340B Drug Pricing Program: Serving Vulnerable Patients or Enriching Hospitals?

Victoria Stern, MA | December 02, 2014

David Peace, MD, has worked at the University of Illinois at Chicago in the Division of Hematology/Oncology for close to two decades, treating a socioeconomic and ethnically diverse population of cancer patients, two thirds of whom lack adequate health insurance.

The main reason that Dr Peace is able to care for so many insured and underinsured patients is because his hospital participates in a drug discount government program, known as the 340B Drug Pricing Program, which provides eligible entities with steep reductions on outpatient prescription drugs.

"Managing a diverse population is a challenge to begin with, and when you add on financial issues that often prevail in these families it becomes even more of a challenge," said Dr Peace. "But because of 340B, we don't have to turn patients away when they can't pay."

The 340B Drug Pricing Program, established in 1992 by Congress, provides a financial safety net for eligible hospitals and clinics, such as the University of Illinois at Chicago, that care for a large percentage of poor, indigent patients. Specifically, 340B-eligible entities are able to purchase prescription drugs delivered in the outpatient setting at steep discounts of 20% to 50%, which helps them cover financial losses incurred while providing free or low-cost care to their uninsured or underinsured patients.

"The 340B program allows funds to come back to our institution that otherwise wouldn't have been there, and helps us maintain the viability of the oncology program," Dr Peace said. "340B has been a lifeline to institutions like ours because the bulk of our patients wouldn't be able to obtain costly cancer treatments otherwise."

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Although the program covers a broad range of prescription drugs, it is especially important for cancer care, as the cost of cancer drugs has skyrocketed in the past few years. In the past decade, the price tag for new anticancer agents has increased from about $4500 to $10,000 per month, with 11 of 12 new cancer drugs approved by the US Food and Drug Administration in 2012 costing more than $100,000 per year.[1,2]

"Given the escalating prices of cancer drugs, 340B is an essential program that provides needed coverage to safety-net hospitals," said Hagop Kantarjian, MD, chair of and a professor in the Department of Leukemia at the University of Texas MD Anderson Cancer Center in Houston. "Without 340B, most of these hospitals and clinics would go broke, leaving many needy patients without access to affordable care."

Despite the need for this safety-net assistance, concerns have emerged in the past few years that the 340B program has grown too large. Between 2001 and 2011, the total number of covered entities almost doubled, from 8605 to 16,572.[3] As of July 2014, 2138 hospitals participated in the program, which encompasses just over 35% of all hospitals in the United States. Additionally, discounts from 340B increased from $1 billion to $6 billion between 2003 and 2010.

It's unclear, however, whether many of these newly eligible institutions are using revenues from 340B drug discounts to

help needy patients. One report from the healthcare advisory firm Avalere Health found that a minority of 340B-eligible hospitals today (20%) appear to shoulder the bulk of the charity care (80%) delivered by all eligible hospitals, and that 69% of covered hospitals provide charity care rates below the 3.3% national average for all hospitals.[4] Perhaps most worrying, however, is a 2014 report from the Office of Inspector General that uncovered many eligible entities that are failing to pass on 340B discounts to their uninsured patients.[5]

"Such findings suggest a need to re-examine policy around a program that was intended to enhance services for medically indigent patients," Peter Yu, MD, president of the American Society of Clinical Oncology (ASCO) and director of Cancer Research at Palo Alto Medical Foundation, told Medscape. "Given the integral role that drug therapies often play in cancer treatment, we are concerned that access to life-extending, life-saving treatments for low-income patients will not be expanded because the program does not require that added revenues be allocated to outpatient clinics serving this population."

Controversy Over 340B Expansion and Oversight

When the 340B program was developed more than 20 years ago, fewer than 100 facilities in the United States qualified for 340B rebates. Eligible institutions included public health clinics, community mental health clinics and disproportionate share hospitals (DSH), which catered to a high percentage of uninsured or underinsured patients.

But over time, Congress introduced provisions that allowed more entities to fall under the 340B umbrella. In 1994, the Health Resources and Services Administration (HRSA) allowed outpatient facilities of a 340B-eligible hospital to participate in the program if the outpatient services could be reimbursed under Medicare.

From 2003 to 2010, Congress supported legislation that expanded 340B benefits to rural, small urban, and children's hospitals, as well as outpatient settings of cancer hospitals, rural referral centers, sole community hospitals, and critical-access hospitals. The criterion for a hospital's eligibility was based on the DSH percentage, or the share of low-income patients insured by Medicare and Medicaid. Although the metric aims to estimate the percentage of needy patients that a hospital treats, some critics contend that the DSH percentage is an inadequate representative for 340 eligibility because it is based on inpatient care and does not reflect the percentage of uninsured patients or charity care assumed by the hospital, nor the hospital's outpatient drug demands.

