Drug manufacturers, and to a lesser extent hospitals, have complained for years about the shortcomings of the 340B Drug Pricing Program, which allows nearly 3,000 hospitals and approximately 10,000 health clinics around the country to buy pharmaceuticals at a deep discount as a means of generating revenue, ostensibly to help lower-income patients and their communities. Complaints from both parties have been validated by the Government Accountability Office (GAO) and the Office of Inspector General (OIG) of the Department of Health and Human Services (HHS) and discussed at congressional hearings, where the program’s opaque guidelines and barely visible program integrity efforts have been thoroughly aired.

Yet since Congress established the 340B program in 1992, very little has changed, except for the program opening to many more hospitals and clinics thanks to the 2010 Patient Protection and Affordable Care Act (PPACA). At the latest hearings on the program’s weaknesses, held in July by the U.S. House of Representatives Committee on Energy and Commerce (E&C) Subcommittee on Oversight and Investigations, U.S. Representative Fred Barton (R-Michigan), who has a number of 340B hospitals in his district, said, “I am just trying to educate the subcommittee how screwed up this program is.”

Of course, Congress, having ignored the program’s multiple deficiencies for years, has had a major role in the program’s dysfunction. Congress’ record on legislating improvements for the 340B program is somewhere between negligible and nonexistent. At the E&C hearings, U.S. Representative Frank Pallone (D-New Jersey), the top Democrat on the committee, said, “Last Congress, this committee worked on a bipartisan basis to address the concerns from stakeholders on all sides of this issue in a balanced and measured fashion.” Nothing came of that effort. Pallone’s spokesman did not respond to an email asking what the barriers were in the last Congress, and whether they are surmountable in this Congress.

But it looks like Democrats and Republicans on the Hill are waking up, and that has a lot to do with the Trump administration. The Centers for Medicare and Medicaid Services (CMS) wants to exact a severe reduction in Medicare reimbursement to hospitals for 340B drugs. That will probably force the House and Senate to confront the program’s problems and make some changes as the price for forcing the CMS to back off either somewhat or fully from its plans to hit some hospitals with revenue losses, a prospect that has hospital lobbyists crawling over Capitol Hill arguing the sky is falling.

Potential Medicare Cut Underlines Need to Rein In Program
Stephen Barlas

How 340B Works

The 340B program allows participating hospitals and clinics to buy drugs at a discount, give them to eligible patients, and then bill the insurers (private companies, Medicare, or Medicaid) for the full price of the drug. That difference between the lower price hospitals pay for a drug and the higher price at which they are reimbursed constitutes an important revenue stream, especially for safety-net hospitals serving large uninsured populations. Medicare currently pays all hospitals, 340B or not, average sales price (ASP) plus 6% for drugs hospitals supply to eligible outpatients, such as oncology drugs provided in outpatient clinics and reimbursed under Medicare’s Part B program. The CMS wants to reduce its reimbursement to 340B hospitals to ASP minus 22.5%.

That proposal has outraged the hospital industry, although only 45% of acute-care hospitals participate in 340B. “The CMS proposal to reduce reimbursement of 340B-purchased drugs has the potential to be very harmful to the sickest and most vulnerable patients by endangering their access to essential health care services,” said Kasey K. Thompson, PharmD, MS, MBA, Chief Operating Officer and Senior Vice President of the American Society of Health–System Pharmacists, in a July press release. “These changes run counter to the statutory intent of the federal 340B program and will incur a steep cost to the people and the organizations that can least afford it.”

The reduction in Part B reimbursement to 340B hospitals would amount to an increase in the funds the CMS would be able to spend on other hospital outpatient services. How that extra money would be distributed has not been decided, and the CMS has asked for suggestions. But in an attempt to assuage concerns about the impact on the most vulnerable hospitals with the highest percentage of vulnerable patients, the agency is considering targeting recouped funds “to hospitals that treat a large share of indigent patients, especially those patients who are uninsured.” Many 340B hospitals already have large populations of uninsured patients; but some academic centers have smaller percentages as measured by their disproportionate share (DSH) percentage, which is an approximate measure of Medicaid patients.

