

## **Highlights from GAO’s Report: “Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement”**

**Overview:** The Government Accountability Office (GAO) released a report on the Section 340B drug discount program, *Manufacturer Discounts in the 340 Program Offer Benefits, but Federal Oversight Needs Improvement*, GAO-11-836 (Sept. 2011). The 340B program was created in 1992 to reduce outpatient drug prices to certain clinics and hospitals serving large numbers of uninsured patients. The 340B program is administered by the U.S. Department of Health and Human Services (HHS) Health Resources and Services Administration (HRSA). “Covered entities” that participate in the program must fit within one of the eligibility categories listed in the 340B law, register with HRSA, and abide by program requirements. These include the 340B law’s “diversion prohibition,” which forbids covered entities from reselling or otherwise transferring 340B drugs to anyone but their own patients.

Manufacturers must participate in the 340B program or their drugs cannot be covered by Medicaid. Participating manufacturers’ prices to covered entities for outpatient drugs are capped at a deeply-discounted ceiling price,<sup>1</sup> set by a formula in the statute. In its report, GAO recommended that HRSA take steps to strengthen oversight regarding program participation and compliance with program requirements.

### **Report Highlights:**

#### **GAO Finds HRSA’s Oversight of the 340B Program Is Inadequate**

In its report, GAO found that “HRSA’s oversight of the 340B program is inadequate because it primarily relies on covered entities’ and manufacturers’ self-policing - - that is, participants ensuring their own compliance with program requirements.”<sup>2</sup> Yet HRSA’s existing guidance is not specific enough to permit effective self-policing, GAO concluded: “HRSA’s guidance on key program requirements often lacks the necessary level of specificity to provide clear direction, making it difficult for participants to self-police or monitor others’ compliance and raising concerns that the guidance may be interpreted in ways that are inconsistent with its intent.”<sup>3</sup> GAO summed up these points as follows:

Because of HRSA’s reliance on self-policing . . . as well as its nonspecific guidance, the agency cannot provide reasonable assurance that covered entities and drug manufacturers are in compliance with program requirements and is not able to adequately assess program risk.<sup>4</sup>

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<sup>1</sup> 42 U.S.C. § 256b(a)(1). The law exempts orphan drugs sold to certain covered entities from these ceiling price requirements. *Id.* § 256b(e).

<sup>2</sup> GAO-11-836, at 21.

<sup>3</sup> *Id.* at 22.

<sup>4</sup> *Id.* at 26.

A key issue that illustrates the related problems of inadequate oversight and guidance is the definition of a 340B “patient.” The law requires that covered entities only use 340B drugs for individuals receiving outpatient services who are “patients” of the covered entity. GAO found that HRSA had never audited a covered entity to identify violations of this requirement;<sup>5</sup> does not verify whether entities have systems in place to prevent diversion;<sup>6</sup> and had adopted a definition of “patient” that was ambiguous in several areas, thus making self-policing problematic. GAO stated that: “HRSA’s current guidance on the definition of a 340B patient is sometimes not specific enough to define the situations under which an individual is considered a patient of a covered entity . . . and thus could be interpreted too broadly or too narrowly.”<sup>7</sup>

“As a result of the lack of specificity,” GAO observed, “[HRSA] has become concerned that some covered entities may be broadly interpreting the [patient] definition to include individuals such as those seen by providers who are only loosely affiliated with a covered entity and thus, for whom the entity is serving an administrative function and does not actually have the responsibility for care.”<sup>8</sup>

### **GAO Notes Increase Growth in Hospital Participation in 340B**

GAO made several key findings regarding the growth of hospital participation in the 340B program. GAO noted that the growth in hospital participation has exceeded that of other eligibility categories. According to the report, “In 2005, hospitals represented 10 percent of program participants, they represent 27 percent today.”<sup>9</sup> GAO also found that “[n]early a third of the nation’s hospitals currently participate in the 340B program.”<sup>10</sup> Despite the large percentage of hospitals already participating in the program, hospital participation is expected to expand in the future, according to GAO. The vast majority of drugs purchased under the 340B program are currently purchased by participating hospitals. GAO found that “DSH hospitals alone [one of six hospitals eligibility categories] represent about 75 percent of 340B drug purchases.”<sup>11</sup>

### **Increased Use of the 340B Program by Contract Pharmacies and Hospitals May Result in Enhanced Diversion Risks, According to Report**

