Specialty Healthcare Benefits Council
Defining Specialty Health

340B Drug Discount Program in the Cross Hairs

William W. Wood, RPh, and Wendy Weingart, RPh

After years of solitude in the backwaters of hospital billing systems, the 340B drug discount program has become controversial. There is a concerted effort by critics in the pharmaceutical industry to significantly scale it back. Pharmacy benefit managers, employer groups, and insurers are also attempting to level the playing field in terms of more consistent pricing between hospitals and alternate treatment sites, with 340B savings as a key point in the discussions.

The intent of the 340B program is to provide additional support for health providers who treat disproportionate numbers of Medicare, Medicaid, and Supplemental Security Income patients. Mandatory discounts for covered outpatient drugs provide an additional financial resource for these hospitals and health centers to support the provision of this care. Safety net hospitals are the largest covered entity and look to 340B savings to fund a wide array of services for the poor, from drug discounts and human immunodeficiency virus/AIDS clinics to diabetes training programs, cancer treatment centers, and primary care facilities.

Critics of the 340B program suggest that the program should be limited to only uninsured patients. If that were to happen, hospitals say they would face steep budget shortfalls that would impact not only needy patients, but also the total provision of services. Some smaller, rural hospitals would likely be forced to close their doors altogether without 340B support.

WHITHER THE MEGA-REG?

Another common complaint about the program made by manufacturers and providers alike has been the lack of clearly defined program standards. Many elements of the 340B program are based on relatively loose opinion letters, which leave open significant latitude in interpretation. The Health Resources and Services Administration (HRSA) is attempting to remedy this situation through the release of more clearly defined standards. Originally slated for July, HRSA's plan to issue a new "mega-reg" has been delayed by a lawsuit regarding orphan drug pricing for rural and cancer hospitals.

A federal district judge ruled in May that HRSA has no authority under the 340B statute to promulgate regulations implementing the Affordable Care Act's 340B orphan drug exclusion, which applies to hospitals registered in 340B as critical access hospitals, sole community hospitals, rural referral centers, and freestanding cancer hospitals. HRSA's orphan drug exclusion rule interpreted the law to mean that rural and cancer hospitals could not get 340B pricing on an orphan drug when used for the disease or condition for which the drug received its orphan designation, but they could access 340B discounts on such drugs when used for nonorphan purposes. The judge said that although he found the HRSA rule to be the most reasonable way of administering the statute, he was bound nevertheless to rule that Congress did not grant HHS the rule-making authority to do so.

Rather than appeal the decision, in July HRSA published an "interpretive" rule that essentially restated its position on orphan drugs. The judge ruled that HRSA lacked authority to issue a substantive or "legislative" rule to carry out the exclusion and that the final rule appeared to him to be legislative. HRSA takes the position that although the judge vacated the rule, he did not invalidate HRSA's underlying interpretation of the orphan drug exclusion.

Many drug makers have decided not to offer 340B pricing on orphan drugs to rural and freestanding cancer hospitals despite HRSA's position that they are required by law to do so. It is unclear whether HRSA will take enforcement action against any drug companies.

A major side effect of the case is the delay in the release of the mega-reg draft. It is now unclear whether HRSA has the power to regulate any facet of 340B policy absent a clear congressional directive to do so.

In June, Office of Pharmacy Affairs (OPA) director Cmdr Krista Pedley said HRSA "is now having to assess the status" of its comprehensive 340B program regulation.

The mega-reg was expected to cover:

- Definition of an eligible patient
- Contract pharmacy provision
- Hospital eligibility
- Off-site facility eligibility.

In March, before the orphan drug decision was handed down, HRSA indicated it was working on 3 other 340B program regulations:

- One would create a mandatory administrative dispute resolution process for 340B.
- Another would impose fines on drug makers for known and intentional overcharges.
- The third would impose fines on safety net providers for violating the 340B statute knowingly and intentionally, and remove them from 340B for systematic and egregious misconduct.

HRSA and CMS are also expected to issue guidance on preventing Medicaid duplicate discounts on 340B-purchased Medicaid managed care drugs. The purpose would be to help states to identify, at the claim level, 340B-purchased drugs that are ineligible for rebates.

CONGRESS

In January, Congress more than doubled the Office of Pharmacy Affairs' (OPA's) budget, from $4.4 million to $10.2 million, and instructed it to use the additional $6 million for new 340B program integrity efforts. HRSA has hired more auditors and has said it will do twice as many audits in fiscal 2015 as it performed in fiscal 2014 (n = 99).

