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Pushing “PAUSE” on the 340B Program: The New Bi-Partisan Bill that Could Reshape the 340B Program

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Summary

In late December 2017, Republican Rep. Larry Bucshon (with bi-partisan support) introduced the “340B Protecting Access for the Underserved and Safety-net Entities Act” (340B PAUSE Act), legislation that would implement a two-year moratorium on most new 340B hospital participants, including both hospitals new to 340B and new locations of existing hospital participants. This is the first significant 340B legislative activity since the provisions that were eventually passed and implemented as part of the Affordable Care Act in 2010.

In Depth

Although the specter of 340B legislation loomed large for much of 2017, Congress did not advance a significant measure. Nonetheless, recent developments indicate that 2018 may be the year for changes to the 340B Program. With the New Year has come the first significant 340B legislative activity since the provisions that were eventually passed and implemented as part of the Affordable Care Act in 2010.

In late December 2017, Republican Rep. Larry Bucshon (with bi-partisan support) introduced the “340B Protecting Access for the Underserved and Safety-net Entities Act” (340B PAUSE Act), legislation that would implement a two-year moratorium on most new 340B hospital participants, including both hospitals new to 340B and new locations of existing hospital participants. The 340B PAUSE Act would also require certain hospital participants in the 340B Program to publicly report detailed data related to the hospital’s patients, services and 340B-related activities and would require the HHS Office of Inspector General (OIG) and Government Accountability Office (GAO) to prepare and submit reports on charity care provided by 340B hospitals and contracts between 340B hospitals and state/local governments, respectively.

Moratorium on New 340B Hospitals and New 340B Hospital Locations

The 340B PAUSE Act would place a two-year moratorium on new hospitals entering the 340B

Program as hospitals in the “Disproportionate Share Hospital” (DSH) eligibility category, that is, those hospitals that qualify by virtue of having a Medicare Disproportionate Hospital adjustment percentage at or above 11.75 percent. Further, the bill would also impose a concurrent two-year moratorium on registration any new off-campus outpatient locations (“child sites”). The moratoriums would begin as of the date of enactment of the bill and run for the immediately following two-year period.

The 340B PAUSE Act does not provide for regulatory authority for the Department of Health and Human Services (HHS) to develop implementing regulations, but the language in the bill also leaves open several questions regarding the scope and implementation. For example, the moratorium applies to hospitals and child sites that were not “identified as a covered entity” in the on-line 340B Database (OPAIS) as of the date of enactment. It is not clear whether this language would prevent an existing hospital covered entity from converting from another hospital eligibility category to a DSH hospital or a hospital registered as a DSH from changing ownership. Similarly, as to child sites, it is not clear whether a child site registered at the time of enactment could relocate and maintain eligibility. The bill does appear to include language that would prevent an individual child site from maintain eligibility if it were sold or transferred to another DSH hospital covered entity during the moratorium period. It is also not clear whether the bill would permit enrollment in the 340B Program of new DSH hospitals and child sites that had registered during the open quarterly registration period immediately preceding the enactment of the bill, but would not become active in the 340B Program until after enactment. Of particular importance as to child sites, the bill would foreclose the opportunity for all new child sites of DSH hospitals during the moratorium- including locations that may have opened prior to the moratorium and are awaiting reporting on a filed cost report for registration. Due to the timing rules for 340B registrations, it is not unusual for there to be a period of a year or more between when a new hospital child site opens and when it becomes eligible for registration in OPAIS.

Information Reporting Requirements

In addition to the moratorium on new DSH hospitals and child sites, the 340B PAUSE Act imposes significant data reporting requirements on DSH hospitals, as well as on hospitals participating in the 340B Program as Cancer Hospitals and Children’s Hospitals. All other 340B Hospital types are exempt from the data reporting requirements.

The bill creates four new categories of data reporting (items 1–4 apply to DSH hospitals, items 1, 2 and 4 apply to Cancer and Children’s Hospitals). Information described in items 1, 3 and 4 would be made available to the public via an online searchable database.

1. For each hospital as a whole and for each child site, the number and percentage of individuals who receive 340B drugs, organized by insurance coverage category (*e.g.*, Medicare, Medicaid, commercial insurance and uninsured).
    - For each child site, the hospital would also be required to report the total costs incurred at the site and the total amount of charity care provided by the site.
2. Aggregate costs and gross reimbursement for 340B drugs (including for child sites, although it is not clear from the language of the bill whether the information would be required to be reported individually for each child site).
3. For non-profit DSH hospitals only, a copy of the contract with state or local government to

provide health care services to low income individuals that is required as a condition of 340B eligibility. The bill explicitly provides that “proprietary information” may be redacted from the contracts before they are publicly posted.

