Key Senator Scrutinizes Pharmacy 340B Selling Practices

Federal Office in Charge of Drug Discounts Begins to Feel the Heat

Stephen Barlas

The federally run Section 340B Drug Discount Program used by many safety-net hospitals to keep their financial heads above water has become a bobbing target for congressional critics and the agency that supervises the program, the Health Resources and Services Administration (HRSA). The 340B program requires brand-name drug companies to sell their medications at deep discounts to nearly 20,000 hospitals and clinics in the U.S. as the price of selling those same drugs at higher prices to state Medicaid programs.

Section 340B has been around since 1992. Congress created it as a way for hospitals with high numbers of uninsured populations to generate revenue, allowing them to swim rather than sink. Section 340B has operated in calm waters for two decades.

Facilities eligible for the program include certain disproportionate-share (DSH) hospitals, children’s hospitals, freestanding cancer hospitals, rural referral centers, sole community hospitals, and critical-access hospitals. DSH hospitals have been eligible for the 340B program since its inception, children’s hospitals became eligible in 2006, and the remaining hospital types became eligible through the Patient Protection and Affordable Care Act (PPACA).

In 2010, the federal Office of Pharmacy Affairs (OPA), located in Rockville, Maryland, became the new name of the Office of Drug Pricing. As part of the HRSA, it has prime responsibility for Section 340B. The OPA greatly expanded the program by allowing hospitals to sell 340B discounted drugs from area pharmacies, not just from outpatient pharmacies attached to the hospital, as had been the rule since the program began.

Those significant expansions of Section 340B led, in part, to the sharks now circling it. Some of the criticisms are on target but at the same time are unfair. The program allows safety-net hospitals with a DSH percentage above a certain rate—essentially a stand-in for the high-uninsured population—to purchase brand-name drugs at discounts of 25% to 40%. Hospitals pass those discounts on to their uninsured patients, but they bill privately insured patients or Medicare for what would otherwise be the full price of the drug. The hospitals then pocket the difference between the discounted price that they pay and the higher price that the insurance company or Medicare pays.

Some hospitals add millions of dollars of revenue to their bottom lines by selling large percentages of their 340B drugs to private-pay patients. Senator Charles Grassley (R-Iowa) calls the practice “upselling.” There is nothing illegal about this. In an interview, a Grassley staffer acknowledges that upselling is not a violation of the program’s legal basis, but she says the senator believes that it is not appropriate. He is particularly rankled when a hospital uses 340B profits to build, for example, oncology clinics that serve a high proportion of private-pay and Medicare patients.

In a letter to the editor published jointly in the Charlotte Observer and in the News and Observer on April 11, Ted Slafsky and Lisa Scholz responded to an editorial in the Charlotte Observer. That editorial (April 5) lauded questions raised by Senator Grassley about the program. The two wrote:

“The purpose of 340B, from day one, has been to enable safety-net health care providers to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”

Mr. Slafsky is Executive Director of Safety Net Hospitals for Pharmaceutical Access (SNHPA), and Ms. Scholz is Chief Pharmacy Officer and Chief Operating Officer.

Senator Grassley spotlighted three North Carolina hospitals for upselling: Duke University Hospital in Durham, University of North Carolina Hospital in Chapel Hill, and Carolinas Medical Center in Charlotte. Duke University Hospital reportedly made $69.7 million in profit last year by selling the discounted drugs to patients. Sara Avery, a Duke spokesperson, declined to comment for this article.

In a press release dated April 18, 2013, Senator Grassley wrote:

When I looked at three North Carolina hospitals’ use of this program, the numbers showed that the hospitals were reaping sizeable 340B discounts on drugs and then upselling them to fully insured patients to maximize their spread. If ‘nonprofit’ hospitals are essentially profiting from the 340B program without passing those savings to their patients, then the 340B program is not functioning as intended. Our inquiry into the Georgia hospital will help us continue to examine hospitals’ use of the 340B program.

