Plan to Settle 340B Disputes Elicits Dispute
Roadblocks Remain to Quieting Drug Pricing Controversies

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Drug companies and hospitals are warring over a proposed administrative dispute resolution (ADR) program meant to settle long-running allegations over pricing and diversion of drugs in the 340B program. In this federally sponsored program, drug manufacturers sell medications at a discount to qualified hospitals and clinics, allowing them to generate revenue to expand services to generally low-income populations.

Sylvia Yu, Assistant General Counsel for Pharmaceutical Research and Manufacturers of America, argues that it will be impossible for drug companies to access the ADR program because they are unable to audit hospitals to see whether discounted drugs have been diverted to ineligible patients. “The existing guidelines for manufacturers to audit 340B entities, issued in 1996, suffer from critical defects that make manufacturer audits nearly infeasible,” Yu states. “The result is a blocked gateway to the ADR process for manufacturers. And a one-sided ADR system in which covered entities can institute ADR claims but manufacturers face nearly insurmountable barriers to instituting ADR claims would weaken confidence in the integrity of the 340B program.”

Congress created the 340B program in 1992 for hospitals with high numbers of uninsured patients, including certain disproportionate-share hospitals, children’s hospitals, freestanding cancer hospitals, rural referral centers, sole community hospitals, and critical access hospitals. Only certain patients are eligible to receive the discounted drugs, which can be dispensed only in hospital outpatient pharmacies and some local retail pharmacies.

Pharmaceutical makers don’t like to be forced to sell products at a discount, but they must do so if they want to sell to state Medicaid programs. The discounts are problematic enough for them, but the drug companies have argued for years that covered entities, either consciously or due to faulty billing systems, “divert” discounted drugs to ineligible individuals. The hospitals and clinics, for their part, complain they do not have access to pricing data that would assure them the discounted prices are what they should be.

The purpose of the ADR process is to resolve: 1) claims by covered entities that manufacturers have overcharged them for covered outpatient drugs; and 2) claims by manufacturers that a covered entity has violated the prohibition on diversion to ineligible patients or duplicate discounts. Historically, the Department of Health and Human Services (HHS) has encouraged manufacturers and covered entities to work together to attempt to resolve disputes in good faith. The ADR process is not meant to replace those good-faith efforts, but would be a last resort when those efforts fail.

The Office of Pharmacy Affairs (OPA), part of the HHS Health Resources and Services Administration (HRSA), which administers the 340B program, has proposed ideas about how the ADR process might work, and various players have voiced opinions. There would be a 340B ADR panel with three voting members, who would differ from case to case. They would be drawn from the HHS or the Department of Veterans Affairs. An OPA member would serve as a nonvoting ex officio member. No member of a given panel could have a conflict of interest.

A covered entity or manufacturer would have to file a written claim within three years of the date of the sale (or payment) at issue. Covered entities could consolidate their claims, or have them submitted by a trade association, when those claims allege overcharges by the same manufacturer for the same drug. How manufacturers might consolidate their claims is trickier. First, the statutory authority for implementing the 340B ADR process does not permit consolidated claims on behalf of manufacturers by associations or organizations representing their interests. There is also some question whether the consolidation of claims by manufacturers generally is legal. Such consolidation may be barred by what the HHS calls “the operational challenges presented by the statutory requirement for a manufacturer to first audit the covered entity.”

“We believe that the 340B statute does not bar association or organization claims on behalf of manufacturers,” states Wayne Sichel, Head of U.S. Federal Policy for Bristol-Myers Squibb.

One imagines that any ADR panel will have its hands full, because key manufacturer pricing information—especially ceiling prices, which are closely linked to the size of a rebate—are not available to covered entities. Hospitals argue that, without such data, it will be hard for them to claim they were overcharged for a drug. The HHS’s proposed rule says the agency will give the panel price ceiling data. That won’t help hospitals develop a strong case that they were overcharged. “We are very concerned that our members do not have access to ceiling prices, and will consequently not be able to provide sufficient documents to demonstrate claims for overcharge,” says Debbie Johnston, Senior Vice President of Policy Development for the Arizona Hospital and Healthcare Association. The HHS is apparently developing a system that would let hospitals access drug prices, but no one seems to know when it will be operational.

Given years of controversy over the 340B program, an ironclad ADR program would be welcome to both hospitals and drug manufacturers. But legal roadblocks and program shortcomings don’t bode well for the effectiveness of any ADR process.

REFERENCE