

applicant will make findings specific to the following categories of health professions schools:

- (A) Health professions schools of historically black colleges and universities.
- (B) Other health professions schools attended by a substantial number of minority individuals.
- (C) Health professions schools generally.

#### Eligibility

Eligible applicants include public and non-profit private entities.

This program was announced in the *Federal Register* at 59 FR 32444, dated June 23, 1994. The program requirements and review criteria were proposed for public comment. No comments were received during the 30 day comment period. Therefore, the program requirements and review criteria remain as proposed.

#### Final Program Requirements

The award recipient shall participate in the cost of the program as follows: For each year funds are awarded under this program, the matching contribution shall be at least one-third of the amount of the Federal award for that year. Up to 50% of the recipient's matching contribution may be in the form of in-kind donations of faculty time, staff time, use of computers or other shared resources.

In addition, each applicant shall evidence that training related to medical education research is occurring or is planned by the organization.

#### Final Review Criteria

The review of applications will take into consideration the following criteria:

- (1) The qualifications and achievements of the proposed center's principal investigator and senior researchers, including level of productivity and quality of research in medical education;
- (2) Demonstration of an understanding of the particular subject areas of medical education research that are relevant to Federal policies and evidence of ability to manage research in such areas;
- (3) The appropriateness of the time commitments of the principal investigator and senior researchers;
- (4) The strength of the applicant's plan to actively promote dissemination of research findings to all health professionals involved in education and training—including those whom are primarily practitioners, and to relevant policy makers;
- (5) The appropriateness of the proposed budget;

(6) The planned level of commitment to the center from the applicant institution, as evidenced by specific plans for the type of financial support that will be offered, and for support of the organizational structure of the center. Evidence of a prior institutional commitment to generalizable research in medical education will also be sought;

(7) The past success and future potential of the proposed center's researchers in receiving funding from other sources; and

(8) The likely effectiveness of the organizational and management arrangements to operate the proposed center.

#### Additional Information:

If additional programmatic information is needed, please contact: Dr. Brian Goldstein, Office of Health Professions Analysis and Research, Bureau of Health Professions, Health Resources and Services Administration, Parklawn Building, Room 8-47, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone: (301) 443-6936, FAX: (301) 443-0463.

This program, Cooperative Agreements for Centers for Medical Education Research, is listed at 93.222 in the *Catalog of Federal Domestic Assistance*. It is not subject to the provisions of Executive Order 12372, Intergovernmental Review of Federal Programs (as implemented through 45 CFR part 100). This program is not subject to the Public Health System Reporting Requirements.

Dated: September 13, 1994.

James A. Walsh,

Acting Administrator.

[FR Doc. 94-23094 Filed 9-16-94; 8:45 am]

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#### Public Health Service

##### Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Outpatient Hospital Facilities

AGENCY: Public Health Service, HHS.

ACTION: Final notice.

**SUMMARY:** Section 602 of Public Law 102-585, the "Veterans Health Care Act of 1992" (the "Act"), enacted section 340B of the Public Health Service Act ("PHS Act"), "Limitation on Prices of Drugs Purchased by Covered Entities." Section 340B provides that a manufacturer who sells covered outpatient drugs to eligible entities must sign a pharmaceutical pricing agreement (the "Agreement") with the Secretary, Department of Health and Human Services, in which the manufacturer

agrees to charge a price for covered outpatient drugs that will not exceed the amount determined under a statutory formula.

The purpose of this notice is to inform interested parties of final program guidelines concerning the inclusion of outpatient disproportionate share hospital (DSH) facilities in the PHS drug discount program.

**FOR FURTHER INFORMATION CONTACT:** Marsha Alvarez, R. Ph., Director, Office of Drug Pricing, Bureau of Primary Health Care, 4350 East West Highway, West Tower, 10th Floor, Bethesda, MD 20814, tel: (301) 594-4353.

EFFECTIVE DATE: October 19, 1994.

