340B Drug Discount Program

Background

The 340B Drug Pricing Program (340B) was established in 1992 by Section 340B of the Public Health Services Act and later significantly expanded by the Affordable Care Act of 2010 (ACA). Initially, the law required pharmaceutical manufacturers participating in Medicaid to sell outpatient drugs at discounted prices to community health centers, children's hospitals, hemophilia treatment centers, and public and nonprofit disproportionate share hospitals. The ACA expanded the 340B program giving many rural hospitals in Iowa the opportunity to participate in the program. In 2011, the Government Accountability Office (GAO) issued a report that criticized the program's administrator, the Health Resources and Services Administration's (HRSA's) oversight of the 340B program. Since then a small group of lawmakers, led by Iowa's Senator Chuck Grassley (R-IA), have become increasingly concerned about government oversight and program integrity efforts related to the 340B program, especially given the great increase in participants since the passage of the ACA. Discussions and investigations with intent to reform the program continue in Congress.

IHA POSITION

IHA strongly supports the expanded 340B program and supports efforts to improve the 340B program by expanding it further to include: inpatient drugs and Medicare Dependent Hospitals (MDHs) and to eliminate the "orphan drugs" exception to the program. While IHA supports program integrity, IHA strongly opposes efforts to scale back or significantly reduce the benefits of the 340B program. IHA maintains that the program was designed to help patients, hospitals and the federal government save money through the discount of certain drugs.

340B Eligible Hospitals

The 340B program is administered by the Health Resources and Services Administration's Office of Pharmacy Affairs. The following hospitals are eligible to participate in the 340B program:

- Critical Access Hospitals (CAHs)
- Sole-Community Hospitals (SCHs) with a disproportionate share hospital (DSH) adjustment of ≥ 8 percent
- Rural Referral Centers (RRCs) with a DSH adjustment of ≥ 8 percent
- Free-standing cancer hospitals with a DSH adjustment of >11.75 percent
- Free-standing children's hospitals with a DSH adjustment of >11.75 percent
- Disproportionate Share Hospital with a DSH adjustment of >11.75 percent

Hospitals may register online to participate in the 340B program, click here for more information. Hospitals may enroll in the program quarterly by submitting an application to HRSA's OPA. The deadlines are as follows:

Private, Nonprofit Hospital Contract Requirement

In addition to other program requirements, 340B eligible hospitals must meet one of the following:

- Owned or operated by a unit of State or local government, or

- A public or private non-profit corporation that is formally granted governmental powers by a unit of State or local government, or
- A private, nonprofit hospital contracting with the State or local government.

In order to qualify under the contracting provision, a hospital must provide, on the same day as the hospital's other registration information, a "Certification of Contract between Private, Non-profit Hospital, and State/Local Government" that certifies that a valid contract is currently in place between the private, non-profit hospital and a state or local government to provide health care services to low income individuals who are not entitled to Medicare or Medicaid. The certification form (available here) must be signed by the hospital's authorizing official and a government official authorized to represent and bind the governmental entity (e.g., governor, county executive, mayor) that is party to the contract.[1] To clarify, public hospitals do not need to contract with the State or local government. There is no required language or dollar amount that must be included in the contract with the State or local government, but the contract should explain that the hospital will provide health care services to low-income populations that are not eligible for Medicare or Medicaid. The intent behind the contract requirement is to formalize something that most hospitals do anyway.

Annual Recertification Requirements

Participation in the 340B program requires hospitals to annually recertify they remain eligible for the program and that all registration and contact information is up-to-date. Program recertification also means that hospitals must verify that the 340B program contact information for the authorizing official and primary contact is current. The hospital's authorizing official is responsible for ensuring program compliance. Hospitals should review the database to verify all registration information is current and that the hospital remains eligible for the 340B program. To update information, 340B participants may submit a program change request form. Click here to access the 340B program change form. For more information, hospitals may listen to HRSA's pre-recorded webinar and download HRSA's recertification user guide.

HRSA encourages hospitals that encounter any issues with the 340B program database or have questions about recertification, to send an email to Apexus Answers at apexusansers@340bpvp.com or call (888) 340-2787.

