

National Institute on Drug Abuse; Meeting

Pursuant to Public Law 92-463, notice is hereby given of the meeting of the National Advisory Council on Drug Abuse, National Institute on Drug Abuse on January 25-26, 1994, at the National Institutes of Health, Building 1, Wilson Hall, 9000 Rockville Pike, Bethesda, Maryland 20892.

The meeting will be open to the public on January 25 from 9 a.m. to 1 p.m. and on January 26 from 9 a.m. to 5 p.m. for announcements and reports of administrative, legislative, and program developments in the drug abuse field.

In accordance with provisions set forth in section 552b(c)(4) and 552b(c)(6), title 5, U.S.C. and section 10(d) of Public Law 92-463, the meeting will be closed to the public on January 25 from 1 p.m. to 5 p.m. for the review, discussion, and evaluation of grant applications. These applications and discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications, disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

A summary of the meeting and a roster of committee members may be obtained from Ms. Camilla L. Holland, NIDA Committee Management Officer, National Institutes of Health, Parklawn Building, room 10-42, 5600 Fishers Lane, Rockville, Maryland 20857 (301/443-2755).

Substantive program information may be obtained from Ms. Eleanor C. Friedenberg, room 10-42, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857 (301/443-2755).

Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact the contact person named above in advance of the meeting.

(Catalog of Federal Domestic Assistance Program Numbers: 93.277, Drug Abuse Research Scientist Development and Research Scientist Awards; 93.278, Drug Abuse National Research Service Awards for Research Training; 93.279, Drug Abuse Research Programs.)

Dated: December 22, 1993.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 93-31762 Filed 12-28-93; 8:45 am]

BILLING CODE 4140-01-M

Public Health Service

Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines

AGENCY: Public Health Service, HHS.

ACTION: 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 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 the covered entities of recent decisions regarding program implementation. Further, covered entities who wish to participate in the drug discount program have certain responsibilities created by the Agreement and section 340B of the PHS Act. These include the prohibition against selling or transferring section 340B discounted drugs to persons who are not patients of the entity, (section 340B(a)(5)(B) of the PHS Act) and generating Medicaid rebates while accepting section 340B discounts on the same drugs, (section 340B(a)(5)(A) of the PHS Act). The Department has developed guidelines related to these prohibitions, and this notice discusses the proposed guidelines and invites public comment.

Section II contains a description of the mechanism to prevent duplicate discounts and rebates and methods for its implementation. The mechanism was published on May 7, 1993, and public comments were submitted at that time. We are not inviting further comment on this section.

DATES: The public is invited to submit comments on the proposed covered entity guidelines (all sections except II which was subject to an earlier notice inviting public comment) by January 28, 1994. Subject to consideration of the comments submitted, the Department intends to publish a final notice regarding these entity guidelines.

FOR FURTHER INFORMATION CONTACT: Marsha Alvarez, R. Ph., Chief Pharmacy Officer, Attn: Drug Pricing Program, Bureau of Primary Health Care, Health Resources and Services Administration, East West Towers Rm 10-3A1,

Bethesda, Maryland 20814, Phone: (301) 594-4353.

ADDRESSES: Comments should be submitted to Marsha Alvarez at the address listed above.

SUPPLEMENTARY INFORMATION: The PHS Act and the Agreement contain several important prohibitions for covered entities.

(I). Confidential Drug Pricing Information

Section III(f) of the Public Health Service (PHS) Pharmaceutical Pricing Agreement states that "[t]he Secretary shall require, under a reasonable schedule of implementation, that covered entities not reveal confidential drug pricing information." "Confidential drug pricing information" includes both "best price" and "average manufacturer price." The quoted price or the actual price given by the manufacturer to the covered entity is not confidential.

(II). Duplicate Discount/Rebate Potential

There is a potential for a drug purchased by a covered entity at the statutory discount to be subject to a Medicaid rebate under section 1927 of the Social Security Act, if the drug is reimbursed by the Medicaid program. Accordingly, the PHS Act directs the Secretary of HHS to establish a mechanism to avoid the potential double price reduction.

In consultation with the Health Care Financing Administration (HCFA), which is responsible for the administration of the Medicaid program, the PHS developed a mechanism. The proposed mechanism was published in the *Federal Register* on May 7, 1993, and the Department requested public comment. The comments were addressed in a final notice published on June 23, 1993, at 58 FR 34058, which adopted the proposed mechanism without substantive change. The Department began implementation of the mechanism on July 1, 1993. The mechanism is as follows:

(a). Billing Per Encounter

For all-inclusive rates (either per encounter or visit), drug purchases are not billed as separate cost items; therefore, there is no opportunity for a Medicaid rebate to be sought. To the extent that covered entities are reimbursed by Medicaid through all-inclusive rates, there is no possibility that the duplicate discount and rebate can occur. These entities included on the initial list of covered entities may request drug discounts retroactive to December 1, 1992, if appropriate

documentation of drug purchases is presented to the manufacturer.