Despite opposition to the reductions, it appears that key House members believe the price of averting some or all of that reduction will be Congress finally addressing some of the many underlying weaknesses of the 340B program. U.S. Representative Diana DeGette (D-Colorado) said at the hearings, “We probably do need to get more controls and that is why I said in my opening statement that we may need to have more—we need to have more legislative reporting and more transparency because you can’t have a program where nobody knows what’s going on.”

Mr. Barlas is a freelance writer in Washington, D.C., who covers issues inside the Beltway. Send ideas for topics and your comments to sbarlas@verizon.net.
The lack of transparency probably leads to understatement of some of the program's substantive failings. The CMS argues that the program encourages hospitals to supply more expensive drugs than are necessary to too many patients. Some of the hospitals in the program that are profitable and serve mostly well-off clienteles, such as academic hospitals, earn substantial revenue from the program while providing limited charity care, raising questions about whether they deserve the discounts. Moreover, reports from the GAO establish that, on average, beneficiaries at 340B DSH hospitals were either prescribed more drugs or more expensive drugs than beneficiaries at the other non-340B DSH hospitals. In fact, it is possible for 340B hospitals to supply any billionaire with discount drugs. At the same time, it is perfectly legal for a 340B hospital to charge an uninsured patient full price for a 340B drug. The program is run by the Office of Pharmacy Affairs (OPA) within HHS's Health Resources and Services Administration (HRSA). The OPA, one of Washington's backwater agencies, has struggled to administer and enforce jumbled rules with just 16 staffers and a severely anemic $10 million budget.

**How a Medicare Reimbursement Reduction Would Affect Hospitals and Patients**

Part of the rationale for the proposed Medicare reimbursement reduction, according to Thomas E. Price, MD, Secretary of the HHS, is to reduce the price of pharmaceuticals. Democrats have lampooned that stance, and even some Republicans are skeptical of it. Theoretically, Medicare beneficiaries could see lower prices since they are required to pay a 20% copay for outpatient drugs they receive under Part B. That copayment is based on the Medicare reimbursement rate, which is ASP minus 22.5%. If that dropped precipitously to ASP minus 22.5%, the "Medicare price" would fall, reducing copayments for Medicare recipients, who are currently paying whopping copayments in some instances. In the Federal Register notice announcing the prospective change in Medicare outpatient reimbursement in calendar year 2018, the CMS explained, citing an OIG report from November 2015: "Based on an analysis of almost 500 drugs billed in the hospital outpatient setting in 2013, the OIG found that, for 35 drugs, the difference between the Part B amount and the 340B ceiling price was so large that, in a least one quarter of 2013, the beneficiary's coinsurance alone was greater than the amount a covered entity spent to acquire the drug."

Of course, to the extent a 340B hospital provides discounted drugs to Medicaid patients and then bills Medicaid, that will not affect the consumer prices those patients pay because the reduction to ASP minus 22.5% will not apply to Medicaid reimbursement. Medicaid patients do not pay much, if at all, for their prescription drugs. In an email response, Margaret Kemeny, MD, Director of NYC Health & Hospitals/Queens Cancer Center, a 340B participant, says the majority of her patients do not have insurance. "If they have cancer, we can put them on emergency Medicaid. Very few patients have Medicare," she writes. "The hospital gets their drugs through 340B. All patients are not charged for the drugs."

The fact that a high percentage of 340B patients are either uninsured or on Medicaid raises the question of how badly a reduction in Medicare payment would hurt hospitals generally, and 340B hospitals specifically. According to 340B Health, which lobbies for 340B "covered entities," total sales to 340B covered entities in 2015 were $4.2 billion, or 0.9% of total U.S. drug spending. So the program itself has a minimal impact on drug pricing nationally. Tom Mirga, Editorial Director for 340B Health, says there are no statistics that shed light on the percentage of that $4.2 billion that went to Medicare patients, so it is hard to estimate the impact a reduction of ASP minus 22.5% would have on 340B providers.

One pharmacy manager for a chain of hospitals, who did not want to be identified, said the cut would affect the local 340B hospitals and nationally within his system in a big way, depending upon each site and their percentage of Part B Medicare patients. That varies from hospital to hospital. He guesses it averages perhaps 30%. Another worry is whether commercial insurances will try to negotiate these types of payment rates in the future.

