



Safety Net Hospitals for Pharmaceutical Access

HRSA's Current Patient Definition Guidelines

340B hospitals are currently subject to a three-pronged test for assessing the eligibility of individuals to receive 340B-discounted drugs from a covered entity.

1. the covered entity must **maintain records** of health care services for the individual;
2. the individual must receive care from a health care **professional** who is **employed** by or **under contract** or other arrangements with the covered entity such that **responsibility** for the care provided remains with the covered entity; and
3. The individual receives health care services from the covered entity which is consistent with the services for which grant funding or FQHC look-alike status has been provided to the entity.

HRSA's Proposed Patient Definition Guidelines

For an individual to be eligible to receive 340B drugs under the proposed guidelines, each of the following eight tests would have to be satisfied:

1. the covered entity would have to continue to **maintain records** of health care services for the individual;
2. the covered entity would also have to **own, control and possess** the records;
3. the records would have to **document** the health care **services that result in** the use of, or prescription for, 340B drugs;
4. the **prescription** or order for a 340B drug would have to result from an **outpatient service**;
5. a health care **provider** both has to **write** the 340B **prescription** or order and **provide** diagnostic and treatment **services of which the prescription is a part**;
6. the health care provider writing the prescription or ordering the 340B drug would have to be **employed** by or **under contract** with the covered entity;
7. the outpatient service resulting in the use of or prescription for a 340B drug would have to be provided by the DSH hospital's main campus or a **provider-based** site of the DSH; and
8. the hospital's provider-based status would have to be reflected in the hospital's **Medicare cost report**.

If the 340B prescription is written by someone other than an employee or contractor of the DSH hospital, criteria (6) through (8) would change to the following requirements:

6. a health care provider employed by or under contract with the covered entity would have to **refer** the patient to the outside prescribing provider;
7. the referral would have to be for **follow-up care** for the **same condition** that was treated or examined by the hospital; and
8. the hospital would have to retain **ongoing responsibility** for the patient such that the patient would have to return for care by the hospital (or provider-based hospital site) within **12 months** after the referral.

These proposed guidelines should be withdrawn and HRSA should work with providers and industry to make any necessary revisions.