#### SUPPLEMENTARY INFORMATION:

##### (A) Background

Proposed guidelines were announced in the *Federal Register* at 59 FR 29300 on June 6, 1994. A period of 30 days was established to allow interested parties to submit comments. The Office of Drug Pricing received 8 letters with comments concerning legal authority for developing the proposed guidelines, responsibility for determining eligibility, the inclusion of non-traditional outpatient facilities, the need for a definition of eligible hospital facility, ambiguity in the policies of the Health Care Financing Administration (HCFA) regarding the Medicare cost report, possible exceptions for unique circumstances, a retroactive effective date, and general comments concerning the definition of "patient" and a contracted pharmacy service mechanism.

The following section presents a summary of all major comments, grouped by subject, and a response to each comment. All comments were considered, and the guideline is adopted as proposed, with minor changes to increase clarity.

##### (B) Comments and Responses

**Comment:** Manufacturers should not be required to provide discounts to outpatient facilities that are included on the Medicare cost reports of eligible DSHs until the PHS Office of Drug Pricing includes the names of the eligible outpatient facilities on the master list of eligible covered entities.

**Response:** When an eligible DSH submits the list of all outpatient facilities (on-site and off-site) included on its Medicare cost report and Medicaid billing status information to the Office of Drug Pricing and the Office adds these facilities to the master list of eligible and participating entities during regular quarterly updates, the facilities will then be able to access PHS discount

pricing. This information will be posted on the Electronic Data Retrieval System (EDRS), maintained by the Office of Drug Pricing. To access this information call (301) 594-4992.

*Comment:* The proposed guidelines have created a new definition of "DSH" which appears to be within the realm of legislating as opposed to rulemaking.

*Response:* Section 340B(a)(4) of the PHS Act lists the various groups of entities eligible to receive PHS discount pricing. Section 340B(a)(4)(L) describes a subset of "hospitals" as defined in section 1886(d)(1)(B) of the Social Security Act as eligible to participate in the program. Because section 1886 addresses Medicare payment for hospital inpatient services only, the scope of the term "hospital" has been limited to the hospital inpatient services. However, section 340B deals exclusively with outpatient drugs. Although Congress clearly intends this narrow definition be used to identify the Medicare disproportionate share hospitals which are eligible for section 340B drug discounts, we do not believe it is reasonable to use this same definition to limit where the section 340B outpatient drugs can be used. Some disproportionate share hospitals offer outpatient services in off-site or satellite outpatient facilities. Further, the movement of nonprofit hospitals in recent years has been to reorganize and offer a variety of services, other than traditional inpatient hospital services, through separate divisions, lines of business, or entities. Therefore, for purposes of section 340B drug discounts, a further interpretation of "hospital" is needed.

*Comment:* In some instances, the Medicare cost report does not include all of the clinics and services which should be eligible for the PHS discount pricing. For example, hospitals refer patients for specific types of treatments to other hospitals, such as large teaching hospitals which have specialized equipment and medical personnel. Further, hospitals are establishing separate primary care services in different areas of the community. These facilities are often free-standing and not included on the DSH Medicare cost report, but generally are customers of the hospitals and have limited financial resources.

*Response:* Although it is understandable that the DSH would desire to obtain PHS pricing for these various facilities, the statute clearly states that it is only the DSH that qualifies for discount pricing. We have attempted to define DSH in a manner consistent with HCFA policy guidelines (Provider Certification, State Operation

Manual, section 2024). Only outpatient facilities which are an integral component of the DSH will be included on the DSH Medicare cost report, and only these facilities will be eligible for PHS discount pricing.

*Comment:* The proposed guidelines would permit any health care entity, by means of its business relations with other health care entities, to make itself eligible for PHS pricing. Any clinic, facility, or community hospital affiliated with a DSH could consolidate its cost reporting requirements and use the Medicare provider number of the DSH to make itself eligible for PHS pricing. This is not consistent with Congress's intent in precisely defining a list of entities eligible for the PHS discount pricing.

*Response:* Congress referred to section 1886 of the Social Security Act (Medicare inpatient hospital payment) for the definition of DSH; therefore, it is reasonable to utilize existing Medicare rules to determine eligibility for PHS discount pricing. The proposed Medicare cost report test was developed by Medicare officials and used, in part, to determine whether a facility is a component of a hospital. If an outpatient facility does not share in the hospital cost report, it is properly viewed as an independent, free-standing facility.