Drug manufacturers have been the loudest complainers about the program. Discounts to 340B hospitals and clinics are mandatory if manufacturers want to sell drugs to state Medicaid programs. They are required to set discounts at whatever level they chose as long as it is below the ceiling price established by HRSA. Would the 600 or so drug manufacturers who participate in the program lower their prices to 340B hospitals if the CMS reduces reimbursement? Nicole Longo, Senior Manager of Public Affairs for the Pharmaceutical Research and Manufacturers of America (PhRMA), declines to answer the question about how reform of the program would affect the prices drug manufacturers charge 340B hospitals. "PhRMA cannot speak to how individual companies might react and whether any companies would adjust drug prices," she says. For companies to increase their prices to 340B participants, Congress would either have to change the calculation HRSA is required to make to establish ceiling prices for each drug or drug companies now selling below the ceiling price could theoretically raise their price.

"The 340B program is in need of fundamental change that is beyond the scope of the Medicare proposed payment reduction," Longo says, "and the congressional hearing held in July was an important first step toward modifying the 340B program to ensure it returns to serving the vulnerable or uninsured patients it was intended to help."

If Congress finally makes an effort to reform the program, it will find a willing partner in the Trump administration beyond Medicare officials determined to slash reimbursement. Krista Pedley, PharmD, MS, CDR, USPHS, Director of the OPA, says, "In the fiscal year [FY] 2018 president’s budget, we did propose to intend to work with Congress on a legislative proposal to ensure the benefit of the program does benefit the low-income uninsured populations."

**340B Expansion Since PPACA**

Reducing Medicare reimbursement would save the agency about $900 million a year based on the agency’s preliminary estimates, which could change going forward. Medicare’s proposal in July to severely reduce what it reimburses hospitals is the result of its soaring 340B costs, which are in part the result of Congress’s decision in the PPACA to greatly increase the number of health facilities, including types of hospitals, eligible to participate in the 340B program.
More Clouds Form Over 340B Program

To be eligible for the 340B program, a hospital must be: 1) owned by a state or local government, 2) a public or nonprofit hospital that is formally delegated governmental powers by a state or local government, or 3) a nonprofit hospital under contract with a state or local government to provide services to low-income patients who are not eligible for Medicare or Medicaid. A 2015 report from the Medicare Payment Advisory Commission (MedPac) said regarding the third option for eligibility, for example, that HRSA has not specified criteria for contracts between nonprofit hospitals and state or local governments, such as the amount of care that a hospital must provide to low-income patients under such a contract. Thus, hospitals with contracts to provide a relatively small amount of care to low-income individuals could be eligible for 340B discounts, which may not have been what HRSA intended.

Several types of hospitals as well as clinics that receive certain federal grants from HHS (e.g., federally qualified health centers and Ryan White grantees) may enroll in the program as covered entities. In addition to DSH hospitals, which were always the key participant in the program since its creation, the PPACA greatly expanded the covered entities eligible to purchase 340B drugs to critical-access hospitals, rural referral centers, sole community hospitals, children's hospitals, and freestanding cancer hospitals. The number of unique participating covered entities has grown from 3,200 in 2011 to 11,180 in February 2015 to 12,148 in October 2016. The number of hospitals in particular has grown significantly from 591 in 2005 to 1,673 in 2011 to 2,871 as of July 2017.

In addition, the number of contract pharmacies has grown greatly since HRSA issued its 2010 guidance on contract pharmacies. Contract pharmacies are retail pharmacies in the community that allow a 340B hospital to expand the number of its patients, if properly qualified, who have access to discount drugs. The more patients getting 340B drugs, the more revenue the hospital gets. Prior to 2010, hospitals could only supply 340B drugs from one outpatient pharmacy, typically located in the hospital. In 2011, the GAO reported that while HRSA did not track individual contract pharmacies in use, there were more than 7,000 contract pharmacy arrangements through the program. In its 2018 Budget Justification, HRSA reported that 27% of covered-entity sites have contract pharmacy arrangements, resulting in approximately 18,078 unique pharmacy locations. The OIG found that contract pharmacy arrangements created difficulties for covered entities in preventing the diversion of drugs and duplicate discounts.

