



## Safety Net Hospitals for Pharmaceutical Access

### Provisions in Health Care Reform Law Affecting 340B Eligibility for New Categories of Hospitals

The health care reform law contains several provisions that will have a significant impact on the 340B drug discount program and its participants. Many of the provisions relate to the eligibility of a number of new categories of hospitals. Safety Net Hospitals for Pharmaceutical Access (SNHPA) has put together the following summary of the eligibility requirements for these hospitals. SNHPA, which has been advising hospitals about 340B implementation matters since the program was created in 1992, is available to provide technical assistance as your institution contemplates enrollment in the program. For more information, please contact SNHPA Associate Counsel Greg Doggett at (202-552-5859, [greg.doggett@snhpa.org](mailto:greg.doggett@snhpa.org)) or Director of Programs and Membership Anna Mangum (202-552-5863, [anna.mangum@snhpa.org](mailto:anna.mangum@snhpa.org)).

- **New Categories of 340B Covered Entities.** The health care reform law extended 340B eligibility to Critical Access Hospitals (CAHs), Sole Community Hospitals (SCHs), Rural Referral Centers (RRCs), free-standing children's hospitals, and free-standing cancer hospitals. To be eligible for 340B drug discounts, entities must meet both 340B program requirements and laws defining what is a CAH, SCH, RRC, free-standing children's hospital, or free-standing cancer hospital. (See attached Appendix for definitions.) Like current 340B enrollees, a newly eligible entity will have to be either a public hospital or private nonprofit hospital that contracts with state or local government to provide indigent care.
- **Lower Medicare DSH Adjustment Percentages for Some Covered Entities.** SCHs and RRCs must now have a Medicare Disproportionate Share Hospital (DSH) adjustment percentage of at least 8 percent to qualify for the 340B program. Fewer than 100 SCHs and RRCs fall between the 8 and 11.75 percent levels. Before the health care reform law, SCHs and RRCs could enroll in the 340B program as DSH hospitals if their DSH percentages were greater than 11.75 percent but are now recognized as separate categories of 340B covered entities with lower required DSH percentages. Although free-standing children's hospitals and free-standing cancer hospitals technically are not DSH hospitals, they must have a payer mix that would give them a DSH percentage of greater than 11.75 percent. While CAHs too are not DSH hospitals, a proxy DSH percentage will not be required for CAHs.
- **No GPO Withdrawal for Some New Covered Entities.** Unlike DSH hospitals, free-standing children's hospitals, and free-standing cancer hospitals, rural hospitals that have been added to the 340B program, including CAHs, SCHs, and RRCs, will not be required to withdraw from their group purchasing organizations (GPOs) for the purchase of outpatient drugs as a condition of enrollment in the program. (Note that the GPO



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exclusion for DSH hospitals, free-standing children hospitals, and free-standing cancer hospitals applies only to the purchase of outpatient drugs. These covered entities can continue to acquire inpatient drugs through their GPOs).

- **No Access to Orphan Drugs at 340B Prices for New Covered Entities.** Unfortunately, the newly eligible covered entities will not have access to 340B discounts on orphan drugs. (To access the federal government's database of orphan drugs, go to <http://www.accessdata.fda.gov/scripts/opdlisting/ood/index.cfm>.) However, pharmaceutical manufacturers must continue to provide 340B discounts for orphan drugs to covered entities already in the 340B program, such as DSH hospitals. SNHPA and other organizations are working to repeal the orphan drug exemption for new entities.



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### Appendix

#### Critical Access Hospital

Under the Balanced Budget Act (BBA) of 1997, certain facilities participating in Medicare can become Critical Access Hospitals (CAHs). CAHs are a separate provider type with their own Medicare Conditions of Participation as well as a separate payment method. This difference means that CAHs do not have a Medicare Disproportionate Share Hospital adjustment percentage, making public and private non-profit CAHs that contract with state or local government to provide indigent care potentially eligible for the 340B program.

A hospital must meet the following criteria to be designated a CAH:

1. Be located in a state that has established a State Flex Program (Connecticut, Delaware, Maryland, New Jersey, and Rhode Island do not have such a program);
2. Be located in a rural area (or be treated as rural under a special provision that allows qualified hospital providers in urban areas to be treated as rural for purposes of becoming a CAH);
3. Furnish 24-hour emergency care services, using either on-site or on-call staff;
4. Have 25 or less inpatient acute care beds (however, a CAH may also operate a rehabilitation or psychiatric unit, each with up to 10 beds);
5. Have an average annual length of stay of 96 hours or less; and
6. Be located either more than 35 miles from the nearest hospital or CAH or more than 15 miles in areas with mountainous terrain or only secondary roads OR be State-certified as of December 31, 2005 as a “necessary provider” of health care services to residents in the area.

