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Protect 340B Drug Pricing Program

Key Points

- The 340B program is an important program that helps hospitals extend care in their communities.
- The program costs the federal government nothing and actually saves money in Medicare by allowing for lower reimbursements to critical access hospitals.
- While Congress has considered additional oversight, hospitals already devote significant resources to ensure program integrity compliance.

Program Background

Created under Section 340B of the Public Health Service Act in 1992, the 340B statute requires pharmaceutical manufacturers participating in Medicaid to sell outpatient drugs at discounted prices to not-for-profit and government-related health care organizations that care for many uninsured and low-income patients. Congress created the program with the goal of helping hospitals "stretch scarce Federal resources as far as possible," and currently limits participation in 340B to following types of hospitals:

- Disproportionate Share (or DSH) hospitals.
- Certain Children's Hospitals
- Certain Cancer Hospitals
- Rural Referral Centers
- Sole Community Hospitals
- Critical Access Hospitals

In Wisconsin, about half of our more than 140 hospitals statewide participate in the 340B program.

How Does 340B Work?

One of the great things about 340B is it costs the government nothing, but is simply a discount required of pharmaceutical manufacturers in exchange for access to Medicaid's beneficiary market. The program stipulates the following discounts that drug manufacturers must offer:

- 23.1% - most brand name drugs
- 17.1% - certain pediatric drugs
- 13% - generic drugs
- Higher discounts for drug prices that increase quicker than the rate of inflation.

In fact, the program actually saves money in the Critical Access Hospital (CAH) program, which reimburses hospitals based on their actual costs. In other words, increasing the cost for CAHs to acquire these drugs would, in turn, increase the cost the federal government pays to reimburse CAHs for the same drugs. While some in the pharmaceutical industry have argued that 340B increases drug costs elsewhere, the total discounts offered in the 340B program in 2016 represented only 2% of total US drug sales that year. Additionally, many pharmaceutical manufacturers offered similar discounts to non-profit entities on a voluntary basis prior to the creation of the program in 1992.

Impact on Rural Communities:

- The 340B program helps hospitals stretch scarce federal resources by offsetting a small portion of the losses hospitals experience due to shortfalls in funding in government programs like Medicare and Medicaid, as well as uncompensated care.
    - According to the most recent data, Medicare and Medicaid pay, on average, about 87 cents on the dollar of what it costs hospital to provide services.
    - In Wisconsin, reimbursements are much worse: Medicare pays closer to 75 cents on the dollar, while Medicaid pays only about 65 cents on the dollar.
- In addition to offsetting government underfunding, hospitals use 340B savings to benefit their local communities by expanding access to important health care services. Examples of this include:
    - Funding low cost or free dental clinics.
    - Funding remote prescription drug dispensing sites, so that folks in rural areas do not have to drive as far to obtain prescription drugs.
    - Funding low cost or free health care clinics to ensure people without insurance or with inadequate insurance have access to essential care and affordable medications.

340B Cuts in the Centers for Medicare and Medicaid Services 2018 Outpatient Payment Rule

- In 2018, CMS reduced 340B payments by 28.5% for many disproportionate share (DSH) hospitals.
- ***Wisconsin's Estimated Impact***: -$40 million annually across 10 DSH hospitals and health systems.
- WHA and other hospital groups believe HHS acted unlawfully in issuing these cuts, and participated in an amicus curiae lawsuit to reverse the cuts.
- A federal judge recently issued a ruling agreeing with hospitals that HHS failed to follow federal law as enacted by Congress, noting:

    "Congress could very well have chosen to treat Medicare reimbursements for 340B drugs differently than reimbursements for other separately payable drugs, but it did not do so. To the extent the Secretary disagrees on policy grounds with Congress's decision, the Secretary may either collect the data necessary to set payment rates based on acquisition costs, or he may raise disagreement with Congress, but he may not end-run Congress's clear mandate."
- Unfortunately, the issue is not yet clearly settled. The court has ordered a briefing to consider how to provide a remedy for hospitals and HHS may appeal the decision.

Recent PBM Issue

- Fortunately, CAHs, cancer hospitals, and other rural hospitals were not impacted by the CMS cuts.
- However, the Pharmacy Benefit Manager (PBM) CVS Caremark recently announced a policy, seemingly modeled off the CMS cuts, where it is planning to cut reimbursements to 340B affiliated entities, including small rural CAHs.
    - We believe **this is wrong;** ***the 340B program was intended to help non-profit hospitals stretch scarce federal resources, and the PBM industry should not be trying to profit off a program designed by Congress to benefit non-profit hospitals.***

WHA Position

- 340B continues to be an important program that stretches scarce federal resources for more than 70 hospitals in Wisconsin and helps them extend important services in their communities.
- Participants in the 340B program already devote significant resources, including conducting internal audits, toward compliance with federal 340B program rules.
- ***The Wisconsin Hospital Association and its members are committed to good stewardship of taxpayer dollars and strongly support reversing the cuts made in the 2018 OPPS rule while protecting access to the 340B program for all participating hospitals.***

January 2019