

receiving such a grant (i.e., "look-alikes"); or

(d) was treated by the Secretary, for purposes of part B of Title XVIII of the Social Security Act, as a comprehensive Federally funded health center as of January 1, 1990; or

(e) an outpatient health program or facility operated by a tribe or tribal organization under the Indian Self-Determination Act (Public Law 93-638) or by an urban Indian organization receiving funds under title V of the Indian Health Care Improvement Act for the provision of primary health services. (Norma Campbell, Division of Community and Migrant Health, 301-594-0287), (Marie Garramone, Division of Community and Migrant Health {for look-alikes}, 301-594-4335), (Charles Woodson, Division of Programs for Special Populations, homeless and public housing health centers, 301-594-4430; Laura Visser, {for 340S school based programs}, 301-594-4470), (Elmer Brewster, DCSP, Special Initiatives Branch {for Urban Indian}, 301-443-4680), and (Merry Elrod, Office of Tribal Activities {for P.L. 93-638}, 301-443-1044).

2. Family planning projects receiving grants or contracts under section 1001, 42 U.S.C. 300. (Sophia Lawson, Office of Population Affairs, 301-594-4000).

3. An entity receiving a grant for outpatient early intervention services for HIV infection under subpart II of part C of title XXVI, 42 U.S.C. 300ff-51 *et seq.* (Laverne Green, Office of Programs for Special Populations, HIV, 301-594-4451).

4. A State-operated AIDS drug purchasing assistance program receiving financial assistance under section 2616 of the Act, 42 U.S.C. 300ff-26. (Richard Schulman, Division of HIV Services, 301-443-9091).

5. A black lung clinic receiving funds under section 427(a) of the Black Lung Benefits Act, 30 U.S.C. 937(a). (Norma Campbell, Division of Community and Migrant Health, 301-594-0287).

6. A comprehensive hemophilia diagnostic treatment center receiving a grant under section 501(a)(2) of the Social Security Act, 42 U.S.C. 701(a)(2). (Patrick McGuckin, National Hemophilia Program, 301-443-9051).

7. A Native Hawaiian Health Center receiving funds under the Native Hawaiian Health Care Act of 1988, 42 U.S.C. 11701 *et seq.* (Julia Tillman, Division of Programs for Special Populations, 301-594-4460).

8. Certain covered facilities must be certified by the Secretary before they become eligible for the discount drug prices, pursuant to section 340B(a)(7) of

the PHS Act. The facilities requiring certification are those that

(a) receive grant funds related to the treatment of sexually transmitted diseases through a state or local government under section 318 of the PHS Act, 42 U.S.C. 247c, or related to the treatment of tuberculosis through a state or local government under section 317 E (a) of the PHS Act, 42 U.S.C. 247b-6, (Carmine Bozzi, Centers for Disease Control and Prevention, National Center for Prevention Services, 404-639-8008), or

(b) receive assistance under title XXVI of the PHS Act, 42 U.S.C. 300ff *et seq.*, other than a State or unit of local government or a grantee for HIV outpatient early intervention services (subpart II of part C of title XXVI of the PHS Act). (Richard Schulman, Division of HIV Services, 301-443-9091).

The criteria for eligibility include State certification that the facility does receive Federal grant funds and is a facility described in (a), or (b) above.

Electronic Data Retrieval System (EDRS) which can be accessed by dialing (301) 594-4992.

#### *Disproportionate Share Hospitals*

Certain hospitals are eligible for section 340B discount outpatient drug pricing if they meet the eligibility criteria. First, section 340B(a)(4)(L)(ii) provides that a hospital must be a "disproportionate share" hospital (DSH) as defined in section 1886(d)(1)(B) of the Social Security Act, which (for the most recent cost reporting period that ended before the calendar quarter involved) had a disproportionate share adjustment greater than 11.75 percent. This percentage is determined by the Health Care Financing Administration (HCFA), and a list of DSHs which meet this criteria is provided to the Office of Drug Pricing.

Second, section 340B(a)(4)(L)(i) provides that DSHs eligible for PHS pricing must meet one of the following requirements: (1) is owned or operated by a unit of State or local government, (2) is a public or private non-profit corporation which is formally granted governmental powers by a unit of State or local government, or (3) is a private nonprofit 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 title XVIII or XIX of the Social Security Act. All DSHs wishing to have access to section 340B discount outpatient drug pricing must provide the ODP a certification of their compliance with one of the three alternative requirements.

Third, a DSH is prohibited from participating in a group purchasing organization or any group purchasing association, pursuant to section 340B(a)(4)(L)(iii). DSHs wishing to access the discount pricing must provide the Office of Drug Pricing with a certification of their compliance with this prohibition.

DSHs must submit all necessary certifications to the Public Health Service DSH contact person—Elizabeth Hickey, Office of Drug Pricing, Bureau of Primary Health Care, West Tower, 10th Floor, 4350 East West Highway, Bethesda, Maryland, 20814, telephone (301) 594-4353.

#### **II. Entity Participation Requirements**

Section 340B(a)(4) of the PHS Act defines a "covered entity" as belonging to one or more of the eligible categories of PHS grantees or disproportionate share hospitals listed in subparagraph (4) and meeting the requirements of subparagraph (5). Subparagraph (5)(A) requires HHS to develop a mechanism to prevent a double PHS discount/Medicaid rebate potential; therefore, as part of this mechanism, each eligible entity must provide the ODP with certification of its pharmaceutical Medicaid billing status. Any entity which does not comply with this requirement will not be deemed a "covered entity" and will not be eligible for section 340B drug discounts. Those entities currently listed on the ODP master list which have not certified their Medicaid billing status will be removed from the ODP master list unless they certify their current billing status by the next quarterly update. Entities listed on subsequent program updates will be given one quarter from the date of the program update or until the next ODP update to certify their Medicaid billing status to ODP. Once the entity has certified its Medicaid billing status, its name will be included on the master list as a covered entity on the next ODP update.

A certification of the following information must be provided to the ODP before an entity will be deemed a "covered entity." First, a covered entity, billing on a cost basis for covered outpatient drugs, must provide the ODP with a pharmaceutical Medicaid number (the number which the entity uses to bill Medicaid for such drugs). Second, a covered entity using an all-inclusive rate (either per encounter or visit) must provide the ODP with certification of this billing status and whether the all-inclusive rate includes covered outpatient drugs. Third, if a covered entity does not bill Medicaid for covered outpatient drugs, the entity