(b) Billing on a Cost Basis for Drugs

For other entities billing on a cost basis for drug purchases, PHS is providing a list of participating covered entities to State Medicaid agencies with the Medicaid provider numbers for each covered entity in the respective State. Based on the provider number, the State Medicaid agency will create a separate provider file for claims from covered entities. They will exclude data from these provider files when generating the rebate bills to the manufacturers under the Medicaid rebate program.

The entity must provide the Drug Pricing Program with the Medicaid provider number so that State Medicaid agencies can create the appropriate exclusion files. The first group of State Medicaid provider numbers was mailed to the State Medicaid agencies on June 25, 1993. The Department will create a separate computer file on the Electronic Data Retrieval System which will list those entities and their Medicaid provider numbers which were added to the eligibility list and entities which chose to withdraw from the program. From October 1993, until June 30, 1994, the computer file will be updated on a quarterly basis. Thereafter, the file will be updated annually.

There are large facilities which house several different clinics. Some of these clinics are covered entities eligible for the section 340B discounts and others are not eligible. Because the exclusion file (i.e., flagging or marking the entity file for exclusion from Medicaid rebate program) will effectively eliminate all of the facility's outpatient drug purchases from the Medicaid rebate program, the facility must request from its respective State Medicaid agency a separate Medicaid provider number for the eligible clinics. With this separate number, only the outpatient drug purchases from the eligible clinics will be excluded from the Medicaid rebate program. For those States which cannot generate additional Medicaid provider numbers for entities, covered entities must discuss an alternative arrangement with the States to accomplish this objective.

A covered entity which bills Medicaid separately for covered outpatient drugs can accept a discount on those drugs for which no claims for Medicaid reimbursement were sent to its respective State Medicaid agency. For drugs reimbursed by Medicaid, the covered entity may accept the discounted price once its Medicaid provider number is received by the Drug Pricing Program, and the Program

provides the number to the respective State Medicaid agency through the regularly scheduled updates to the covered entity file. If a covered entity has adequate documentation proving drugs purchased at the section 340B discount were not billed separately to Medicaid or did not generate Medicaid rebates, the entity may accept the discount and also request discounts retroactive to December 1, 1992. For retroactive adjustments, the entity must have been listed on the initial eligibility list.

(c) Billing Medicaid at Acquisition Cost

When a covered entity submits a bill to the State Medicaid agency for a drug purchase by or on behalf of a Medicaid beneficiary, the amount billed may not exceed the entity's actual acquisition cost for the drug, as charged by the manufacturer at a price consistent with the Veterans Health Care Act of 1992, plus a reasonable dispensing fee established by the State Medicaid agency. This will assure that the cost savings to the covered entity will be passed on to the State Medicaid agency, offset the loss of the collection of the rebate by that agency, and prevent the duplicate discount/rebate by the drug manufacturer. This mechanism is consistent with the Veterans Health Care Act and the limitations established in the Medicaid regulations, 42 CFR 447.331-447.334, which limit the amount the Medicaid State agency may reimburse providers.

(III). Eligibility for Retroactive Discounts

Until November 30, 1993, or 30 days after publication of the final entity guidelines, whichever is later, eligible covered entities included on the initial eligibility list may request retroactive discounts (discounts, rebates, or account credit) for covered outpatient drugs purchased retroactive to December 1, 1992. Only those entities on the initial eligibility list that (1) bill covered outpatient drugs using an all-inclusive rate (either per visit or per encounter), (2) have not billed Medicaid for those covered outpatient drugs since December 1, 1992, or (3) have adequate documentation proving that drugs for which a retroactive discount is being requested have not generated Medicaid rebates, may request the retroactive discount.

(IV). Entity Guidelines Regarding Drug Diversion

Section 340B contains a number of prohibitions related to drug diversion which might require entities to develop alternate systems. These systems will be

necessary to avoid diversion and will provide adequate documentation for audit purposes.

(a) Diversion to Nonpatients of the Covered Entity

Covered entities are required not to resell or otherwise transfer outpatient drugs purchased at the statutory discount to an individual who is not a patient of the entity. If individuals, other than patients of the covered entity, obtain covered outpatient drugs from the pharmaceutical dispensing facility, the entity must take affirmative steps to prevent their receipt of discounted drugs. The entity must develop and institute adequate safeguards to prevent the transfer of discounted outpatient drugs to individuals who are not eligible for the discount (e.g., separate purchasing accounts and dispensing records).

(b) Diversion to Ineligible Entities Within the Same Facility

Section 340B(a)(6) of the PHS Act recognizes that a covered entity may be part of a larger facility and states that the larger facility (e.g., a hospital) will not be considered eligible for the discounted drug prices unless it is listed as a covered entity. Only the covered entity (e.g., the eligible clinic) housed within the hospital organization will be eligible for section 340B drug discounts. Another example is a department of health that contains an eligible family planning clinic but itself is not covered. Only the family planning clinic is eligible for section 340B discounts. Therefore, the facility which contains an eligible entity within its structure is required to establish separate purchasing accounts and maintain separate dispensing records for the eligible entity.

