Insight

Reforming 340B

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The 340B Program

The 340B drug pricing program requires pharmaceutical manufacturers to provide outpatient medications at steeply discounted prices to certain types of hospitals and health clinics. Intended to provide critical cost savings for hospitals and other entities that provide charitable care for patients without health coverage, eligibility for the largest proportion of entities participating in the program is based on a funding formula that relies on the proportion of Medicare and Medicaid inpatients served by a given hospital. As 340B enters its third decade as part of the federal health funding structure, now is a good time to reevaluate and make sure it is working as intended. This short paper argues that a fundamental change in the formula would better reflect the program's stated priority.

Background

In 1990 Congress created the Medicaid Drug Rebate Program to regulate the prescription drug manufacturer ceiling price for drugs provided to Medicaid patients. Under the statute, Medicaid became a "preferred provider," which requires manufacturers to offer Medicaid the 'best price' offered to any other health insurance provider.

Though the statute was written with the intent to lower the cost of Medicaid care, it contained no exception in the 'best price' calculation for charitable giving. Before the statute was passed, many drug manufacturers regularly donated prescription drugs to health care facilities with high volumes of low-income patients in exchange for a tax deduction and the good-will of the community. However, under the 1990 statute, if a drug manufacturer donated drugs to any health care facilities it would be obligated to offer the drugs at the same price for all Medicaid patients. With this mandate in place, charitable giving constricted and facilities with high volumes of low-income patients had to absorb the

added cost of providing drugs.

In 1992 Congress attempted to address the lack of voluntary pharmaceutical drug donations by amending the Public Health Service Act (PHS) to create the 340B program. The purpose of the program, according to the Secretary of the Department of Health and Human Services (HHS) was to "stretch scarce Federal resources" further. The program functions by setting a "ceiling price" for what drug manufacturers can charge health care providers that qualify as Covered Entities (CEs).[1]

House 340B Discussion Draft

During committee consideration of H.R. 6, the 21st Century Cures Act, a discussion draft detailing potential changes to the 340B program leaked to the public. Although those provisions did not make it into the final version of H.R. 6, they still give us a glimpse into how some in Congress may view 340B and the role it will play in the future.

While the provisions contained in the discussion draft may have been intended to help patients, the effect is to reimage 340B as a program to benefit CEs. This is evident in the language stating the purpose of the program as "enable[ing] covered entities who serve as safety net providers for uninsured, underinsured, underserved, and medically vulnerable patients to utilize scarce resources to the maximum extent practicable for purposes of increasing such patients' access to, and receipt of, health care services."

The discussion draft also contained numerous new reporting requirements intended to enable the Department of Health and Human Services (HHS) to audit hospitals and ensure that savings from 340B are passed along to patients. Accountability in federal programs is always desirable, however aside from the difficulty, if not futility, of measuring whether patients receive a tangible benefit from 340B, especially when compared to the benefit received by the hospitals, the added administrative burden itself would greatly diminish any benefits which would otherwise be passed on to patients.

A Better Approach to 340B Reform

Currently, in large part because of 340B's reliance on the DSH percentage, eligibility is granted to hospitals with the most Medicare and Medicaid inpatient cases. 340B, however, was intended to reimburse CEs for uninsured outpatient cases. These programs have entirely different measures that have been used interchangeably with disastrous results. Even the Government Accountability Office (GAO) has recommended changing this usage of the DSH percentage as GAO was unable to find *any* correlation between DSH eligibility and the amount of uncompensated care an entity provided. Some CEs are receiving benefits that

they were not intended to receive, while facilities in need of help with uncompensated care cases are going without.

For one quarter of 340B hospitals, charity care made up less than 1 percent of hospital patient costs, and 45 percent of 340B hospitals provide charity care that makes up between 1 and 3.3 percent of patient costs. The national average for charity care, including in for-profit hospitals, was 3.3 percent. In fact, only 20 percent of 340B CEs provide 80 percent of total charity care under the 340B program.[2]

These unintended results will only become magnified as a result of the Affordable Care Act (ACA). The ACA expands Medicaid eligibility to a new population – those up to 138 percent of the Federal Poverty Level (FPL) and childless adults. The ACA also forces some people who were previously insured in the private market into the Medicaid program, further increasing the Medicaid population. This increase in Medicaid eligibility will inevitably increase hospitals' DSH percentage and thus likely the number of hospitals that qualify for the 340B program, despite the fact that levels of uncompensated care should be decreasing.

Solution

By removing the connection between the unrelated DSH and 340B programs, lawmakers could significantly improve the effectiveness of the 340B program. Because DSH eligibility is such a poor approximation of the level of uncompensated care a CE provides, removing this qualification will help ensure that 340B benefits reach their intended beneficiaries.

It would be difficult to simply remove the DSH calculation without finding an appropriate replacement. Without the DSH qualifier, many CEs that do provide a great deal of uncompensated care would become ineligible because they do not meet one of the few, restrictive categories of otherwise approved entities.

The replacement calculation should be based on a minimum amount of charitable care provided to uninsured patients as a percentage of total patient costs, including both inpatients *and* outpatient treatments. DSH eligible hospitals would still receive Medicaid and DSH funds, so there is less need to compensate them for this care than care provided to the entirely uninsured. Those facilities that do qualify for 340B would retain their current ability to use 340B for cross-subsidization.

Though the national average cost of charity care provided by all hospitals is 3.3 percent of patient costs, 69 percent of 340B hospitals provide charity care at rates below 3.3 percent. If lawmakers were to make 340B benefits available only to entities that meet or exceed this

national average of 3.3 percent charitable care (subject to upward adjustment as necessary), the 340B program would be more narrowly tailored while providing incentives for more hospitals to provide charity care to indigent patients.

This formula would help the 340B program to reach its target population while encouraging hospitals and other facilities to provide more charitable care in order to reach the 3.3 percent benchmark. By basing 340B eligibility on charitable spending, we could mitigate the incentive to rush uninsured patients out the door, helping to ensure that all patients receive the best possible care. At the same time, because 340B eligibility would require charitable care as a minimum proportion of total patient costs, CEs would also have an incentive to keep costs low for other insured patients so as not to exceed this 3.3/ 96.7 ratio. These incentives will be all the more powerful if total patient costs include both the inpatient and outpatient setting: denying benefits to facilities that fail to provide charitable care in either setting, while rewarding an entire facility for its charitable work.

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[1] Covered entities are deemed eligible to participate in the program if they receive one of 10 federal grants or are one of the following six types of hospitals: children's or cancer hospitals exempt from the Medicare prospective payment system, sole community hospitals, rural referral centers, critical access hospitals, or Disproportionate Share Hospitals (DSH).