The Georgia hospital refers to Columbus Regional Healthcare System. On April 18, 2013, Senator Grassley and Representative Bill Cassidy (R-La.) wrote to the Columbus hospital in Georgia after a hospital executive said during a public interview that the hospital does not receive a “windfall of profits” from participating in the program and puts the proceeds into the hospital.

Mr. Cassidy said, “I recognize the value and importance of the 340B drug discount program. Given this importance, we must be sure that its good work is not threatened by those who misuse. Our common goal must be better care for those who are less fortunate.”

The three North Carolina hospitals do serve a high percentage of the less fortunate.

In its most recently filed cost report, the Duke University Hospital’s Medicare DSH adjustment percentage is 18.9%,

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compared with the threshold requirement of 11.75% for its participation in the 340B program. However, it is true that a high percentage of Duke patients who receive 340B drugs are not uninsured. The hospital's 340B drugs are distributed as follows: Medicare patients, 19%; North Carolina Medicaid patients, 9%; private-pay patients, 67%; and self-pay patients, 5%. Those statistics are from Duke's response to an inquiry from Senator Grassley.3

Carolinas Medical Center has a much smaller percentage of private-pay patients, although the hospital, in its response to the Grassley inquiries, breaks down its 340B distribution into two distinct segments: outpatient pharmacies, and its four in-house pharmacies attached to its four community clinics. In the first instance, based on 2011 numbers, nearly 42% are private-paying patients and 11.3% are uninsured. These numbers are reversed for the four community in-house pharmacies: uninsured patients, 73.9%; private-pay patients, 0%.4

Carolinas charges from $0 to $10 per prescription for uninsured patients, based on the individual's financial resources. These negligible patient payments and low Medicaid reimbursements do not cover the total direct and indirect costs of operating the outpatient community clinic in-house pharmacies. In fact, Carolinas operates the outpatient community clinic in-house pharmacies at an average annual deficit of $9.8 million to the hospital.

What is not clear from Carolinas' response is the volume in the 340B distribution outpatient pharmacy versus the community clinic in-house pharmacy. Given the fact that Carolinas told Senator Grassley that it "saved" (a synonym for "profits") $21 million in 2011, one would assume that the outpatient pharmacies served many more patients than the four pharmacies at the community clinics; hence its total private pay percentage is considerably higher than 41.9%. A Carolinas spokesperson did not respond to repeated e-mail requests for clarification.

However, Carolinas put those profits to good use, particularly in the area of pharmacy services. At its cost, the center dedicated multiple clinical pharmacists to the community clinics to provide intensive management of diabetes, asthma, HIV infection, anticoagulation, and heart failure. For example, since an intensive shared decision-making asthma pilot program has been in place in Carolinas outpatient community clinics, hospitalizations and emergency visits for asthma patients dropped from 14.5% to 9.3%. In this same asthma pilot program, emergency department visits and hospitalizations reduced Medicaid average costs by about 11% over usual care. Patients with asthma make up a significant portion of the North Carolina Medicaid population; therefore, any reduction in hospitalizations or additional care ultimately benefits the state Medicaid program.

Senator Grassley would probably say that most of Carolinas Medical Center's Section 340B profits are plowed back in to help the uninsured. The trouble is that 20,000 sites in the program do not have to inform the OPA of how they use 340B profits. So the program lacks transparency, according to the senator, and the small agency has done little in the past two decades to either require transparency or even to audit hospitals to see whether they are adhering to program rules.

A report issued in September 2011 by the Government Accountability Office (GAO) helped to seed Mr. Grassley's unhappiness. That report basically said that the OPA was a watchdog without either a bark or a bite. The GAO concluded:5

HRSA's oversight of the 340B program is inadequate to provide reasonable assurance that covered entities (i.e., hospitals) and drug manufacturers are in compliance with program requirements—such as entities' transfer of drugs purchased at 340B prices only to eligible patients and manufacturers' sale of drugs to covered entities at or below the 340B price. HRSA primarily relies on participant self-policing to ensure program compliance. However, its guidance on program requirements often lacks the necessary level of specificity to provide clear direction, making participants' ability to self-police difficult and raising concerns that the guidance may be interpreted in ways inconsistent with the agency's intent.

