

IHA Policy Brief

340B Outpatient Drug Discount Program: The health care reform law greatly expanded the number of hospitals that can participate in the 340B outpatient drug discount program. Hospitals can generate real savings on outpatient drugs by participating in the program and IHA explains what hospitals need to know.

Background:

The 340B Drug Pricing Program (340B) was established in 1992 by Section 340B of the Public Health Services Act. Before the health care reform law expanded the program, the law required pharmaceutical manufacturers participating in Medicaid to sell outpatient drugs at discounted prices to taxpayer-supported health care facilities that cared for the uninsured and those with low income. Only community health centers, children's hospitals, hemophilia treatment centers and public and nonprofit disproportionate share hospitals (DSH) that served low-income and indigent populations were eligible to participate in the program.

The *Patient Protection and Affordable Care Act of 2010* expanded the 340B program giving many rural hospitals the new opportunity to participate in the program. Today, the 340B program is administered by the Health Resources and Services Administration's Office of Pharmacy Affairs (OPA). OPA began accepting applications last August and continues to accept new applicants on a quarterly basis.

As explained below, the requirements to participate in the newly expanded program are not the same for all hospitals and there are certain program limitations and restrictions.

Newly eligible entities:

- Critical Access Hospitals (CAHs)
- Sole-Community Hospitals (SCHs) with a 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

Private, Nonprofit Hospitals Must Contract with State or Local Government

All of the newly eligible entities must be publicly owned or private, non-profit hospitals with a contract with the state or local government. Public hospitals do not need a contract; only private, non-profit hospitals need to create this contract. 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 who are not eligible for Medicare or Medicaid. The intent behind the contract requirement is to formalize something that most hospitals do anyway.

The Group Purchasing Organization (GPO) Exclusion

The GPO exclusion is applicable to free-standing cancer hospitals and children's hospitals. The GPO exclusion does not apply to RRCs, SCHs, or CAHs.

Registration Deadlines

Hospitals may enroll in the program quarterly by submitting an application to OPA. The deadlines to enroll in the program are **December 1, March 1, June 1 and September 1**. Application forms may be found on the [HRSA OPA website](#).

The Health Resources and Services Administration's Pharmacy Services Support Center (PSSC) has prepared a helpful [pre-registration checklist](#) for hospitals to use as they work to complete the registration process with OPA.

Key Limitations and Restrictions

Though there were several versions of the new 340B provision as the health care reform bill was being negotiated, the final 340B expansion that was signed into law did *not* expand the program to include **inpatient drugs, "orphan drugs," or Medicare-Dependent Hospitals**. Advocates continue to work on expanding the program to address these exclusions.

OPA has explained there are two key program prohibitions: diversion and duplicate discount. **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. **Duplicate discount** refers to receiving a 340B discount and a Medicaid rebate on the same drug. For example, 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, that would be considered a duplicate discount.

Hospitals must also maintain **auditable records** that demonstrate compliance with 340B program requirements.

Additional information can be found on the HRSA OPA [website](#).