OPA also has contracted for the development of a new online database to help it monitor covered entity compliance more systematically. Conversely, the inability to check manufacturer pricing has been an area of fierce unhappiness among providers in the program. The agency recently announced plans to start collecting this information from drug companies to arrive at an official ceiling price for 340B medications that will be shared with providers.

In September, Congress passed and President Obama signed legislation to keep the federal government open through December 11. The bill keeps OPA level-funded at a spending rate of $10.2 million per year. It appears that the odds are good that Congress will maintain OPA's spending at that level for the rest of the fiscal year.

In July, the Senate Appropriations Subcommittee on Labor, Health and Human Services, and Education said in the report that accompanied its draft federal health spending bill for fiscal 2015 that "more than an individual discount program, the 340B program was designed to help safety net providers maintain, improve, and expand patient access to healthcare services generally."

Also in July, more than 100 members of Congress signed letters expressing bipartisan support for the 340B drug discount program, which the lawmakers say allows "hundreds of hospitals and other safety net providers across the country to do more with less."

The congressional letters say that 340B facilitates "access to health care services … by reducing pharmaceutical costs for hundreds of hospitals serving our most vulnerable constituents" and expands "community-based services to serve our most vulnerable." Because of help from 340B, hospitals are able to increase the number of patients they serve and "offset losses from uncompensated care," the letters add.

A major point in this regard for hospitals to consider is how they use the 340B program to extend care to these vulnerable patient populations. It is in the hospitals' best interest to have a clearly defined strategy and reliable documentation to validate exactly how these funds are supporting extension of care to the indigent. Simply using these funds as an offset to the drug budget or incorporating them into the hospital general fund makes it very difficult to defend the program.

This was the second straight year that more than 100 members of Congress have added their names to joint letters of support for 340B. The 77 House and 31 Senate

PRACTICAL IMPLICATIONS

Recent guidance and proposed rulemaking by CMS for the Medicare hospice program will require changes for Medicare Part D plans.

- The 340B drug discount program is currently in an unusual legal limbo keeping the government from publishing regulations. These rules are wanted by both supporters and critics of the program to provide clarity on such areas as patient definition, contract pharmacy, and the definition of outpatient clinics. It is anyone's guess when the government will actually issue these regulations.
- The pharmaceutical industry is lobbying heavily against 340B in Washington. Drug companies want the program limited to uninsured patients only. Safety net hospitals argue this move would effectively derail the program and cause providers to cut services to the poor and/or look to local taxpayers to fill the funding gap.

signatories said any regulatory or legislative changes to the program should not impair participating hospitals' ability to serve vulnerable patients.

If the Republican Party takes control of the Senate in November, the scrutiny of the 340B program is expected to intensify. Complicating matters is that 340B is losing 2 of its most dependable champions to retirement: Sen Tom Harkin (R-Iowa) and Rep Henry Waxman (D-California).

CONTRACT PHARMACY

In February, HHS Office of Inspector General (OIG) reported that hospitals and healthcare centers vary in how they ensure compliance with 340B requirements for prescriptions filled at contract pharmacies, leading to different decisions about patient eligibility.

The report also found that 22 of the 30 entities studied prevent duplicate discounts by not dispensing 340B-purchased drugs to Medicaid beneficiaries through their contract pharmacies. Two others that do dispense such drugs to Medicaid patients reported having methods for avoiding duplicate discounts.

OIG also found that a majority of the providers studied (18 out of 30) offered the discounted 340B price to uninsured patients in at least 1 of their contract pharmacy arrangements, often via a discount card that the patient gives to the pharmacist.

Finally, OIG said that 25 of the 30 covered entities reported that they monitor their contract pharmacy arrangements internally to detect potential diversion or duplicate discounts. Few, however, said they retain independent auditors for their contract pharmacy arrangements as recommended in HRSA guidance.

A group of Republican Senate and House lawmakers who have voiced concerns about lax enforcement of 340B program requirements released statements in response to the report:

"Congress expects the discounts to go to low-income patients, but according to this report, that isn't always happening because of the complexities that have developed around this program," said Sen Charles Grassley (R-Iowa). "Maintaining program integrity is fundamental to the work of every federal agency. In this case, HRSA needs to faithfully execute its responsibilities or account for why it can't do so."