This report, coming on the heels of the PPACA's expansion of Section 340B, forced the OPA to get off its duff. As a result, the OPA announced it would be conducting its first-ever audits of hospitals starting in fiscal 2012. As of February 2013, the OPA had completed audits of 18 of the targeted 51 health systems; 16 passed with flying colors. Two had violations related to inaccurate database entry and were required to submit corrective action plans. Six audits were performed by drug manufacturers, and three of these were finalized; however, David Bowman, a spokesperson for the HRSA, says those results have not been made available. The HRSA has not completed any audits of drug manufacturers, who, hospitals have alleged, sometimes charge higher prices for medications than are allowed.

It's hard to blame the OPA, which has a minuscule budget of $4.4 million. The Grassley staffer says that her boss is really pleased with some of the steps the OPA has taken in the past year but that the agency "has a long way to go." In addition to the first-time audits, the OPA also did its first-time recertification of the program's participants. In March 2013, it announced it had kicked out 598 of the 20,000 covered entities.

"We were really pleased with that," she notes. "But even with that decertification process, HRSA is not perfect."

She argues that those 598 covered entities, probably mostly hospitals, which were using 340B when they were no longer eligible, should have been penalized in some shape or form; they were not.

"That is very frustrating for us," she added.

The staffer claims that HRSA, the OPA's parent agency, has the authority to require hospitals to release data on how they use 340B profits. She also says the agency needs to narrow its definition of "patient" so that fewer private-pay patients qualify. The agency tried to do that in 1997, but the rulemaking never became final because of opposition from Safety Net Hospitals Pharmaceuticals Access. David Bowman (personal communication) said:

HRSA is committed to continuous improvement in all its programs, including 340B. The program is currently engaged in drafting regulations to clarify and refine our implementation of the statute. We welcome input from all stakeholders, including Congress, on ways to improve the program.

The HRSA's tame approach to oversight has been a function not only of inadequate funding; it has also been a constant

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political tug of war between hospitals that want more leeway and drug manufacturers who would rather see the program narrowed. Both sides have pressed the OPA to alter program rules, but an effort by the HRSA in the late 1990s to redefine which patients were eligible for 340B drugs faltered. Congress finally got up the nerve to make some changes in the PPACA; however, those changes primarily benefited the hospitals.

The OPA has since tried to balance the equation somewhat. Earlier this year, this agency issued new guidance relating to whether 340B hospitals could use group-purchasing organizations (GPOs) to buy 340B drugs. That practice had been prohibited from the start, but some hospitals have danced around the prohibition by purchasing covered outpatient drugs through a GPO and subsequently either (1) “replenishing” through accounting by “replacing” the GPO-purchased drug with a drug purchased under Section 340B or (2) otherwise reclassifying the method of purchase after dispensing.

Rick Pollack, Executive Vice President of the American Hospital Association, stated numerous concerns about the GPO policy in a letter dated April 3, 2013, addressed to the OPA’s director, Krista Pedley, PharmD, MS:6

As we discussed with you at our March 14 meeting, we remain very concerned that the policy changes outlined in the February 7 notice could threaten hospitals’ access to this crucial program. We have heard from many 340B hospitals affected by the notice that they face numerous challenges in modifying existing inventory management practices by April 7 to comply with HRSA’s new GPO guidance. Such challenges include working with vendors to adapt or change current inventory management systems, working with wholesalers to establish new accounts, and working to ensure sufficient time to train staff and audit their internal processes.

The OPA subsequently postponed the compliance date from April 7, 2013, to August 7, 2013.