When a DSH attempts to certify multiple components as a single hospital for purposes of Medicare certification, it must follow guidelines developed by HCFA. These guidelines (Provider Certification, State Operation Manual, section 2024) establish tests to determine whether an additional hospital facility, geographically separated but in the same metropolitan area, is a separate facility from or a component of a single hospital. These tests include: (a) all components subject to the control and direction of one common owner (i.e., governing body) which is responsible for the operational decisions of the entire hospital enterprise; (b) one chief medical officer who reports directly to the governing body and who is responsible for all medical staff activities of all components; (c) integration of the organized medical staff (e.g., all medical staff members having privileges at all components); and (d) one chief executive officer through whom all administrative authority flows and who exercises control and surveillance over all administrative activities of all components. This does not preclude the establishment of a deputy or assistant executive officer position.

If the off-site clinic meets these tests, it would be included in the DSH

Medicare cost report. This test clearly determines whether a facility is an integral part of a DSH hospital, and is an appropriate standard to determine eligibility. It incorporates Medicare criteria that are not ambiguous and forms an independent and objective basis on which to determine eligibility.

*Comment:* The proposed guidelines should be applied uniformly to all DSH outpatient facilities, regardless of whether they fit the common perception of a traditional hospital outpatient clinic (e.g., include facilities that serve prison inmates, HMOs, home infusion and home health patients). Anything short of this would be extremely difficult to administer since separating traditional from non-traditional facilities would be a highly subjective and time-consuming exercise. Further, PHS should include in the final notice a specific definition for eligible "outpatient facility."

*Response:* Section 340B(b) of the PHS Act refers to section 1927(k) of the Social Security Act for the definition of "covered outpatient drug." This definition does not include any limitations on outpatient settings and there is no requirement that the covered drug be used in a "traditional" outpatient setting. Any outpatient facility included on an eligible DSH's Medicare cost report can access PHS pricing if it is included on the master list of eligible entities.

*Comment:* There are certain circumstances which might prevent an otherwise eligible outpatient facility from billing under the DSH's provider number (e.g., State or local laws requiring a facility or pharmacy to bill all third party payers directly). In these instances, the facility should be permitted to access PHS discount pricing if the eligible DSH facility can demonstrate that the pharmacy would meet the proposed Medicare test but for the unique circumstances.

*Response:* The test used to determine the eligibility of hospital outpatient facilities must incorporate criteria that form an independent and objective basis. This will provide fair and easy administration. To include a "but for" test would create a difficult standard to administer. If an outpatient facility is not included on the eligible DSH's Medicare cost report, it will not meet the requirements for eligibility.

*Comment:* The effective date of this notice should be made retroactive to December 1, 1992. Further, the June 13 deadline for requesting retroactive rebates or credits should be extended.

*Response:* In a Federal Register notice, dated May 13, 1994, a deadline was announced for requesting retroactive discounts. Eligible and

potentially eligible covered entities could request these discounts until June 13, 1994. See 59 FR 25112. The notice permits an off-site outpatient DSH facility to receive retroactive discounts if it meets the following requirements: (1) is included on an eligible DSH's Medicare cost report, (2) has not participated in a group purchasing arrangement for covered outpatient drugs, (3) has not billed Medicaid for the covered outpatient drugs for which retroactive discounts are being requested, and (4) has preserved its right to such discounts by sending manufacturers a letter requesting such refunds and providing adequate documentation of drug purchases by June 13, 1994. After this date, the right to retroactive discounts ceased. See 59 FR 25112. ("Any DSH outpatient clinic which is or will be eligible for retroactive discounts may preserve its right by sending manufacturers a letter requesting such refunds and providing adequate documentation of purchases.")

**Comment:** There is no definition of the term "patient," thereby permitting a DSH to distribute discounted drugs to virtually anyone it can argue is a patient without running afoul of the drug resale prohibition of section 340B(a)(5)(B) of the PHS Act.

**Response:** PHS will address this issue in a future Federal Register notice which will request public comment. All comments concerning the definition of "patient" will be addressed at that time.

**Comment:** PHS has approved a contracted pharmacy service model without public notice and an opportunity to comment.

**Response:** PHS will discuss the contracted pharmacy service model in a future Federal Register notice which will invite public comment. All comments concerning this issue will be addressed at that time.

