340B: A programme worth fighting for

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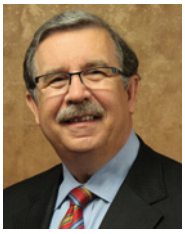

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Abstract The federal 340B drug discount programme is essential to helping safety net providers meet their missions to treat the underserved. The programme is under heavy attack in Washington, DC by the drug industry, which wants to gut it to maximise profits. At stake is US$4.5bn in savings that funds free/low-cost medicines for the needy and a panoply of clinical and pharmacy services to help uninsured, underinsured and other vulnerable Americans. Strong advocacy from health providers is crucially needed to protect the 340B programme. The authors present a strategy to clearly and publicly state the benefits of the programme to the media and Congress.

KEYWORDS: 340B, safety net hospital, drug discount

At a time of skyrocketing medicine prices, the little-known 340B drug discount programme is under attack by the pharmaceutical industry. This calls for focused action by safety net healthcare providers and a clear strategy to protect a programme essential to treating the underserved in the United States.

The programme was created with bipartisan congressional support in 1992 to give safety net hospitals and other healthcare providers a way to stretch resources and serve more patients. These non-profit and public hospitals treat nearly twice as many poor patients and shoulder a staggering US$24B per year in uncompensated care.[1]

Under the 340B programme, providers receive discounted medications from pharmaceutical manufacturers. The providers supply the medications for free or at a substantial discount to needy patients. Hospitals can also sell the drugs to insured patients at market rates and use the proceeds to help fund vital services for the community, including oncology, HIV/AIDS, mental health, diabetes, dental and primary care clinics.

Even with the arrival of the Affordable Care Act, 28 million Americans remain uninsured.[2] As well, 31 million Americans are underinsured with high deductible policies, a number that has tripled since 2003.[3] Often, these individuals don't realise the extent of their financial exposure until they get sick. In a recent survey of members of the trade association 340B Health, close to 80 per cent of hospitals reported an increase in the number of underinsured outpatients.[4]

Simply put, the 340B programme is needed now more than ever.

The positive effects of the programme are felt every day at safety net hospitals across the United States. At MetroHealth in Cleveland, OH, 80 per cent of patients are on Medicare, Medicaid or are uninsured. The system spends US$57m per year on uncompensated care. The 340B programme is instrumental in helping low-income patients with diabetes and cancer afford treatment.[5]

The 340B programme also helps MetroHealth embed care coordinators and behavioral health professionals in hospital clinics to promote integrated treatment for patients.

At Bon Secours Hospital in Baltimore, MD, the programme helps fund discounted prescriptions for patients in one of the poorest areas of the city as well as health fairs in the community and other services.[6] Hospitals throughout the nation that serve high low-income populations depend on the 340B programme to continue this healthcare mission.

Pharmaceutical companies want to scale back the programme by limiting hospital and patient eligibility. And this from an industry that has pushed drug prices to astronomical levels. Brand name prices are surging and a recent analysis by Bloomberg found that 400 formulations of drugs are up 10 per cent since December 2015. Since 2014, 60 medicines have doubled and 20 have quadrupled in price.[7]

The price increases are staggering for hospitals, even for many common drugs that have been used for years. For example, the anti-fungal medicine flucytosine has shot up from US$500 to US$11,433 for 100 500mg capsules. The heart drug Isuprel has jumped nearly 15,000 per cent and now costs US$1,522 per vial.

The result for patients? Higher healthcare costs.[8] State Medicaid leaders are also deeply concerned that the trend towards the new generation of ultra-expensive drugs like Harvoni for Hepatitis C (US$95,000) is unsustainable and will shatter their budgets.[9]

The price increases aren't just problematic from a healthcare economy standpoint. They directly affect health outcomes because patients are less likely to fill prescriptions they can't afford. As it stands now, more than 20 per cent of prescriptions go unfilled in the United States.[10] The adherence issue is particularly acute for low-income individuals,

the primary patient population treated by safety net hospitals.

When patients don't fill their prescriptions, or take fewer doses to stretch their supply, they get sick again — often seriously. That leads to an estimated US$100bn each year in excess hospitalizations.[11]

It's important to understand that 340B is not taxpayer funded. The programme is paid for by drug companies and represents just 2 per cent of the US$457bn pharmaceutical market.[12] By contrast, the drug industry spends 6 per cent — or US$27bn[13] per year — on marketing alone. Gilead Sciences spent a staggering US$100m to market Harvoni in 2015 and much of that money went to buying 'ask your doctor' television advertisements.[14]

THE CURRENT POSITION

The drug industry says it wants to 'reform' the 340B programme. In Washington-speak, that means dismantle it. Big Pharma is aggressively pursuing the strategy both legislatively in Congress and through proposed regulatory changes at the Health Resources and Services Administration (HRSA), the federal agency responsible for overseeing 340B.

At a congressional hearing in March 2015, both critics and supporters weighed in. '. . . Through the years, the [340B] programme has allowed covered entities to stretch scarce resources to better serve millions of patients in Michigan and across the country who are uninsured, underinsured, or dependent on programmes like Medicaid and Medicare,' said Rep. Fred Upton (R-Mich.), chairman of the US House Energy and Commerce Committee.

Some members expressed concern about growth in the programme and the extent to which hospitals in the programme use savings to treat the underserved.

The bottom line: a hospital has to demonstrate that close to 30 per cent – at a minimum — of its patients either participate in Medicaid or are or are low-income, disabled Medicare beneficiaries in order to qualify for 340B. These hospitals treat significantly more Black, Hispanic, disabled, and low-income qualifying for Medicaid patients as other providers.[15]

Despite the programme's demonstrated success, 340B critics will continue to lobby Congress and the administration with the stated goal to limit 340B to indigent, uninsured patients. Such a move would eliminate providers' savings on drugs through 340B and cause the majority of providers to drop out. The outcome? Reduced access to medications and clinical services for the poor and other vulnerable populations.

