

Date March 7, 2013

**340B DRUG PRICING PROGRAM NOTICE**  
Release No. 2013-3

**CLARIFICATION OF ELIGIBILITY FOR HOSPITALS THAT ARE NOT PUBLICLY OWNED OR OPERATED**

This policy release is being issued to restate the criteria that hospitals that are not publicly owned or operated must meet to be eligible for the 340B Drug Pricing Program (340B Program).

**Background**

Section 602 of Public Law 102-585, the “Veterans Health Care Act of 1992,” enacted section 340B of the Public Health Service Act (PHSA), “Limitation on Prices of Drugs Purchased by Covered Entities.” The Office of Pharmacy Affairs within the Healthcare Systems Bureau of the Health Resources and Services Administration (HRSA) is charged with administering the 340B Program established by Section 340B of the PHSA.

**340B Hospital Eligibility Criteria**

Section 340B(a)(4)(L)(i) of the PHSA requires that in order for a disproportionate share hospital to be eligible for the 340B Program, it must be owned or operated by a state or local government; be a public or private non-profit corporation which is formally granted governmental powers by a unit of state or local government; or be a private non-profit hospital which has a contract with a state or local government to provide health care services to low income individuals who are not entitled to benefits under Medicare or Medicaid. Section 340B(a)(4)(M)-(O) of the PHSA extends this 340B Program requirement to children’s hospitals, freestanding cancer hospitals, critical access hospitals, rural referral centers, and sole community hospitals.

A hospital participating in the 340B Program has an ongoing responsibility to notify HRSA immediately if the hospital no longer meets 340B eligibility requirements and must cease purchasing 340B drugs. The hospital may have to repay manufacturers if 340B purchases were made when the hospital was ineligible for the 340B Program. HRSA reserves the right to request additional information from a covered entity to ensure that the covered entity meets all eligibility requirements.

**Formally Granted Governmental Powers**

For 340B Program purposes, a hospital is “formally granted governmental powers” when a state or local government formally delegates to the hospital a power usually exercised by the state or

local government. The delegation may be granted through state or local statute or regulation; a contract with a state/local government; creation of a public corporation; or development of a hospital authority or district to provide healthcare to a community on behalf of the government. Examples of governmental powers include, but are not limited to, the power to tax, issue government bonds, act on behalf of the government, etc. Without one of the aforementioned, powers generally granted to private persons or corporations upon meeting of licensure requirements, such as a license to practice medicine or provide healthcare services commercially, do not by themselves constitute governmental powers.

A hospital seeking to demonstrate compliance with 340B(a)(4)(L)(i) on the grounds of having been granted governmental powers must submit to HRSA on the same day as the hospital's other registration information the following information:

- the identity of the government entity granting the governmental power to the hospital;
- a description of the governmental power that has been granted to the hospital and a brief explanation as to why the power is considered to be governmental; and
- a copy of any official documents issued by the government to the hospital that reflect the formal grant of governmental power.

### **Contract with a State or Local Government**

In order to qualify under this 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.).