Today, the President will submit the Administration’s Fiscal Year 2019 budget blueprint to Congress. The document will set in motion an annual process to analyze the substance, business implications and prospects for various proposals. Draft documents have already begun to circulate that suggest that both the budget and a forthcoming addendum would, if enacted, have significant impact on the biopharmaceutical industry. As this exercise begins, it is important to note the context in which the President’s budget is presented and expectations for its consideration by Congress.

While the President is required by law to annually submit a budget, it is really a request — it is ultimately the responsibility of Congress to adopt Budget Resolutions, which themselves do not have the force of law but rather are intended to set parameters that guide the development of department-specific appropriations bills to fund the federal government each fiscal year.

The reality is that the federal budget and appropriations process rarely works as it is supposed to — beginning with the President’s budget proposal which, regardless of party control and politics, has in the past couple of decades been considered “dead on arrival” on Capitol Hill. Congress has increasingly relied on “Continuing Resolutions” and short-term leadership-driven deals like the one that passed last
week to avoid a second government shutdown. In this election year and hyper-partisan environment, we do not expect Congress to pass a budget resolution that would allow the Senate to consider legislation with a majority vote. Rather, any proposals considered this year will need 60 votes for adoption in the Senate.

In years past, even if a budget is adopted by Congress, it typically is not significantly shaped by the priorities in the President's budget. That said, given this President's use of tweets and direct communications with the “street,” the Administration’s proposals intended to bring down drug prices, likely will be the subject of considerable attention and discussion in upcoming congressional hearings. Secretary Azar will testify before the Senate Finance Committee and House Energy and Commerce and Ways and Means Committees this week. Those hearings will keep the attention on the biopharmaceutical proposals we expect to see today. In an election year, hot-topics such as drug pricing will also serve as campaign themes in races across the country and possibly set the stage for more serious deliberation next year, depending to a large degree on the results of the elections and the political environment going forward.

In this context, it is too early to know which, if any, of the biopharma-related proposals might actually be enacted into law outside of the budget process or pursued by regulation. It might turn out that the broad issue of drug pricing emerges as an issue on which President Trump and the GOP seek some common ground with congressional Democrats, and that certain concepts offered by the Administration — such as establishing Medicare Part D spending caps and expanding the catastrophic benefit for seniors, addressing Part B payment formulas for newly launched drugs and revising the definition of generic drugs in Medicaid as well as the launch of a pilot program to allow states to negotiate lower Medicaid drug prices — could gain legislative traction or move by regulatory action. Other Administration proposals, such as reforms to the 340B program that would ensure that savings go to hospitals delivering adequate levels of uncompensated charity care or be returned to the trust fund, might be a bridge too far in light of election year partisan politics and continuing Democratic support for the program’s growth.

Over the next several months, it is critical that biopharmaceutical industry stakeholders remain vigilant and actively engaged, while recognizing that policy recommendations in the presidential budget are a starting point and anything but written in stone — especially in a politically turbulent and largely unpredictable year such as this.

© 2020 Covington & Burling LLP