Federal Investigative Report Questions 340B Contract Pharmacy Programs
Office of Pharmacy Affairs Promises Regulatory Response
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The storm clouds have gotten a little thicker over the outpatient pharmacy program many hospitals use to raise substantial revenue. A recent investigative report on the 340B program probably galvanized the federal Office of Pharmacy Affairs (OPA), which has been talking about tightening the program’s rules for years. The report was published by the Office of the Inspector General (OIG) at the Department of Health and Human Services.1 It did not produce any blockbuster conclusions. But the report underlined program weaknesses that have concerned Congress for some time—weaknesses the OPA has been slow to address.

Congress created the 340B program in 1992 as a way for so-called safety net hospitals caring for low-income patients to generate revenue they could use to provide otherwise unaffordable (for the hospital) medical services to all patients. In 2010, the OPA, the tiny office that runs the program, allowed hospitals to use contract pharmacies such as Walgreens and CVS so that patients could get 340B discounted drugs beyond the hospitals’ outpatient pharmacies and clinics. The OIG report concerned the contract pharmacy program, which has exploded but suffers from somewhat murky ground rules. Around 20 percent of 340B hospitals use contract pharmacy networks.

The 340B program requires pharmaceutical manufacturers to sell their drugs at a discount to “covered entities,” typically disproportionate share hospitals (i.e., those with a Medicare population above 11.75 percent), community health centers, and various types of clinics. The hospital or center is supposed to provide the drugs, either from the in-house or contract pharmacy, to patients who see a physician in the hospital. Insured patients are the key target group. That is because the hospital pharmacy bills that patient’s insurance company for the full price of the discounted drug and pockets the difference. That “difference” goes to the hospital’s bottom line.

It is noteworthy that even the Safety Net Hospitals for Pharmaceutical Access (SNHPA), the lobby for 340B programs, acknowledged problems disclosed by the OIG report. “The report underscores the challenges that stakeholders face when implementing the contract pharmacy program, which is in need of clearer guidance,” the group said in a statement.2

Obviously anticipating the OIG’s February 2014 report, the OPA published a note on its website in January saying that it planned to convert guidance on the contract pharmacy program into a regulation and would start the process in June. The proposed regulation, which would be open for public comment, “will address the definition of an eligible patient, compliance requirements for contract pharmacy arrangements, hospital eligibility criteria, and eligibility of off-site facilities.”3

Pharmaceutical manufacturers, who are unhappy about providing their drugs at around a 30 percent discount, argue that the 340B program, particularly the contract pharmacy extension, is running amok. Congress has been aware of the program’s fuzzy guidelines and the OPA’s enforcement hesitancy for some time. The fiscal 2014 federal budget approved by Congress in January included an additional $6 million more than fiscal 2013 for enforcement actions.

The OIG report looked at 30 covered entities with contract pharmacy networks. There were three key takeaways. First, some of the 30 were allowing nonqualified patients to get 340B drugs. That kind of diversion is illegal. Robert Nahoopii, PharmD, MS, BCPS, CEO/co-founder of Turnkey Pharmacy Solutions, a 340B management company, doesn’t think hospitals are trying to take advantage of drug companies by opening their programs to unqualified patients. Rather, the unintended diversion is the result of a couple of hospital/third-party-vendor administrative shortcomings that could be eliminated if the 340B programs submitted themselves to an external or internal audit.

Covered entities should be voluntarily auditing their programs. But the OPA doesn’t require it. Guidance from the OPA says it “expects” 340B programs to conduct an annual audit of contract pharmacy programs. The OPA found that only seven of the 30 covered entities retained independent auditors for their contract pharmacy arrangements.

Second, the OIG report found that hospitals were selling 340B drugs, which had already been discounted by the manufacturer, to Medicaid patients, and state Medicaid programs were charging the manufacturers a second discount. That is illegal, and doesn’t sit well with the drug companies, to put it mildly.

Lastly, eight of the 30 hospitals and community health centers were not making the discounted drugs available to uninsured patients. The program doesn’t require them to do so, and the hospitals, of course, are more interested in selling the drugs to insured patients. The hospital can bill insured patients at full price and pocket the difference between the full-price reimbursement and the discounted price the hospital pays the manufacturer. But denying low-cost drugs to uninsured patients doesn’t go over well in some political quarters.

However, the hospitals argue that they use the revenue to provide all kinds of charity care. Dr. Nahoopii says he has a couple of geographically isolated critical access hospitals, defined as having fewer than 25 beds, that would close if not for 340B revenues.

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Hospitals may actually appreciate clearer rules for the 340B program, even if they come via regulations, which can be federally enforced, as opposed to the current guidance. But they will be happier still if the OPA at the same time addresses their concerns about pharmaceutical manufacturer drug pricing. The Patient Protection and Affordable Care Act contained some provisions on that score, which, according to the SNHPA, the OPA has never implemented.

REFERENCES

CMS Shelves Proposal To Eliminate Classes of ‘ Protected’ Part D Drugs

Complaints from patient groups and drug companies have forced the Centers for Medicare and Medicaid Services (CMS) to drop its intention to change some Medicare Part D drug plan policies.

A March P&T article by Stephen Barlas detailed how the CMS wanted to drop antidepressants and immunosuppressants from the list of Part D “protected” drug classes, for which prescription drug plans must provide “all or substantially all” drugs in the class. In a March 10 letter to U.S. Representative Henry Waxman (D-California), Marilyn Tavenner, the CMS administrator, referred to a number of changes the CMS had proposed and said, “Given the complexities of these issues and stakeholder input, we do not plan to finalize these proposals at this time.”