### (C) DSH Outpatient Facility Guidelines

Set forth below are the final guidelines regarding the inclusion of DSH outpatient facilities: The outpatient facility is considered an integral part of the "hospital" and therefore eligible for section 340B drug discounts if it is a reimbursable facility included on the hospital's Medicare cost report. For example, if a hospital with one Medicare provider number meets the disproportionate share criteria and this hospital has associated outpatient clinics whose costs are included in the Medicare cost report, these clinics would also be eligible for section 340B drug discounts. However, free-standing clinics of the hospital that submit their own cost reports using different Medicare numbers (not under the single

hospital Medicare provider number) would not be eligible for this benefit.

A DSH, eligible for PHS pricing, must first request that the Office of Drug Pricing include in the PHS drug discount program the outpatient facilities that are included in its Medicare cost report. A list of these outpatient facilities along with Medicaid billing status information must be included with the request. Second, an appropriate official of the DSH must sign a statement that he/she is familiar with HCFA guidelines concerning Medicare certification of hospital components as one cost center, has examined the list of outpatient facilities, and certifies that the facilities are correctly included on the DSH's Medicare cost report. When these facilities are added to the master list of eligible and participating covered entities, the off-site facilities will be able to access PHS discount pricing. On-site clinics that are not included on the Medicare cost report will not be eligible for PHS discount pricing. This information will be posted on the Electronic Data Retrieval System (EDRS), maintained by the Office of Drug Pricing, on a quarterly basis. To access this information, call (301) 594-4992.

DSHs which have questions concerning this process, or manufacturers which have questions concerning the eligibility of certain DSH outpatient clinics, should contact Elizabeth Hickey (301-594-4353), at the Office of Drug Pricing.

Dated: September 13, 1994.

James A. Walsh,  
Acting Administrator, Health Resources and  
Services Administration.  
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### Social Security Administration

#### Privacy Act of 1974; Computer Matching Programs (SSA/Bureau of Prisons)

**AGENCY:** Social Security Administration, HHS.

**ACTION:** Notice of Computer Matching Program.

**SUMMARY:** In accordance with the provisions of the Privacy Act, as amended, this notice announces a computer matching program that SSA plans to conduct.

**DATES:** SSA will file a report of the subject matching program with the Committee on Governmental Affairs of the Senate, the Committee on Government Operations of the House of

Representatives and the Office of Information and Regulatory Affairs, Office of Management and Budget. The matching program will be effective as indicated below.

**ADDRESSES:** Interested parties may comment on this notice by either telefax to (410) 966-5138 or writing to the Associate Commissioner for Program and Integrity Reviews, 860 Altmeyer Building, 6401 Security Boulevard, Baltimore, MD 21235. All comments received will be available for public inspection at this address.

**FOR FURTHER INFORMATION CONTACT:** The Associate Commissioner for Program and Integrity Reviews as shown above.

#### SUPPLEMENTARY INFORMATION:

##### A. General

The Computer Matching and Privacy Protection Act of 1988 (Public Law (Pub. L.) 100-503) amended the Privacy Act (5 U.S.C. 552a) by adding certain protections for individuals applying for and receiving Federal benefits. Section 7201 of the Omnibus Budget Reconciliation Act of 1990 (Pub. L. 101-508) further amended the Privacy Act regarding protections for such individuals. The Privacy Act, as amended, regulates the use of computer matching by Federal agencies when records in a system of records are matched with other Federal, State or local government records. It requires Federal agencies involved in computer matching programs to:

- (1) Negotiate written agreements with the other agency or agencies participating in the matching programs;
- (2) Obtain the Data Integrity Boards' approval of the match agreements.
- (3) Furnish detailed reports about matching programs to Congress and the Office of Management and Budget;
- (4) Notify applicants and beneficiaries that their records are subject to matching; and
- (5) Verify match findings before reducing, suspending, terminating or denying an individual's benefits or payments.

##### B. SSA Computer Matches Subject to the Privacy Act

We have taken action to ensure that all of SSA's computer matching programs comply with the requirements of the Privacy Act, as amended.