340B Guidance Riles Hospitals, Drug Makers
They Push in Opposite Ways on Eligibility, Discounts, and More

Stephen Barlas

The Health Resources and Services Administration (HRSA) may have gotten it more right than wrong with its new proposed guidance on the 340B outpatient drug program.1 Hospitals and drug manufacturers, the program’s two key constituencies—long at loggerheads—are both complaining to high heaven about proposed changes. The program requires drug companies to sell medicines at deep discounts to hospitals (generally those located in rural or poor areas with significant indigent populations) that use those discounts to fund medical services they couldn’t otherwise afford.

The guidance, which may be revised based on public comments, greatly reduces the number of patients who would qualify to purchase 340B drugs. That has enraged hospitals and buoyed pharmaceutical companies. But the guidance proposed in August does very little to crack down on how hospitals use contract pharmacies, to prevent duplicate discounts where drug companies can be billed once for the 340B discount and again for a Medicaid discount, and to prevent private hospitals with no local or state government contracts from participating in the program. The HRSA’s failure to propose such restrictions is just fine with hospitals, but drug companies are beside themselves because of those and other omissions.

The 340B program is controversial, and some of its requirements are sketchy. The HRSA, part of the Department of Health and Human Services (HHS), has been prohibited by federal courts from issuing legally binding regulations in all but a few areas—hence the guidance the HRSA published in an attempt to clear up confusion about program rules. It would change the standard for patient eligibility, make it more difficult for patients receiving infusion to qualify for drugs, require hospitals to implement new billing and tracking systems, and make other changes. However, guidance, as opposed to regulation, is not legally enforceable.

Upward of 2,000 covered entities—general, rural, and children’s hospitals and AIDS and rural clinics—buy drugs from nearly 650 manufacturers. The drugs are sold at discounts of around 25% to qualified patients who receive the drugs at outpatient pharmacies, either on the grounds of the hospital or at satellite locations, including nonaffiliated contract pharmacies. Covered entities make money because insured patients buy the drugs at discounted prices and the covered entity bills their insurance company for the full price of the drug, pocketing the difference between that price and the lower, discounted 340B price. Over the years, the program rules have been abused both by covered entities and drug manufacturers, each side says, and the HHS inspector general has confirmed their suspicions—hence the need for clarification.

The key change riling hospitals concerns the way the HRSA would limit the number of patients eligible to purchase 340B drugs. The HRSA wants to substitute a six-pronged test for the current three-pronged test. The new standard would restrict the number of physicians who could write 340B-eligible prescriptions. Even if they were somehow affiliated with a hospital, physicians who did their own billing could not write a 340B-eligible script. Physicians would have to be employed by the hospital; having “privileges” would not meet the test. The guidance would limit the covered-entity facilities where individuals could be seen and still fit the definition of “patient.” For example, outpatient facilities would have to be listed on a reimbursable line in the hospital’s most recently filed Medicare cost report and the services provided would have to have associated outpatient Medicare costs and charges. An inpatient who receives a prescription while in the hospital, from an eligible provider, could not go to his or her local pharmacy and qualify for a 340B prescription.

“The guidance would require every prescription to pass at least 10 requirements to qualify for 340B discounts,” says Bruce Siegel, MD, President and CEO of America’s Essential Hospitals, which represents 340B hospitals. “The test must be applied to each prescription written and depends on where an individual patient sought care for a particular medical condition, which clinician wrote the prescription, and what type of insurance, if any, the patient has. This would be disastrous for patients and providers.”

The Pharmaceutical Research and Manufacturers of America (PhRMA) wants the HRSA to narrow the requirements for hospitals to qualify as covered entities. Over the past few years, U.S. Senator Charles Grassley (R-Iowa) has questioned whether academic medical centers are using 340B revenue for purposes intended by Congress, and whether they ought to qualify given their upscale patient mix. So PhRMA wants the HRSA to require private, nonprofit hospitals that have a contract with a state or local government to provide “at least a specified amount of care to low-income people ineligible for Medicare and Medicaid with the specified minimum threshold selected so as to ensure that a minor contract to care for this population cannot confer 340B eligibility.”

The HRSA guidance appears to try to split the difference between the demands of two opposing interest groups. But given its failure to do that successfully, and the fact that guidance is only guidance, Congress is likely to step in. If so, it is not clear which side of the scale Congress will put its thumb on.

REFERENCE