GAO found that “over time, the settings where the 340B program is used has shifted to more contract pharmacies and hospitals than in the past,” and “increased use of the 340B program by contract pharmacies and hospitals may result in a greater risk of drug diversion, further heightening concerns about HRSA’s reliance on self-policing to oversee the program.”<sup>12</sup> With respect to hospitals in particular, GAO explained, “[O]perating the 340B program in the hospital environment creates more opportunities for drug diversion compared to other entity types. . . . In light of this and given HRSA’s nonspecific guidance on the definition of a 340B patient, broad interpretations of the guidance may be more likely in the hospital setting and diversion may be more difficult to detect.”<sup>13</sup>

### **Unclear Criteria for Private Hospitals to Participate in 340B Increase the Risk that the Program is Not Tailored to its Mission**

The 340B law has different eligibility requirements for the six types of hospitals that are now 340B-eligible; however, all 340B hospitals must be: (1) owned or operated by State or local government; (2) a public or

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<sup>5</sup> Id. at 25.

<sup>6</sup> Id.

<sup>7</sup> Id.

<sup>8</sup> Id. HRSA is currently reviewing updated guidance on the patient definition internally.

<sup>9</sup> Id. at 27

<sup>10</sup> Id. at 20

<sup>11</sup> Id. at 29

<sup>12</sup> Id. at 28

<sup>13</sup> Id. at 29

private nonprofit hospital “formally granted governmental powers by a unit of State or local government”; or (3) a private nonprofit hospital with “a contract with a State or local government to provide health care services to low-income individuals who are not [Medicare or Medicaid eligible].”<sup>14</sup> While the question of whether a hospital is publicly owned or operated is straightforward, GAO found that the criteria for identifying 340B-eligible private hospitals are more vague - - and no HRSA guidance exists interpreting these criteria, thus creating a risk that the program will go beyond its safety-net mission. In particular, GAO found that, “HRSA has not issued guidance specifying the criteria under which hospitals that are not publicly owned or operated can qualify for the 340B program. . . For the second requirement, HRSA requires a State or local government official and a hospital executive to certify that a contract exists to meet the requirement but does not require hospitals to submit their contracts for review or outline any criteria that must be included in the contracts, including the amount of care a hospital must provide to these low-income individuals.”<sup>15</sup>

### **Criteria for Hospital 340 Participation Based on the “DSH Adjustment Percentage” do not Appropriately Target 340B Eligibility to Safety-Net Hospitals.**

In its 340B report, GAO noted that using the DSH adjustment percentage as part of the 340B eligibility criteria for hospitals has the effect of making eligibility for 340B - - a program created to help providers that serve large numbers of uninsured people - - expand as more people become insured due to broader Medicaid coverage. State-level Medicaid expansions may have already increased 340B eligibility, GAO observed: “One reason for hospital growth [in 340B] could be that more hospitals may have become eligible as a result of State-level Medicaid expansions in recent years,” as “[t]he number of Medicaid patients served by a hospital affects its DSH adjustment percentage, which helps determine hospital eligibility for the 340B program.”<sup>16</sup> Likewise, GAO noted the future implications of this link between Medicaid coverage expansion and 340B eligibility.<sup>17</sup>

GAO also noted earlier MedPAC work that found that the DSH adjustment percentage does not correlate with the amount of uncompensated care a hospital provides. Citing the MedPAC report on this issue, GAO stated that one organization it interviewed “questioned whether the DSH adjustment percentage is the best measure to determine hospitals’ eligibility for the 340B program, because of research indicating that it may not be an adequate proxy for the amount of uncompensated care a hospital provides.”<sup>18</sup>

**GAO Recommendations:** GAO recommended that HRSA take steps to strengthen oversight regarding program participation and compliance with program requirements. Specifically, GAO recommended the Secretary of HHS instruct the administrator of HRSA to take the following action:

- conduct selective audits of 340B covered entities to deter potential diversion;
- finalize new, more specific guidance on the definition of a 340B patient;
- further specify its 340B non-discrimination guidance for cases in which distribution of drugs is restricted and require reviews of manufacturers’ plans to restrict distribution of drugs at 340B prices; and
- issue guidance to further specify the criteria that hospitals that are not publicly owned or operated must meet to be eligible for the 340B program.

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<sup>14</sup> 42 U.S.C. § 256(a)(4)(L)-(O).

<sup>15</sup> GAO-11-836, at 23.

<sup>16</sup> Id. at 27, n. 62.

<sup>17</sup> Id. at 29.

<sup>18</sup> Id.