The potential for dramatic restrictions to the programme are not limited to the congressional arena. In August 2015, The Health Resources and Services Administration, the agency that oversees the programme, published wide-ranging proposed changes to the programme. While the agency should be applauded for its efforts to update and clarify its guidance, the proposed rules would severely limit patient eligibility and the ability of safety net providers to generate savings through the programme to help treat the needy.

In a survey in 2016 of 340B hospitals, half of hospitals said the combined impact of the draft provisions would be 'highly problematic' to their patient-care mission. Close to one-third of hospitals said they would consider dropping out of the programme if the proposal is not altered.[16]

One of the most troubling provisions in the proposed guidance is a new definition of 'patient' that includes a demanding, six-part test. Under the proposal:

- Prescriptions given to patients upon discharge from a hospital would be ineligible for discounts. This would be a major departure from how 340B has always functioned and would eliminate an important tool for preventing hospital

readmissions. It also limits a major source of savings that enables safety net hospitals to treat uninsured, underinsured and other vulnerable patients.

- Cancer drug prescriptions written outside of the hospital would be ineligible for 340B. This new interpretation of the 340B patient definition would penalise hospitals when patients consult outside experts for diagnoses and treatment plans and then return to their local hospital for drug administration. This practice is particularly common in rural hospitals that often do not have an oncologist on staff. The result? Infusion clinics will close, medication discounts for the needy will become less available and many patients will have to travel hundreds of miles to receive care.
- 340B discounts would be prohibited for outpatients later admitted to the hospital. This proposal would not allow certain outpatient drugs provided in the emergency room from 340B pricing. This includes lifesaving medicines administered to stroke patients upon arrival in the emergency room (ER) before being admitted.

Not all of the proposed guidance is negative. HRSA let stand the important contract pharmacy programme, which helps patients obtain medications closer to home. There are also provisions that would require manufacturers to issue refunds for overcharges without having to be formally asked to do so by a hospital.

Another challenge to the programme comes from Medicare, which is considering ways it could steer part of the estimated US$1.3bn in 340B savings that accrue to hospitals annually through the Part B programme.

The Medicare Payment Advisory Commission (MedPAC) has recommended that Congress reduce Medicare Part B drug reimbursement for 340B hospitals by 10 per cent of average sales price, which would cut the amount a hospital saves on a Part B drug by about 30 per cent. The panel, the recommendations of which are non-binding, suggests putting the savings into the Medicare-funded hospital uncompensated care pool and to distribute payments from the pool on the basis of data from Medicare cost reports.

Advocates for providers serving the poor have serious concerns with the proposal. They point out correctly that 340B is outside of MedPAC's purview and warn that vulnerable patients would suffer if Congress were to adopt the recommendation.

In an earlier report, the agency cautioned that 'it is important to note that our analysis was entirely financial. We did not examine the effect these changes would have on covered entities' ability to serve their communities.'[17]

That's a rather large caveat. While such a plan might be conveniently advantageous to the government, cutting Medicare Part B payments would be inconsistent with the purpose of 340B—to help safety net providers care for the poor and continue their indigent-care mission.

CLEAR IMPACT

The Charleston Area Medical Center is the tertiary teaching and safety net hospital for central and southern West Virginia. The hospital's mission is to take care of all patients, including those who are critically ill requiring highly specialised acute care services and have no ability to pay. CAMC has the only Level I trauma center for the region and runs one of two Level III neonatal intensive care units in the state.

The hospital provided US$73m in uncompensated care in 2014. CAMC supplies 22.4 per cent of all charity care provided by acute care hospitals in the state.

Savings from the 340B programme, which total US$8m at CAMC annually, are extremely critical to its mission. The funding is used to partially offset uncompensated and Medicaid losses and to provide direct financial assistance to a free clinic and a

programme that provides access to healthcare to the working poor.

West Virginia Health Right is a large free clinic located a few blocks from the hospital's main campus. The clinic treats 16,000 patients and receives more than 65,000 visits annually. CAMC provides all outpatient and inpatient services at no charge for the uninsured—a write off of US$10m per year. Despite Medicaid expansion, 50 per cent of West Virginia Health Right's patients remain uninsured.

340B savings also help the hospital fund the Community Access Programme, which provides access to free healthcare for the working uninsured.

The hospital has some important concerns about the proposed guidance from HRSA, including limitations on 340B pricing on discharge medications and overly onerous bundled billing requirements.

It is critically important that hospitals step forward and publicly document how they use their 340B savings to benefit underserved patients. A one-sheet impact profile designed by 340B Health makes that process quick and easy. It gathers data on patient population, payer mix, annual savings, annual uncompensated care and weaves in examples of drug discounts and clinical services provided. We encourage safety net hospitals to post the document on their websites and update it regularly.

ACTION ITEMS

In this era of intensified scrutiny, it is crucial that safety net hospitals become proactive in publicly documenting how they use 340B savings to help poor, uninsured and underinsured patients. Every provider has an important and compelling story to tell. Recommended actions for hospital CEOs:

- Fill out an impact profile and post on your website.
- Write a pro-340B op-ed in your local paper.
- Reach out to your congressional delegation and explain the importance of the programme and how it helps you treat the underserved in their districts.
- Invite your congressional delegation to visit your hospital and its pharmacy.
- Join 340B Health's 340B Executive Council.
- Ask your oncologists and other cancer clinicians to join 340B Health's Oncology Council.

The 340B programme is essential to the future of a strong healthcare safety net in the United States. Tens of millions of underserved patients depend on it every year. We need to ensure that the healthcare providers that take care of these patients can continue this critical mission.

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