

HOSPITALS FEAR PANDEMIC MAY THREATEN THEIR ELIGIBILITY TO PARTICIPATE IN THE 340B DRUG PROGRAM

In a March 20, 2020 [letter](#) to HHS Secretary Azar, 340B Health, a membership organization consisting of more than 1,400 nonprofit hospitals in the 340B drug pricing program, advised the Secretary that its member hospitals fear the COVID-19 public health emergency could have a “material impact” on hospital admissions and payor mix, which, in turn, could threaten hospitals’ ability to participate in the 340B program. Senator Ben Sasse (R-Neb.) then introduced Senate Bill 3631 with provisions that would prevent hospitals from losing their 340B program eligibility during the COVID-19 pandemic provided they met 340B eligibility requirements for the cost reporting period prior to the date the COVID-19 public health emergency went into effect. The bill has stalled and passage is unlikely. Since uncertainty remains regarding the impact of the COVID-19 effect on patient payor mix and associated 340B eligibility, 340B hospitals should closely monitor their inpatient admissions and disproportionate share hospital (“DSH”) payment adjustment percentage unless and until a legislative or administrative agency fix is implemented to protect against pandemic-related 340B program disqualifications.

340B PROGRAM BACKGROUND

The 340B program requires drug manufacturers to sell outpatient drugs at a discount to safety net providers (defined under the Public Health Service Act as “covered entities”) that care for high numbers of low-income Medicaid and Medicare/Supplemental Security Income (“SSI”) patients. Six categories of hospitals—DSHs, children’s hospitals and cancer hospitals exempt from the Medicare prospective payment system, sole community hospitals, rural referral centers and critical access hospitals (“CAHs”)—as well as ten categories of non-hospital covered entities are eligible to participate in the 340B program.

Except for CAHs, 340B hospitals must have a certain level of DSH adjustment percentage. For example, DSH hospitals must have an adjustment percentage greater than 11.75% and others at least 8%. The magnitude of a hospital’s DSH adjustment percentage depends on the number of inpatient days of its Medicaid and SSI patients, and this requirement is key insofar as the pandemic potentially could result in DSH adjustment percentages decreasing if hospitals are admitting a higher number of self-pay or non-Medicare/Medicaid patients.

THE ISSUE

During the height of the pandemic, a number of 340B hospitals temporarily increased their inpatient bed capacity and halted non-emergent/non-urgent procedures in order to manage a potential COVID-19 surge in admissions. Hospitals fear these changes may have resulted in temporary changes in their payor mix due to an influx of non-Medicaid and non-Medicare/SSI admissions. Payor mix also may have changed due to an intentional shift to outpatient care and virtual care to preserve inpatient beds for critically ill COVID-19 patients and to prevent the spread of infection. If any of these changes reduced a 340B hospital’s DSH adjustment percentage to a level under the threshold for 340B program participation, hospitals potentially could be terminated from the 340B program for factors outside their control. Since a 340B qualification determination is based on cost report data, a hospital might not know whether it was being terminated from the program for some time.

A PROPOSED FIX

Senator Ben Sasse (R-Neb.) introduced [Senate Bill 3631](#) entitled the “Relief for Rural Providers During Emergencies Act” (the “Act” or “S.B. 3631”) on May 6, 2020, in part, to address an unintended outcome of the pandemic that could result in hospitals no longer being eligible to participate in the 340B pricing program.

Sections 2(a)(1) and (2) of the Act provide that for cost reporting periods ending in 2020 or 2021 or for other cost reporting periods in which the COVID-19 public health emergency is still in effect, the Secretary of HHS must “pause” the process for determining whether a 340B covered entity continues to be a covered entity and deem a covered entity that prior to the COVID-19 public health emergency met all 340B requirements as continuing to meet all requirements for being a covered entity. Further, the Act would require the Secretary of HHS to extend the application of subsections 2(a)(1) and (2) to *other* cost reporting periods (e.g., cost reporting periods after the public health emergency has ended), if necessary, to ensure no covered entity loses its eligibility to participate in the 340B program for any reason related to the COVID-19 public health emergency.

PRACTICAL TAKEAWAYS

1. 340B hospitals should monitor their inpatient admission statistics during the pandemic to determine whether they might be in danger of failing to meet applicable DSH adjustment percentage requirements. Hospitals may not have much control over their inpatient admission payor mix but at least can be prepared to start advocating for their continued 340B program eligibility status.
2. To date, no other senator has agreed to co-sponsor B. 3631 with Senator Sasse. The bill likely does not have enough support or traction to progress to enactment. That said, it is possible that the 340B provisions of S.B. 3631 could be incorporated into a future, larger COVID-19-related bill later this year. However, 340B hospitals should not assume there will be a quick legislative fix.
3. The HHS HRSA Office of Pharmacy Affairs (“OPA”) administers the 340B program. To the extent no law passes that provides for mandatory flexibility on 340B requirements, hospitals that may be affected by a pandemic-related DSH adjustment percentage drop below threshold requirements should contact the OPA to work through this issue from both a legal and advocacy perspective.
4. It is possible that additional hospitals not previously eligible to participate in the 340B program will become eligible due to *increased* Medicaid admissions during the pandemic that drive up the DSH adjustment percentage. Low-income individuals may not have the option to do their jobs remotely and, thus, may have a greater chance of becoming infected and needing hospitalization.

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Hall Render’s attorneys and professionals continue to maintain the most up-to-date information and resources at our [COVID-19 Resource page](#), through our 24/7 COVID-19 Hotline at (317) 429-3900 or by contacting your regular Hall Render attorney.

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