Congress has also considered additional post-PPACA changes to the program. At the end of the last congressional session in late 2012, Representative Bill Cassidy, who signed the letter to Columbus Regional Healthcare System with Senator Grassley, introduced legislation—the Patient Access to Drugs in Shortage Act of 2012 (H.R. 6611)—that would have allowed Medicare and Medicaid to reimburse 340B hospitals at the discounted price that hospitals pay, not the higher prices the two federal health care programs have used for reimbursing. That would diminish hospital profits considerably in some cases.

Representative Cathy McMorris Rodgers (R-Wash.) also introduced a bill in 2012 called the Rural Hospital and Provider Equity and 340B Improvement Act of 2012 (H.R. 5624). Going in the opposite direction from the Cassidy bill, it expanded the program to make inpatient drugs eligible for 340B pricing. However, her bill also required hospitals enrolled in the 340B program to provide a credit to each state on the estimated annual purchases by such hospitals of covered drugs provided to Medicaid recipients for inpatient use.

Both Representatives Cassidy and McMorris are on the House Energy & Commerce Committee. As Republicans, they are in the majority and have the weight to get these bills through the House, at least, if they reintroduce them in 2013. But neither has responded to e-mails asking whether a re-introduction was likely.

President Obama, in his fiscal 2014 budget request released in early April, included a new fee that 340B hospitals would have to pay. The fee amounts to about 1 cent for each $10 of 340B drugs purchased by the hospital. That could add up to real money for some hospitals. The proposal was offered, too, in the last Congress. The Senate passed it; the House did not.

The heat from the Grassley investigations and the OPA audits, as well as the elimination of access to GPOs, come at an inopportune time for many 340B hospitals, which make up one-third of all hospitals in the U.S. They had been expecting that many of their uninsured patients would suddenly have Medicaid insurance by January 1, 2014, thanks to the PPACA. But many states have rejected a Medicaid expansion. The AHA’s Rick Pollack, citing the Congressional Budget Office, says about 5 million fewer people are likely to be covered by Medicaid than originally expected because of state refusals to buy in.

Because of the once-expected flood of new-paying Medicaid patients to hospitals, the PPACA greatly reduced DSH payments, starting January 1, to those very same hospitals. DSH payments go to safety-net hospitals from both Medicare and Medicaid. The rationale, of course, was that the hospitals no longer needed so much federal aid, because Medicaid would now cover many of those uninsured patients (whose care was causing the hospitals to lose money).

In an interview with The Washington Post, John Haupert, president of Grady Health System in Atlanta, said that about 30% of its patients lack insurance coverage and an additional 30% receive Medicaid, which usually pays lower rates than private health plans do. Grady estimated that it would lose $45 million each year under the PPACA’s Medicaid cuts to DSH payments, or about 7% of the hospital’s budget of $670 million. If these cuts are implemented, Mr. Haupert is considering reducing some of the hospital system’s clinical services. The state of Georgia has rejected the PPACA Medicaid expansion.7

Hospitals, of course, are already losing Medicare reimbursement to the tune of 2% because of the sequestration in fiscal 2013 (the current fiscal year), in which all agency and department budgets were cut after Congress failed to come up with a long-term deficit-reduction plan. For hospital pharmacies, though, this is both good news and bad news.

The bad news: inpatient pharmacy reimbursement is down from the average sales price (ASP) plus 6% to the ASP plus 4.3%. The “good” news (in a jaundiced sense): physicians who administer chemotherapy in the office are beginning to turn patients away, because the 2% reduction makes oncology infusion unprofitable. In some instances, these patients are turning to oncology clinics affiliated with 340B hospitals, which also are losing some Medicare reimbursement. However, these hospitals are in a better position to slough off that loss and accept new patients because they are obtaining very expensive oncology drugs at big discounts.

Of course, if Senator Grassley attempts to rein in the Section 340B program, he is likely to try to cap the percentage of private-pay, and maybe even Medicare, patients eligible for discount drugs. If so, and if he is successful, hospitals themselves may have to start turning away desperate oncology patients who need infusions.

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