The expansion of 340B can also be traced by the HRSA's decision in April 2010 to allow 340B entities to contract with an unlimited number of pharmacies as opposed to just one, as HRSA originally had stated in 1996. According to HRSA, the number of contract pharmacies has increased from 3785 in 2010 to 30,046 in 2013.

One of the biggest drivers of 340B expansion appears to be an unintended consequence of the Medicare Modernization Act of 2003, which changed the Medicare reimbursement formula. Prior to 2003, Medicare felt that it was overpaying for these drugs and providing overly generous profit margins to private oncologists. In response, Congress reduced reimbursement to reflect the drug's sale price more closely. The legislation, which took effect in 2005, lowered the rate at which Medicare reimbursed oncologists for chemotherapy drugs by as much as 75%. The decreased reimbursement for drugs left many oncology clinics and private practices unable to survive financially, with some going bankrupt or selling their practice to a hospital. Between 2007 and 2013, 288 oncology clinics shut their doors and 469 were purchased by a hospital, according to research conducted by the Community Oncology Alliance (COA).[6]

According to a 2013 ASCO survey, 63% of smaller community practices said they might merge, sell, or close in the next year. This landscape of cancer care, which appears to be shifting care away from private practices and community clinics and towards hospitals, may be allowing some 340B hospitals to expand their 340B patient network.

The cost of agents has gotten so high that smaller practices have had a lot of difficulty keeping their head above water economically because they aren't eligible for 340B pricing or don't have the sway to negotiate better discounts with drug manufacturers that a larger system can.

"I think 340B probably drives some of the consolidation of oncology care that we're seeing," Dr Peace said. "The cost of agents has gotten so high that smaller practices have had a lot of difficulty keeping their head above water economically because they aren't eligible for 340B pricing or don't have the sway to negotiate better discounts with drug manufacturers that a larger system can. Without 340B pricing and robust negotiating power, it is likely difficult for many of these independent practices to survive too long in the current system."

Given the expanding scope of 340B, there has also been debate over which patients should qualify for 340B discounts. According to HRSA's 1996 definition, a patient is an individual treated by a covered entity regardless of his or her insurance status. Under most conditions, Medicaid-insured patients are excluded from 340B rebates, but the definition does not otherwise specify the patient's insurance coverage or ability to pay. Thus, a fully insured patient treated in the outpatient setting can receive drugs at 340B prices.

"These safety-net hospitals are allowed to pass the discounts on to needy outpatients and also sell the medications to insured individuals at negotiated rates," a spokesperson for Safety Net Hospitals for Pharmaceutical Access (SNHPA) told Medscape. "They can then use the funds generated to provide vital clinical and specialized services for people who cannot afford to pay for care."

But, Rena Conti, PhD, an assistant professor of hematology/oncology in the Department of Pediatrics at the University of Chicago, pointed out that such a broad definition of a 340B-eligible patient means that some hospitals will bill a patient and insurer at the full price of a drug and pocket the difference. "In this scenario, a 340B hospital is overcharging insured patients and their insurers," Dr Conti said. "In exchange for this money, there is very limited oversight regarding whether these profits are being used to help more vulnerable patients receive care."

Indeed, she points out that, according to a report commissioned by SNHPA, only approximately 30% of the 290 hospital systems participating in the survey said that they use their 340B profits to reduce or eliminate prescription drug copayments, 15% of respondents use them to implement or maintain patient medication therapy management programs, and 4% use 340B profits for disease management programs to improve quality of care.[7]

Dr Conti is not alone in her concern that some 340B hospitals are failing to reinvest the profits gleaned from the drug discounts into their needy-patient population. In October 2012, senator Chuck Grassley (R-Iowa) sent letters to three hospitals in North Carolina—Duke University Hospital, Carolinas Medical Center, and University of North Carolina Hospital—inquiring about the revenue they received from 340B and how they reinvested those savings to benefit uninsured patients.

In its response, Duke University Hospital reported saving $48.3 million from 340B drug discounts in 2012, and a total of $158.4 million over 5 years. But only 5% of the patients for whom the hospital claimed a 340B discount were uninsured. The other 95% had Medicare, Medicaid, or private insurance.

Duke University Hospital also boasted spending about $69 million in charity care in 2012, but "arguably, some or all of these expenditures or discounts are provided in return for nonprofit status," said Adam Fein, PhD, president of Pembroke Consulting, Inc., and CEO of Drug Channels Institute in Philadelphia. According to its publically available tax returns, Duke University Hospital earned over $2.5 billion in 2012 and thus spent about 2.75% of its budget on charity care, which is below the national average of 3.3% for charity care provided by all hospitals.

"That's an enormous amount Duke is earning, and ultimately it's not clear that that money from 340B is benefiting the

uninsured or indigent patients in any way," said Dr Fein. "The problem is that there are very worthy safety-net providers that need financial assistance, but there are many others that don't and are taking it in the absence of any regulations or oversight."

