were multiple hearings on 340B Program and several reform bills were introduced (mostly by Republicans). When defending hospital use of 340B Program funds, DeGette noted that nobody has ever alleged there were inappropriate uses of 340B Program proceeds.

Instead, it appears that lawmakers are focusing their efforts on other aspects of health and industry tied to prescription drugs. For instance, DeGette recently announced two hearings as part of a congressional investigation over rising insulin costs. On February 26, 2019, the Senate Committee convened a panel of executives from the seven largest pharmaceutical companies to testify and respond to questions about drug pricing, transparency and industry practices. Many Senators expressed concern over the cost of medications and the opacity in the degree of information asymmetry. Although the 340B Program was not a primary focus, Senator John Thune (D-SD) noted that the 340B Program discounts account for less than two percent of the total drug market. Also, AbbVie CEO Richard Gonzalez expressed support for transparency "across the entire… supply chain, [which] would also include where government rebates are, such as the 340B Program."

These developments are consistent with our prior analysis which noted that the Democratic takeover of the House of Representatives meant

major legislative reform to the 340B Program would be unlikely. Congressional leaders largely centered their efforts elsewhere, but some Congressional interest in 340B Program oversight remains. During a Senate floor speech on April 4, Sen. Lamar Alexander (R-TN), Chairman of the Health, Education, Labor, and Pensions ("HELP") Committee, mentioned the 340B Program when discussing suggestions for lowering prescription drug costs. Sen. Alexander noted that health care think tanks such as American Enterprise Institute and Brookings Institution both recommend that Congress increase oversight of the program. Notably, without additional bipartisan initiatives and support, it is unlikely that additional legislation in this area will move forward.

PROPOSED FEDERAL BUDGET - 340B IMPACT

Although legislative 340B Program reform is unlikely, the executive branch continues to consider options for modifying the program. The president's proposed 2020 budget includes several policies that would potentially impact the 340B Program and Covered Entities. While the proposals are not binding on Congress, and many are almost certain to never become law, they demonstrate the continued interest of the administration in modifying the 340B Program and could impact the 340B Program considerably.

One significant change in the proposed budget would further reduce Medicare Part B payments for 340B Drugs, the subject of ongoing litigation between the administration and several Covered Entities as further described below. If implemented as proposed, CMS would apply a new methodology to the distribution of the savings from those reductions. CMS would provide the savings based on hospital levels of uncompensated care, which would make the distribution no longer budget-neutral. The distribution amounts would be relative to other hospitals, and some hospitals that fall below one percent of patient care costs in uncompensated care would not receive any savings.

The proposed budget seeks to give HRSA greater authority to issue regulations governing the 340B Program by setting standards of participation for all aspects of the 340B Program. At the present, HRSA's regulatory authority is limited to setting standards for the aforementioned 340B Drug ceiling price calculations, implementing civil monetary penalties and resolving claim disputes between Covered Entities and pharmaceutical companies. As a result, the proposed policy would significantly expand HRSA's control over the 340B Program, especially as it relates to Covered Entities and pharmacies.

The draft budget also resurrects an oft-seen proposal for Covered Entities to pay HRSA a user fee of 0.1 percent of total 340B Drug purchases or $1.00 of every $1,000.00 of 340B Drugs purchased. According to the administration, the fee would cover improvements to the OPAIS database, assist with funding for program audits, and provide money to enhance the 340B Program compliance management tool. In total, the administration projected that this fee would generate an additional $19 million above the $10 million in discretionary funding for HRSA.

Furthermore, the proposed budget calls for Covered Entities to report the amount of their 340B Program savings and uses of those savings. This proposed requirement would require disclosure of the "net income" for Covered Entities. It is unclear if this term references the difference between what Covered Entities spent on 340B Drugs and what those Covered Entities received as reimbursement for those 340B Drugs. Or, alternatively, the term may be interpreted as the difference between what Covered Entities pay for 340B Drugs and what the Covered Entities would otherwise have to spend on the same drugs if they did not participate in the 340B Program.

Finally, the proposed budget also seeks to eliminate "pass-through payments" for newly approved drugs, biologics or biosimilars, making them eligible for lower payment rates through the 340B Program.

PRACTICAL TAKEAWAYS

Efforts in the legislative branch to modify the 340B Program dissipated with the change to a democratic majority and a renewed focus on prescription drug prices more broadly. However, 340B Program stakeholders should remain vigilant about policy proposals and potential regulatory changes from the executive branch. The proposed budget suggests that the president and his administration continue to seek reforms to the 340B Program. While the proposed budget is considered aspirational, it is a look at the administration's priorities for the next year and some of the provisions, especially those related to drug pricing, could find their way into legislation on Capitol Hill.

Stakeholders should work with their advocacy teams and legislators to demonstrate the value of the 340B Program. We will continue to monitor developments in potential 340B legislation and other aspects of the 340B Program, and we will issue additional health alerts if and as those developments become relevant.

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