Healthcare Law

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GAO Issues New Report on 340B Drug Discount Program

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As directed by the Patient Protection and Affordable Care Act ("PPACA"), the U.S. Government Accountability Office ("GAO") released a report on September 23, 2011 on the federal 340B Drug Discount Program (the "340B Program"). Under the 340B Program, eligible safety-net health care providers ("covered entities") receive discounts on outpatient prescription drugs. In addition to commissioning the GAO report, PPACA expanded eligibility for the 340B Program and included a number of provisions to improve program compliance by covered entities and drug manufacturers.

To develop the report, GAO interviewed several different types of covered entities (e.g., federally qualified health centers, family planning clinics, AIDS Drug Assistance Programs, hemophilia treatment centers and certain hospitals) as well as a number of pharmaceutical manufacturer representatives. GAO also interviewed the Health Resources and Services Administration ("HRSA") and reviewed information from other departments within the U.S. Department of Health and Human Services.

GAO made three main findings, each of which is described briefly below.

1. HRSA'S Oversight of the 340B Program is Inadequate

GAO found that HRSA's oversight of the 340B Program is inadequate to ensure that covered entities and drug manufacturers are in compliance with program requirements. HRSA primarily relies on participant self-policing to ensure program compliance. However, GAO suggested that HRSA's guidance on program requirements often lacks the necessary level of specificity to provide clear direction, calling participants' ability to self-police into question. GAO reported that HRSA's oversight is further limited because the agency lacks effective mechanisms to resolve suspected violations and enforce program requirements when situations of non-compliance occur.

2. Some Covered Entities Generate Revenue under the 340B Program; All Use the Program in Ways Consistent with Its Purpose

GAO found that nearly half of the covered entities it interviewed reported that the reimbursement rates they received for 340B drugs were higher than their costs, resulting in what GAO referred to as "revenue." According to GAO, all covered entities reported using the program in ways consistent with its purpose. For example, all covered entities reported that program participation allowed them to maintain services and lower medication costs for patients. Covered entities generating 340B Program revenue that exceeded drug-related costs

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were also able to serve more patients and to provide additional services.

3. Covered Entities Generally Do Not Have Difficulty Accessing 340B Drugs

In response to questions about the extent to which HRSA ensures compliance with requirements that manufacturers not distribute drugs in ways that discriminate against covered entities in favor of other health care providers, GAO interviewed stakeholders about their access to drugs. GAO found that manufacturers' distribution of drugs at 340B prices generally did not affect providers' access to drugs except in two situations: (i) for intravenous immune globulin, which is a lifesaving immune deficiency drug prone to short supply because it consists of human plasma; and (ii) when there was a significant drop in the 340B price for a drug resulting in increased 340B demand.

PPACA outlined a number of provisions that could help improve many of the 340B Program's integrity issues, and GAO made a handful of additional recommendations to further strengthen HRSA's oversight of the program. However, whether HRSA can increase its oversight activities will depend on its funding levels, which HRSA has claimed are too low to support a significant amount of additional oversight activities.

Readers can access the report by clicking here.

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