Key Limits and Restrictions

- The 340B program does not include **inpatient drugs, "orphan drugs"** (click here for information about the orphan drug exclusion)," or **MDHs**. Advocates continue to work on expanding the program to address these exclusions.

- OPA has explained there are two key program prohibitions: drug diversion and duplicate discount. **Drug diversion** occurs when dispensing drugs to individuals who are not patients of the covered entity or dispensing drugs in an area that is not covered in the 340B program. **Duplicate discount** refers to receiving a 340B discount and a Medicaid rebate on the same drug. For example, a duplicate discount occurs if a covered entity receives a 340B discount at the time of purchase from the manufacturer, and later the state Medicaid agency also claims a rebate from the manufacturer on the same drug.

- Hospitals must maintain **auditable records** that demonstrate compliance with 340B Program requirements.

[1] HRSA program notice, March 7, 2013: http://www.hrsa.gov/opa/programrequirements/policyreleases/hosptialeligibilitypolicy.pdf

- **Group Purchasing Organization (GPO) prohibition**: The GPO prohibition is applicable to free-standing cancer hospitals and children's hospitals. The GPO prohibition does not apply to RRCs, SCHs, or CAHs.

Related Regulatory Action

- In 2014, HRSA was expected to release a rule that will address many key issues related to the 340B program. Issues under consideration for inclusion in the proposed rule include: definition of a patient, duplicate discounts, drug diversion, GPO prohibition, contract pharmacies and audit standards.

- Late in 2014, the mega-rule was pulled by HRSA before ever being proposed. HRSA is expected to issue a Guidance document on the 340B program this summer.

- On July 23, 2013 HRSA released a final rule clarifying the ACA's provision that excludes certain hospitals from purchasing orphan drugs under the 340B drug discount program. Hospitals impacted by the orphan drug exclusion include: CAHs, RRCs, SCHs, and free-standing cancer hospitals. The final rule allows these hospitals to purchase outpatient orphan drugs at 340B prices when used to treat conditions for which the drugs are approved, but not to treat the rare conditions or diseases for which the drugs were given their orphan drug designation. While IHA opposes the orphan drug exclusion, IHA is pleased that HRSA limited the exclusion for these affected hospitals. After litigation, this rule was reissued as Guidance, rather than a final rule.

340B Program is Important to Iowa hospitals:

- Participation in the 340B program has expanded in Iowa because of the Affordable Care Act of 2010 (ACA). The ACA opened the program to many of Iowa's small and rural hospitals that were excluded previously. The 340B program has become a very important program not only to Iowa's safety net and rural hospitals, but also to the Iowans living in communities with access to the 340B program.

- The 340B program is good for the local health care system and it is doing what it was designed to do—help hospitals, patients and the government stretch scarce resources.
- Hospitals in Iowa have experienced substantial savings because of the 340B program and that means they are able to use the money saved for other aspects of providing healthcare to the patients they serve in their communities.

- Hospitals can pass on the discount to their patients, expanding patient access to affordable medications.

- Iowa hospitals continue to invest in innovative ways to improve Iowa's health care delivery system, but Congress continues to cut payments to hospitals and the benefits from the 340B program are extremely important.

- Congress did not intend for the program to be limited to patients without insurance. The purpose of the program, as explained by Congress and included in the Congressional Committee Report from 1992, is to permit covered entities "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." In another Congressional Committee Report from 2010, when Congress was discussing expanding the 340B program to include inpatient drugs, Congress again focused on the importance of reducing costs to hospitals, not the insurance status of the patient. The program was not intended to separate patients by insurance status and doing so would

greatly undermine the program and be administratively burdensome, if not impossible, with existing software limitations.

- Iowa hospitals strongly support program integrity and understand that HRSA has markedly increased its oversight efforts through audits of drug manufacturers and 340B entities as well as requiring annual recertification for 340B entities.

- Iowa hospitals want to work with Congress to expand the program to include inpatient drugs, Medicare Dependent Hospitals, and to eliminate the "orphan drug" exclusion that covers so many of the very expensive cancer drugs used by 340B hospitals. The Congressional Budget Office has estimated that expanding the 340B program to cover inpatient services would save the federal government more than $1.2 billion.

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