Once a hospital has determined it is eligible and has been accepted by HRSA for participation, it supplies discounted drugs to “eligible patients,” a term that has been murky from the start. The definition of “patient” was established in 1996 and includes three criteria:

- The covered entity must have a relationship with the individual, which HRSA defines as maintaining the individual’s health care records;
- The individual receives health care services from a health care professional who is employed by the entity or who provides care under contractual or other arrangements (e.g., referral for consultation), such that responsibility for the individual’s care remains with the entity; and
- The individual receives a service or range of services from the covered entity that is consistent with the service or services for which grant funding or federally qualified health center look-alike status has been provided (this criterion does not apply to hospitals).

HRSA audits from FY 2012 to FY 2016 demonstrate that noncomplying entities violate program requirements in at least one of three ways: duplicate discounts, diversion to ineligible patients and facilities, and incorrect database reporting. In FYs 2012, 2015, and 2016, close to half of HRSA’s audited entities diverted benefits to ineligible patients: 31% of covered entities in FY 2012, 47% of covered entities in FY 2015, and 44% of covered entities in FY 2016 were found to have diverted drugs. Diversion violations reached a 54% high in FY 2014 and FY 2015, when more than 50 audited entities offered drug-pricing benefits to ineligible patients.

HRSA has issued guidance on the definition of “patient.” According to part of the guidance, the individual must receive health care services from a health care professional who is employed by the entity or who provides care under contractual or other arrangements, such that responsibility for the individual’s care remains with the entity. But the MedPac report of 2015 stated HRSA has not clarified the meaning of “other arrangements” or “responsibility for the individual’s care.” The lack of specificity in the guidelines for who is an eligible patient makes it possible for covered entities to interpret this term either too broadly or too narrowly, according to the GAO. For example, HRSA has expressed concern that some covered entities may consider individuals to be eligible patients even when the entity does not have actual responsibility for their care.

Drug Pricing

Drug manufacturers have been vocal critics of the elasticity of the 340B program definitions, such as who are eligible patients and whether hospitals are providing adequate charity care. The hospitals, in turn, have criticized drug pricing within the program. HRSA establishes the ceiling price as the difference between the drug’s average manufacturer price and its unit rebate amount (URA). HRSA calculates URAs using a statutory formula that is based on the formula used to calculate Medicaid drug rebates. The statutory formula for the URA varies based on whether the drug is a single-source or innovator drug, a multiple-source drug (e.g., a brand-name drug), a noninnovator multiple-source drug (e.g., a generic drug), or a clotting factor or exclusively pediatric drug. According to statute, HRSA is allowed to disclose ceiling prices to covered entities but not to the general public.

Hospitals buy their drugs either directly from the manufacturer or from a company called Apexus, which manages the 340B Prime Vendor Program (PVP). By pooling the purchasing power of covered entities, Apexus negotiates subceiling prices on many 340B drugs with manufacturers, which allows covered entities to pay less than the ceiling price. By the end of FY 2013, Apexus had more than 7,000 drugs under contract, with an estimated average savings of 10% below the ceiling price. Apexus also negotiates discounts on other pharmacy products and services not eligible for 340B pricing, such as

630 P&T® • October 2017 • Vol. 42 No. 10
vaccines, billing software, and contract pharmacy vendors. As of April 2014, about 82% of covered entities participated in the PVP and accounted for $5 billion in 340B drug purchases, according to Apexus. DSH hospitals, children’s hospitals, and freestanding cancer hospitals that participate in 340B are prohibited from purchasing covered outpatient drugs through a group purchasing organization.

What the Hospitals Do With 340B Revenue

The premise of the 340B program is that the covered entities will use the revenue they earn to improve health care for low-income individuals and families in their communities. Mirga of 340B Health says nearly three-quarters (71%) of 340B Health members report that savings from participation in 340B increase their ability to provide free or discounted drugs to low-income patients. But it is not clear what levels of discounts are passed on to whom. No statistics on that exist. There is no denying that poor cancer patients at venues such as Dr. Kemeny’s Queens Cancer Center are able to obtain treatment at rock-bottom prices or for free. But the serious shortcomings of the program are starting to overshadow the “good” the program does.

REFERENCES


More Clouds Form Over 340B Program