

The Past, Present, and Future of the **340B Program**



HOW WE MOVE FORWARD FROM COVID-19: A WATERSHED EVENT





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There have been many watershed events over the past 150 years in the U.S. and around the world – moments that forever changed the course of history, moments from which you can only move forward, not back. World War I, the attack on Pearl Harbor, the rise of the internet, 9/11, and the 2008 financial crisis are just a few that come to mind.

Without a doubt, the COVID-19 pandemic has been our watershed moment of the decade, especially as it relates to health care. So many aspects of life will be impacted long-term because of this virus, from the way we do business to the way we receive health care. Of course, the federal 340B Drug Pricing Program is one of the elements of health care that has been affected and may undergo permanent change going forward. The good news is, for almost 30 years, the 340B program has proven to be dynamic and versatile. It has adapted to the changing health care landscape before and will do so again.

What is the 340B Program?

The 340B program was first enacted in 1992

to stretch scarce federal resources for safety-net hospitals and other health care providers. Under the program, pharmaceutical manufacturers sell medications used in outpatient settings at discounted prices in exchange for having their drugs covered under Medicaid and Medicare. The discounts give participating providers — known as covered entities — savings of between 25% and 50% on their medication purchases.

Covered entities use their 340B savings for a wide range of purposes, including providing low-cost or free prescriptions for uninsured and indigent patients, offering additional health care services, and expanding access to care. The 340B program involves no federal spending. About one in four Texas hospitals participates in the program.

340B in Pre-Pandemic Days

Before the pandemic, some of the big news in the 340B space was that the Health Resources and Services Administration (HRSA), which manages the program, had finalized its secure pricing website. The U.S. Government Accountability



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Office had finalized studies on both contract pharmacies and Medicaid. The Office of Inspector General had released a report on Medicare Part D, while the Centers for Medicare and Medicaid Services (CMS) released a proposed rule for a new International Pricing Index (IPI) model and a notice about Medicaid duplicate discounts. In general, government bodies were quite focused on 340B, and there was a lot of debate around reporting and transparency.

On the judicial front, Medicare Part B reimbursement cuts that CMS implemented in 2018, 2019, and 2020 were all tied up in the legal system, with appeals pending. In the legislative branch, state legislation, as well as House and Senate bills, seemed to spring up daily — some calling for more reporting on the part of covered entities, and others aiming to protect the 340B program or mandating more transparency from pharmaceutical manufacturers.

340B During COVID-19

Much of the flurry and debate around 340B has been paused as hospitals, pharmaceutical companies and government agencies have turned their focus toward figuring out how to shift priorities when faced with the realities of COVID-19.

HRSA began to pivot towards virtual audits and implemented other flexibilities. At the same time, the U.S. Department of Health and Human Services (HHS) focused on how to distribute funding appropriately to help hospitals face the expenses associated with COVID-19. CMS quietly released its 340B acquisition cost survey, despite protests from industry groups and hospitals that the timing was not appropriate given the current crisis.

The appeals process for lawsuits against CMS for its unlawful Medicare Part B cuts was put on hold, as was the Supreme Court case regarding states' ability to regulate Pharmacy Benefit Managers (though the latter has resumed). A few state bills have cropped up, including in New York and California, but they were fewer and further between

than what we'd come to expect in the days before the pandemic.

Some good arose from the public health crisis, as covered entities were not forgotten when it came to stimulus packages intended to help health care facilities and the economy overall. The Paycheck Protection Program and Health Care Enhancement Act in April provided hospital reimbursements for COVID-19-related testing and treatments for uninsured patients, as well as \$10 billion in funding for rural health clinics and hospitals. And in early June, HHS announced that, as part of the CARES Act, it would deliver \$25 billion to providers and hospitals that serve the nation's most vulnerable patients. Of that amount, \$15 billion was for providers that primarily serve Medicaid and CHIP patients, while the other \$10 billion was reserved for safety-net hospitals.

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What Does the Future Hold?

As we approach the end of the year and colder weather, COVID-19 infections are rising as testing continues to ramp up, with several states reporting record numbers of daily confirmed cases, and hospitalizations and deaths are once again on the rise in certain parts of the country. With Election Day looming, a great deal remains unknown about the medium- and long-term trajectory of COVID-19, the efforts to combat it, and our economic fate. How bad will this new spike be? Will more bankruptcies be filed? Will uninsured rates continue to rise? Will an effective vaccine finally emerge? How will vertical integration impact health care? Will the pharmaceutical industry stop its latest attempts to circumvent 340B law?

States have largely reopened their economies as the public has shown weariness with quarantines and other measures to suppress the outbreak. Many activities have resumed, which means renewed



momentum on issues such as the IPI pricing model proposal to lower the cost of prescription drugs, a decision about the Medicare Part B cuts and whether it will make it to the Supreme Court, the Supreme Court case on Pharmacy Benefit Managers, and more. Debates about drug pricing, reporting, and transparency will inevitably pick up again with manufacturers and hospitals ever struggling to find common ground.

There will also be aspects of the health care system that won't go back to the way it was before, nor pick up right where it was left off. For instance, CMS Administrator Seema Verma said that she "can't imagine going back" to a health care system where telehealth was less prominent, and so the agency is looking for ways to make the expanded access to telehealth, which was such a crucial part of care at the height of COVID-19, more permanent.

More questions remain. With high employment rates leading to fewer lives insured and expansion of Medicaid rolls, will insurers continue to provide discount drug plans? Will small pharmacy benefit managers shutter due to increased consolidation, ultimately impacting contract pharmacy benefits? Will reimbursement be at risk for high-cost specialty pharmacy drugs? With these shifts, we will need

to be more vigilant to protect any harm to 340B's intent- to help the safety-net stretch scarce resources to provide more comprehensive services to patients.

It will be up to us collectively — the hospitals, government agencies, pharmaceutical companies, and patients— to decide what we take away from this experience and what we leave behind. Resilience and adaptation are everything. Can you imagine a world before the internet? A world before Amazon became a household name? A world before 9/11 changed how we travel and how we think about security? The moments that change us forever can be positive or negative, but it's how we react to them that makes the difference.

Whatever the future holds, there is no doubt that covered entities will continue working to serve vulnerable and medically underserved populations and that the 340B program will continue to help you achieve that goal. We must protect the 340B program now more than ever to combat the health care disparities that have become even more evident amid COVID-19 and beyond. This is our time to leave disparities behind and set a new course forward.

Opinions expressed in this publication do not necessarily reflect official policy of THT.

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with powerful solutions that deliver the precision, compliance, insights and savings needed to run a successful program.

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