"This report from HHS's own watchdog raises serious questions about whether the 340B program is serving its core mission to help the uninsured," added Rep Joe Pitts (R-Pennsylvania), the chairman of the House Energy and Commerce Subcommittee on Health. "This report underscores the need for strong oversight so that the program is best suited to help those most in need."

Hospitals countered that the OIG report specifically targeted providers with many contract pharmacy arrangements and the information should not be extrapolated to make policy decisions about the program overall. However, it is clear that contract pharmacy provision is a major source of program compliance vulnerability for covered entities. The contract pharmacy providers bear no responsibility or liability for program compliance. The covered entity is solely responsible, and it is in the covered entity's best interest to conduct an independent third-party audit of contract pharmacy services on a regular basis.

OIG also is working on a separate study that will seek to answer how much Medicare Part B spending could be reduced if Medicare were able to share in the savings for 340B-purchased drugs.

CAMPAIGN AGAINST 340B

Critics of the 340B program in the pharmaceutical industry have been ramping up their efforts. Opponents want to greatly reduce the number of hospitals eligible for 340B pricing and the number of patients who can get 340B drugs. Meanwhile, private cancer clinics and other 340B critics suggest reconfiguring 340B in a way that bypasses hospitals and gives prescription drug assistance directly to patients who lack insurance or have substantial prescription drug cost-sharing obligations.

The pharmaceutical industry is worried about growth in the 340B program. Although it is true that the number of eligible hospitals has doubled since 2007 to about 2000, nearly 1000 are small, rural facilities with 25 or fewer beds. The program has consistently represented 2% of the estimated $329 billion US pharmaceutical market for the past several years. Critics of the program have blamed 340B for rising drug costs and drug shortages. However, they have brought forth no credible evidence to support this claim. At the same time hospitals are also experiencing steep challenges surrounding the release of new, high-priced medications like sofosbuvir (Sovaldi), which costs $84,000 for a 6-week course of therapy.

Another major point of controversy is raised by private oncologists and oncology groups who feel 340B gives an unfair advantage to safety net hospitals. They blame savings from the program for fueling hospital purchases of private oncology practices. Although it is true that 340B hospitals can purchase drugs less expensively than private oncology groups, a safety net hospital typically provides 10× the amount of unfunded care that it receives in 340B discounts.

Hospitals also counter that although they do purchase private oncology practices, they are also partnering with

cardiologists, hematologists, orthopedists, dermatologists, and a variety of other medical professionals. This is a fact of modern healthcare, based on deep economic changes in the marketplace driven largely by low reimbursement, the elimination of "buy and bill" strategies, and the move toward integrated delivery systems and accountable care organizations. There are no credible data showing that 340B hospitals are buying up oncology practices any faster than hospitals outside the program.

Advocates of 340B say private oncologists have the luxury of shunting their poorest patients to the nearest safety hospital for care. In turn, hospitals must shoulder the enormous burden of treating all the people who cannot pay for treatment. Hospitals also offer a much broader range of oncology services, including advanced diagnostics, surgery, radiation therapy, infusion services, patient and family counseling, home care services, and palliative care.

However, hospitals must address the significant cost differential that is present for hospital-based services. As we noted in the beginning of this article, that is a major source of frustration for employer groups and payers. As hospitals purchase private oncology groups, payers often see prices double for the same treatment regimens. Payers are looking for strategies that create a more level pricing model between sites of care. If hospitals expect to be paid more than other sites of care, then it is incumbent on hospitals to demonstrate that the care they are providing produces better outcomes or better value to justify the higher cost, particularly when they may be receiving 340B discounts for the most expensive portion of that care—the drugs. Although payers do not have a legitimate claim to a portion of 340B savings directly, they do have an argument for more consistent pricing across sites of care.

SUMMARY

The 340B drug discount program has become controversial. Drug industry and private oncology critics want to shrink the program by limiting hospital and patient eligibility. All stakeholders are awaiting regulatory guidance from the government, which has been held up because of legal wrangling. Safety net hospitals argue that 340B savings are essential to helping them meet their missions to treat the underserved.

Acknowledgments

Author Affiliations: Visante, Inc, St. Paul, MN (WWW, WW).

Funding source: None reported.

Authorship Information: Acquisition of data (WWW); drafting of the manuscript (WWW, WW); critical revision of the manuscript for important intellectual content (WWW, WW).

Address correspondence to: William W. Wood, Visante Inc, 101 E 5th St 2220, St. Paul, MN 55101. E-mail: bwood@visanteinc.com. ajpb