#### Sole Community Hospital

A hospital is eligible to be classified as a Sole Community Hospital (SCH) if it is located more than 35 miles from other like hospitals. A hospital may also be classified as a SCH if it is located in a rural area AND it meets at least ONE of the following three conditions:

1. The hospital is located between 25 and 35 miles from other like hospitals AND meets ONE of the following criteria:
  - a) 25 percent or less of residents who become hospital inpatients or 25 percent or less of the Medicare beneficiaries who become hospital inpatients in the hospital’s service area are admitted to other like hospitals located within a 35-mile radius of the hospital or, if larger, within its service area;
  - b) The hospital has fewer than 50 beds and would meet the 25 percent criterion were it not for the fact that some beneficiaries or residents were forced to seek



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- specialized care outside of the service area due to the unavailability of necessary specialty services at the hospital; or
- c) Other like hospitals are inaccessible for at least 30 days in each of two out of three years because of local topography or prolonged severe weather conditions;
- 2. The hospital is located between 15 and 25 miles from other like hospitals but because of local topography or prolonged severe weather conditions, other hospitals are inaccessible for at least 30 days in each of two out of three years; or
- 3. The travel time between the hospital and the nearest like hospital is at least 45 minutes.

SCHs must have a Medicare Disproportionate Share Hospital adjustment percentage of 8 percent or higher to participate in the 340B program. In addition, a SCH must be a public hospital or private non-profit hospital that contracts with local or state government to provide indigent care to be eligible.

### **Rural Referral Center**

The Rural Referral Center (RRC) Program was established to support high-volume rural hospitals that treat a large number of complicated cases. In general, a Medicare participating hospital is classified as a RRC if it is located in a rural area and it meets ONE of the following criteria:

1. It has 275 or more beds available for use during its most recently completed cost reporting period; OR
2. It meets the following three requirements:
  - a) At least 50 percent of the hospital's Medicare patients are referred from other hospitals or from physicians who are not on the staff of the hospital;
  - b) At least 60 percent of the hospital's Medicare patients live more than 25 miles from the hospital; and
  - c) At least 60 percent of all services the hospital furnishes to Medicare beneficiaries are furnished to beneficiaries who live more than 25 miles from the hospital; OR
3. If the hospital does not meet the criteria in items 1) or 2) above, it must be located in a rural area and must meet the criteria listed below in a) and b) AND at least ONE of the criteria listed below in c), d), or e):
  - a) Case-Mix Index— The hospitals case-mix of discharges for the most recent year must be at least equal to the national case-mix index value as established by the Centers for Medicare & Medicaid Services (CMS) or the median case-mix index value for urban hospitals located in each region; AND
  - b) Number of Discharges—The number of discharges is at least 5,000 or the median number of discharges for urban hospitals set by the CMS yearly. For an osteopathic hospital, its number of discharges is at least 3,000; AND



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- c) Medical Staff—More than 50 percent of the hospital’s active medical staff are specialists; OR
- d) Source of Inpatients—At least 60 percent of all discharges are for inpatients who reside more than 25 miles from the hospital; OR
- e) Volume of Referrals—At least 40 percent of all inpatients treated at the hospital are referred from other hospitals or from physicians who are not on the hospital’s staff. Under the Balanced Budget Act of 1997, any hospitals designated as RRCs in FY 1991 are grandfathered in.

RRCs must have a Medicare Disproportionate Share Hospital adjustment percentage of 8 percent or higher to participate in the 340B program. In addition, an RRC must be a public hospital or private non-profit hospital that contracts with local or state government to provide indigent care to be eligible.

### **Free-Standing Children’s Hospitals**

Free-standing children’s hospitals are exempt from the Medicare prospective payment system (PPS). To be a PPS-exempt children’s hospital, most of a facility’s patients must be under age 18. Although free-standing children’s hospitals technically are not Medicare Disproportionate Share Hospitals (DSH), they must have a payer mix that would give them a DSH percentage of greater than 11.75 percent to participate in the 340B program. Lastly, a free-standing children’s hospital must be a public hospital or private non-profit hospital that contracts with local or state government to provide indigent care to be eligible.

### **Free-Standing Cancer Hospitals**

Free-standing cancer hospitals are exempt from the Medicare prospective payment system (PPS). A hospital not currently designated by the Medicare program as a free-standing cancer hospital can become so only through legislative action. Eleven hospitals are currently recognized as free-standing cancer hospitals nationwide.

Although free-standing cancer hospitals technically are not Medicare Disproportionate Share Hospitals (DSH), they must have a payer mix that would give them a DSH percentage of greater than 11.75 percent to participate in the 340B program.

Lastly, a free-standing cancer hospital must be a public hospital or private non-profit hospital that contracts with local or state government to provide indigent care to be eligible.