



A driving force for health equity

July 28, 2023

The Honorable John Thune
511 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Debbie Stabenow
731 Hart Senate Office Building
Washington, DC 20510

The Honorable Shelley Moore Capito
172 Russell Senate Office Building
Washington, DC 20510

The Honorable Tammy Baldwin
709 Hart Senate Office Building
Washington, DC 20510

The Honorable Jerry Moran
521 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Benjamin L. Cardin
509 Hart Senate Office Building
Washington, DC 20510

Re: Request for Information on the 340B Drug Discount Program

Dear Senators Thune, Stabenow, Capito, Baldwin, Moran, and Cardin,

On behalf of OCHIN, I appreciate the opportunity to provide comments on the 340B Drug Discount Program. [OCHIN](https://ochin.org) is a national nonprofit health information technology and research network that offers technology solutions, informatics, evidence-based research, and policy insights. OCHIN serves more than 2,000 community health care sites with 25,000 providers in 40 states, reaching more than 8 million patients. For two decades, OCHIN has advanced innovative health care solutions by leveraging the strength of our network's unique data set and the practical experience of our members to drive health innovation at scale for patients and providers in rural and underserved communities. We strongly urge Congress to advance legislation that will ensure patients' access to affordable medication and health care services and ensure their providers are able to leverage the savings and resources of the 340B program that are currently being whittled away by pharmaceutical companies, pharmaceutical benefit managers, and through state Medicaid clawbacks.

The urgency of legislative action continues to mount as rural providers face extreme financial crisis leading to worsening health outcomes and community-based clinics, including federal qualified health centers, look alike, and other providers serving patient populations facing significant structural barriers, face the confluence of increasing needs due to long COVID health effects, the opioid use disorder public health emergency and deepening mental health crisis. Our members are on the frontlines of these challenges just as pharmaceutical companies and insurers further reduce resources needed to maintain and expand access to care.

BACKGROUND

The 340B Affordable Prescription Drug Program (340B) ensures that patients receiving care from health centers, rural providers, and other qualifying providers obtain the prescriptions they need, regardless of their ability to pay. Equally important, the savings afforded to health centers through the 340B Program help sustain them financially, ensuring they remain open to meet community care needs. Under 340B, pharmaceutical manufacturers participating in federal health care programs are required to provide a discount to providers designated as "covered entities," which include federally qualified health centers (FQHCs) among a variety of providers. In turn, commercial and public health care payors reimburse covered community health clinics at the higher payment rates set for other providers. Community health clinics, rural clinics, and hospitals use

these savings to provide patient services, increase access to care, and provide free or reduced-price prescription drugs to patients.

In the past several years, the critical savings generated by the 340B program has been continually eroded by pharmaceutical drug companies, pharmaceutical benefit managers (PBMs) as well as some state Medicaid programs. Despite lacking the legal authority to do so, several drug manufacturers have unilaterally imposed onerous reporting requirements on participating 340B community clinics. These requirements have created costly reporting, monitoring, technical, and administrative re-engineering, staff training, and workflow re-design obligations as well as other policies that result in reduced payment. At the same time, PBMs have “pick pocketed” the savings due to the asymmetrical market power of the PBMs that allow them to force clinics to provide them a portion of the savings. Additionally, state Medicaid programs have imposed mandatory “clawbacks” of savings without making clinics whole. These practices reduce the revenue of clinics that are already stretching insufficient resources to serve their expanding patient populations due to COVID-19 and other growing public health emergencies. As a result of these actions, health centers are stripped of 340B savings mandated by Congress and their ability to provide affordable pharmaceuticals and other critical services to their patients and communities is undermined.

OCHIN examined available accounting data for 26 OCHIN network members and found that most of them depend on 340B to stay financially solvent. OCHIN members serve everyone, regardless of their ability to pay. These patients are some of the most medically and socially complex individuals in the country and without the 340B, many members would not be able to cover their costs of providing patient care. Further, we found the scale of potential revenue shortfall without the 340B program to be considerable, accounting for three times the margin of revenue over expenses on average needed to keep doors open and provide affordable medication. In the OCHIN network, the 340B program is used more by providers in rural communities. Given the health care crisis in these communities, attacks on the 340B program by pharmaceutical and health insurance companies have an increased negative impact on these patients and their providers and worsen the barriers faced by them.

OCHIN POLICY RECOMMENDATIONS

Currently, 340B provides patients with access to affordable medication and serves as a financial lifeline to community clinics. However, swift action is needed by Congress to strengthen 340B, particularly for community health clinics and rural hospitals that have a documented track record of re-investing the savings to ensure medication affordability as well as the delivery of expanded medically necessary services.

OCHIN urges Congress to take legislative action or work with HHS to:

- Ensure continued funding for each community health clinic equivalent to the annual 340B discounts and payment through policies that hold 340B providers harmless when passing affordable prescription drug reform legislation.
- Enforce current obligations of pharmaceutical manufacturers to participate with contract pharmacies and abide by requirements under 340B.
- Clarify that additional reporting requirements imposed by pharmaceutical manufacturers are prohibited.
- Implement an administrative dispute resolution process that provides covered entities a forum to adjudicate disputes.

- Stop anti-competitive practices of pharmaceutical benefit managers that are using undue market power to “pick pocket” community health clinic savings through enforcement action by the Federal Trade Commission and state laws banning such practices.
- Increase transparency, standardization of data reporting, and accountability throughout the 340B system to align with the obligations of federally qualified health centers to use savings to ensure medication affordability and expanded access to health care services.
- Block practices and policies to scale back and significantly reduce the benefits of, or increase the burden of, the 340B Program for patients and providers in rural and underserved communities including state Medicaid clawback practices.
- Revise the 340B covered entity eligibility formula to account for the level of clinical care and services provided to those who are uninsured, underinsured, or who have a qualifying low income.

Finally, OCHIN strongly urges policymakers to advance new payment and delivery models that address current funding shortfalls that, to date, have been ameliorated by 340B savings. Given the ongoing attacks on 340B, it is not a predictable nor reliable source of funding as new delivery and payment models are developed.

- While COVID-19 related congressional funding has proven essential as a stop gap to near term financial instability, providers in rural and underserved communities need support for their efforts to develop, design, test, and then fully implement alternative payment by including value-based models that innovatively incorporate and account for and address the social drivers of health.
- Although policymakers want to drive delivery reform to value-based models, there are few examples currently of sustainable models and demonstrations that can reliably scale in underinvested communities. Structural barriers and social drivers of health impact outcomes disproportionate to health care services which means providers are not able to assume risk unless highly innovative, whole patient and community approaches are tested and validated.

Thank you for your leadership and inclusive approach to gathering stakeholder feedback on the 340B program. Please contact me at stollj@ochin.org if we can provide any additional information or be of further assistance.

Sincerely,



Jennifer Stoll
Executive Vice President
External Affairs