4. For the hospital and each child site, the names of vendors and similar entities that provide services in connection with the hospital’s 340B Program-related activities.

Unlike the provision establishing the moratorium, the bill also provides for authority for HHS to promulgate regulations to implement the data reporting requirements and provides for some flexibility to HHS into how to make the data available and in what format. HHS is instructed to issue interim final regulations within six months of enactment, with final regulations required prior to the end of the hospital registration moratorium. The data reporting requirements would begin within 14 months of enactment of the bill, with subsequent annual reporting

Office of Inspector General and Government Accountability Office Reports

The 340B PAUSE Act requires 340B Program-related reports by both OIG and GAO. The OIG would cover charity care services provided by 340B DSH, Cancer and Children’s hospitals, including specific analysis of child site charity care services. The OIG report must be completed within two year of enactment. The GAO would be required to issue two separate reports. One report would analyze the contracts between 340B DSH hospitals and state/local governments, including how the agreements define low-income individuals, whether HHS reviews the low-income individual definitions and the amount of care provided by hospitals under the agreements. The second report would analyze the data reported by hospitals related to aggregate costs and gross reimbursements for 340B drugs. The GAO reports would be required to be released within one and two years of enactment of the bill, respectively.

Analysis

The 340B PAUSE Act has the potential to disrupt and burden 340B Program operations for DSH, Cancer and Children’s hospitals participating, or intending to participate, in the 340B Program. However, in its current form, the 340B PAUSE Act itself would not incorporate many of the more significant changes to the 340B Program that many have been expecting in anticipated 340B legislation. For example, the 340B PAUSE Act does not propose to change the definition of “patients” eligible to receive 340B drugs or place restrictions on the prices that may be charged for or dispensing arrangements for 340B drugs. Further, the provisions in the bill apply only to DSH, Cancer and Children’s hospitals. Federal grantee and contractor participants in the 340B Program are completely outside of the scope of the bill, as are hospitals participating in the 340B Program as Critical Access Hospitals, Rural Referral Center (RRC) and Sole Community Hospitals (SCH).

Nevertheless, the 340B PAUSE Act represents a potential turning point for the 340B Program. The bill reflects a desire by some in Congress to increase hospital information transparency in the 340B Program, as well as a concern that hospitals participating in the 340B Program are exceeding the original Congressional intent and scope of the 340B Program. Notably, the 340B PAUSE Act imposes new requirements on 340B-participating hospitals without offering any commensurate benefits in return. For example, hospital advocates and others have pushed for relief from the recently implemented Medicare payment cuts for 340B drugs, but many observers speculated that such relief would come with some program changes, like a moratorium and data reporting requirements. The 340B Pause Act imposes the moratorium and data reporting, but does not include

changes sought by hospitals. Separate from the 340B PAUSE Act, legislation has also been introduced in Congress that would prevent HHS from continuing to impose the Medicare payment cuts to 340B drugs that took effect on January 1, 2018.

Of further note is the attention the bill pays to the contracts between hospitals and state/local governments. These contracts have been a requirement for nonprofit hospitals participating in the 340B Program since its creation in 1992, but have not historically been a focus of 340B Program eligibility, Congressional inquiry or HHS oversight. Hospitals requiring such contracts must attest to the existence of the contract at registration, but are not routinely required to provide copies of the contracts to HHS for review. The attention to the contracts in the bill suggests that Congress is contemplating future changes to the 340B Program that would relate to the scope of or services furnished under the contracts. If that were to occur, it could have the potential to materially shrink the 340B Program for most hospitals.

For hospitals currently-participating as DSH hospitals that are contemplating new or relocating off-campus outpatient locations, recently opened off-campus outpatient locations or recently registered off-campus outpatient location, those off-campus locations may be unable to receive the benefit of 340B Program participation for at least two years following the date of enactment of the bill, if it were to be enacted. Therefore, these hospitals should be prepared to evaluate what the loss of expected 340B participation might mean for those location, closely track the status of the bill, and consider aligning future expansion plans with legislative developments. Such hospitals may also want to evaluate whether the hospital is eligible for participation in the 340B Program as a RRC or SCH, which, at least under this bill, would not be subject to the moratorium. Hospitals not currently enrolled in the 340B Program, but contemplating participating in the 340B Program as a DSH hospital, may also wish to evaluate eligibility to participate as a RRC or SCH.

The 340B PAUSE Act is likely just the starting point for a larger conversation on legislative changes to the 340B Program that will occur in 2018. It is also expected that the House Energy and Commerce Committee will release a report on their recent 340B Program hearings, which will likely include additional recommendations for 340B Program legislative changes.

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