Sen. Grassley's inquiries spurred an investigation by the Office of Inspector General as well as expanded oversight from HRSA. In 2013, the Office of Inspector General interviewed 30 340B institutions to learn how they operate and manage their contract pharmacy arrangements.[5] In the sample, seven of 15 DSH hospitals reported not offering 340B discounts to uninsured patients, and one of 15 community health centers failed to do so. Of the remaining 22 covered entities, 18 reported offering the discounted 340B price to uninsured patients in at least one of their contract pharmacy arrangements, and four did not provide sufficient information for the authors to conclude whether uninsured patients received the discounts. The report stated that although neither the 340B statute nor HRSA guidelines addresses whether covered entities must provide discounts to uninsured patients, without these discounts, uninsured patients end up paying full price for their prescription drugs.

In February 2013, the Office of Pharmacy Affairs performed its first audits of 340B hospitals and required all to recertify for the program. According to the federal official in charge of the program, over the course of its audits, the Office inspected 51 hospitals and expelled 271 treatment sites from the program.

Several other recent analyses have attempted to understand how 340B hospitals, clinics, and contract pharmacies are using the program. A report published earlier this year found that expansions of DSH hospitals and outpatient clinics may be increasingly serving a wealthier and more insured patient population.[8] Specifically, the study uncovered that from 2004 on, 340B DSH hospitals and affiliated clinics tended to be in communities with fewer low-income people than those registered before 2004.

"Our take-away was that 340B discounts are likely generating substantial profits from the insured patients treated in these hospital-affiliated clinics," Dr Conti said. "With the data we have, we have no way of understanding exactly how much money is being made off of 340B by each of these institutions, or how those profits are being used to care for underinsured, uninsured, and medically needy patients."

In another study, Dr Conti teamed up with Walgreens, which boasts the largest network of 340B contract pharmacies in the United States, to provide a cross-sectional snapshot of all drugs dispensed through Walgreens via 340B in 2012.[9] The aim of the study, published on November 3, was to determine what patterns emerged when comparing the drugs coming through 340B with all drugs dispensed by Walgreens. The analysis revealed that 340B prescriptions amounted to less than 1% of all prescriptions filled through Walgreens. Antiretroviral drugs were much more likely to be dispended to 340B-eligible patients, and the rest of the drugs flowing through the program treat the chronic disease burden of the entire US population.

"These findings appear to be consistent with how the 340B contract pharmacy program should be operating." Dr Conti said. "We have other evidence to suggest that Walgreens' contract pharmacies are actively serving poor and medically needy communities."

One finding, however, gave Dr Conti cause for concern. She found that the rate of generic dispensing in the overall population is about 80% across all therapeutic classes for all drugs, but in certain therapeutic categories, the percentage of 340B branded drugs dispensed by these pharmacies was dramatically higher—almost double in some cases—compared with all dispensing.

"This finding is puzzling because generic drugs provide as much clinical benefit as their branded counterparts, at dramatically lower prices for patients and payers," Dr Conti said. But she acknowledged that this study could not examine

the records of specific patients and why the use of the branded drug over the generic counterpart may be medically indicated. "This is an important direction for future work."

Future of the Program Remains Uncertain

The growth of the 340B program—and in many cases the lack of transparency with how 340B profits are being used—has prompted ASCO to issue a statement outlining its concerns over whether the program is meeting its original intent and whether better safeguards should be put in place to ensure compliance and oversight. The policy statement asked, among other appeals, for covered entities to be more transparent and accountable with their 340B revenue by providing full, comprehensive reports of their 340B savings and how much of those savings are used to serve the uninsured, underinsured, and Medicaid patients.

In response to concerns, HRSA had planned to issue a "mega-rule," which would limit the purview of the program by promoting greater scrutiny of how 340B funds are spent, stricter guidelines on which patients and hospitals should be eligible for the discounts, and clearer requirements for contract pharmacy arrangements.

SNHPA supports proper oversight of 340B and applauds HRSA for conducting audits of covered entities, but the organization has expressed some concern over HRSA's proposed rules. "Many of HRSA's recommendations could limit the ability of safety-net providers to meet their missions and provide healthcare services to their vulnerable patients, regardless of their ability to pay," a SNHPA spokesperson told Medscape.

The launch of HRSA's mega-rule remains uncertain, however. Over the summer, a district court decision put constraints on the government's ability to regulate the 340B program, postponing the rollout of the new regulations indefinitely.

In the meantime, supporters and critics worry that the program may be headed for elimination.

"I don't know how much longer the program is going to survive," Dr Peace said. "The program has expanded considerably, which has created a lot of pushback. If 340B were to be dismantled, we'd need to install a different safety net in its place." This is worrisome, he says, because "currently the Affordable Care Act is still taking root and there are a lot of patients who aren't fully covered."

Dr Kantarjian fears that the program is in peril because of the strong influence of the pharmaceutical lobby, which is also pushing to restrain or do away with 340B.

"We do want to monitor the program to make sure the money goes to expand safety-net care, but if the program is curtailed, we will see rural hospitals that barely make it already shut down," he said.

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