

## Critical Access Hospitals Can Now Register for the 340b Discount Drug Program

Monday, August 2, is the first day a critical access hospital (CAH) can register for the 340b Discount Drug Program (the Program). CAHs can participate in the Program as part of the *Affordable Care Act*. Attached are the three forms necessary to register. Information and the registration forms can be found on Health Resources and Services Administration (HRSA), Office of Pharmacy Affairs (OPA) website at <http://www.hrsa.gov/opa>.

### Overview

The Program allows for the purchase of drugs used in an outpatient setting on patients of a covered entity to be purchased at or below the 340b statutory ceiling price. This can include over-the-counter drugs if prescribed by a physician and is only for outpatients. Outpatient services not considered provider-based by Medicare do not qualify; inpatient services do not qualify. Likewise, retail pharmacy drugs do not qualify as the customer does not meet the definition of a patient (see below). Under the Program, drug manufacturers sell drugs at discounted prices leading to significant savings for an eligible entity. The ceiling discount for name brand drugs is 15.1%; the ceiling discount for generic or physician prescribed over-the-counter drugs is 11%. Therefore, if the average manufacturer price (AMP) of a name brand drug is \$50, the most the drug would cost under the Program is \$42.45. It could be purchased for less, but never more.

There is no list of AMP published. The calculation is based on “confidential figures” and, therefore, not public. The drug wholesalers have the pricing file and will share it with covered entities.

A hospital should have written policies detailing how the hospital plans to meet requirements such as eligible patients (as defined below) and how to ensure the price paid excludes any state rebate (see below).

There is also a governmental program, Prime Vendor Program (PVP), an eligible facility may join that should decrease drug costs below the “ceiling” (the guaranteed maximum cost for outpatient drugs under the Program); their website is <https://www.340bpvp.com>.

### Qualifications

To qualify, a CAH must attest and provide support that they are one of the following:

1. a private non-profit hospital which has a contract with a state or local government to provide healthcare services to low income individuals who are not entitled to benefits under Medicare or Medicaid
2. entity owned or operated by a unit of state or local government
3. public or private non-profit hospital which is formally granted governmental powers by a unit of state or local government

For outpatient clinics to qualify, they must be provider-based to the hospital. HRSA defines this as they are reported as a department on the hospital's Medicare cost report and not as a non-allowable cost center. These clinics are on line 60 of the cost report; ineligible clinics will be on lines 90-100s.

### **Rules and definitions**

***Patient definition*** – an individual is a patient if:

- The covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care; and
- The individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements (e.g. referral for consultation) such that responsibility for the care provided remains with the covered entity; and
- The individual receives a health care service or range of services from the covered entity which is consistent with the service or range of services for which grant funding or federally-qualified health center look-alike status has been provided to the entity. CAHs are exempt from this requirement.
- An individual will not be considered a "patient" of the entity for purposes of the Program if the only health care service received by the individual from the covered entity is the dispensing of a drug or drugs for subsequent self-administration or administration in the home setting.
- An individual registered in a state operated AIDS drug purchasing assistance program receiving financial assistance under title XXVI of the PHS Act will be considered a "patient" of the covered entity for purposes of this definition if so registered as eligible by the state program.”

***Medicaid discount rule*** – since the drugs are sold at a discount, the same drug cannot be claimed for a Medicaid rebate by the state. The hospital can either choose to not give 340b drugs to a Medicaid recipient, or they must be carved out of the state's rebate calculation.

***Tracking/audit*** – the hospital must maintain auditable records of the drugs purchased through the Program. If audited, HRSA must verify the drugs were only used on hospital **outpatients** and the state did not receive a Medicaid rebate. The hospital is subject to audit by HRSA and the drug manufacturers.

***Enrollment*** – Enrollment is done quarterly. However, for newly eligible facilities (like CAHs) there is a rolling enrollment period starting Monday, August 2. Once the hospital's eligibility status has been verified by OPA, it will be eligible to receive discounts. After the initial rolling enrollment period (e.g. the hospital does not apply until the end of the year), eligibility starts the first day of each quarter (January 1, April 1, July 1, October 1) and enrollment forms are due thirty-days prior to the start dates. OPA is behind on setting up the registration process for CAHs; therefore, it has allowed a rolling enrollment period for the current quarter. Once enrolled, an eligible facility will remain on OPA's list until it no longer qualifies for the Program.

**Enrollment process**

Facilities that previously attempted enrollment using the forms listed on OPA's website prior to July 29, 2010 must also follow these steps:

1. Fill out the attached paperwork (make sure each area is completely filled out)
2. Send the attached paperwork, along with documentation indicating the hospital is a government entity or has an agreement with a government entity to provide charity care to:

HRSA, Office of Pharmacy Affairs  
5600 Fishers Lane, Mail Stop 10C-03  
Rockville, Maryland 20857

**Who should enroll**

We believe most all CAHs will benefit from this program. Those we believe will benefit the most are those with busy emergency rooms and chemotherapy departments.

**Closing**

If you have any questions or require additional information, please Shar Sheaffer at 509.242.0874.