(c) Diversion to Excluded Services of the Covered Entity

Section 340B mandates the statutory price only for outpatient drugs; therefore, the covered entity must use these discounted drugs only in connection with outpatient services. Because the covered entity may not use the covered outpatient drug in excluded services such as inpatient, a separate method for purchasing and dispensing the discounted drugs (or alternate systems as approved by the Secretary) is required.

(d) Adequate Systems To Safeguard Against Diversion

Developing a separate purchasing system, including separate purchase number and a separate dispensing system for outpatient drugs, should

provide a sufficient audit trail to prove the prevention of drug diversion.

The covered entity may, at its option, develop an alternative system, short of tracking each discounted drug through the purchasing and dispensing process, by which it can prove compliance. If an alternate system of tracking is proposed to be used, this system must meet criteria developed by the Drug Pricing Program. These criteria will be developed at a later date. The Drug Pricing Program welcomes comments or suggestions concerning alternative tracking systems that could be included in the program.

(V). Audit Requirements

All entities receiving statutory prices are required to maintain records of purchases of covered outpatient drugs and of any claims for reimbursement submitted for such drugs under title XIX of the Social Security Act. The entity must permit HHS and the manufacturer to audit any record of a covered drug purchase that was subject to the discount. Manufacturer audits will be conducted in accordance with procedures developed by the Secretary of HHS. Until these guidelines are developed and published in the *Federal Register*, entities are not required to permit audits by manufacturers except as approved by the Secretary. This notice addresses only audits related to purchases as a covered entity; it does not address other audit requirements related to participation in State Medicaid programs or receipt of Federal grant funding.

(VI). Entity Participation

Covered entity participation in the section 340B drug discount program is voluntary. Once an entity has elected to participate in the program and has submitted its Medicaid provider number to the Drug Pricing Program, the entity must wait to withdraw from the program until the next official updating of the eligible entity list. The entity must comply with all requirements of the discount program until the date it is removed from the eligibility list. This date can be obtained from the Office of Drug Pricing Program. This restriction does not apply to entities that use all-inclusive rates or that do not bill Medicaid for covered outpatient drugs.

(VII). Group Purchasing

(a). Disproportionate Share Hospitals

The Department has interpreted the group purchasing restriction of section 340B(a)(4)(L)(iii) regarding disproportionate share hospitals ("DSH") that are covered entities as

follows: (1) A DSH may participate in a group purchasing arrangement for inpatient drug use without affecting its eligibility to purchase section 340B discounted drugs. (2) If a DSH participates in a group purchasing organization (GPO) or arrangement for covered outpatient drugs, the DSH will no longer be an eligible covered entity and cannot purchase covered outpatient drugs at the section 340B discount prices. This is a new policy approach which we are considering adopting for two reasons. First, this approach appears to carry out more fully the legislative intent. Section 340B(a)(4)(i) states that a hospital is a covered entity if it meets three criteria. This first two criteria deal with the public nature of the hospital and the level of its disproportionate share adjustment percentage. The third criterion states that the hospital must not "obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement," section 340B(a)(4)(i)(iii). The proposed policy would appear to achieve the Congressional intent better than the earlier interpretation.

Second, the earlier interpretation which allowed DSHs to participate both in the section 340B discount program and also in a GPO resulted in Federal dollars being lost. When a DSH elected to participate in the program, it provided its Medicaid provider number to allow the State Medicaid agency to exclude it from the Medicaid rebate mechanism. The result was that GPO drugs were excluded from rebate mechanism, with Medicaid losing the statutory rebate it would otherwise receive. Thus, while the DSH could obtain comparable price reductions for outpatient drugs purchased through a GPO, the corresponding Federal savings would be lost.

(b). Group Purchasing Arrangements - Other

States, or other groups, which purchase drugs for covered entities (other than disproportionate share hospitals) are not included on the list of covered entities; however, they are eligible to purchase at the section 340B discount if the following requirements are met: (1) The group purchasing arrangement must be comprised of only covered entities, or (2) if group purchasing arrangements contain entities which are not eligible for the discount, separate purchasing accounts and dispensing/distribution must be maintained.

(VIII). Purchasing Agents

A covered entity is permitted to use a purchasing agent without forfeiting its right to the section 340B drug discounts. If a purchasing agent is used, the arrangement must be in writing and the terms of the agent's relationship with the entity must be clearly defined. The entity and the agent should decide whether the agent simply negotiates the drug purchasing contracts on behalf of the entity or actually receives drug shipments for distribution to the entity. If the latter, the transfer of purchased pharmaceuticals from an agent to the entity would not be viewed as drug diversion. This paragraph does not supersede the statutory limitations that DSHs eligible to receive the section 340B drug discounts may not participate in group purchasing arrangements.

(IX). Definition of Covered Outpatient Drug

The Department has adopted an interpretation of the statutory definition of "covered outpatient drug" developed by the Health Care Financing Administration ("HCFA"). Section 1927(k)(2) of the Social Security Act defines "covered outpatient drug" to include most drugs and biologicals which may be dispensed only by prescription and which require approval by the Food and Drug Administration or a license under section 351 of the PHS Act. Section 1927(k)(3) limits the definition of "covered outpatient drug" to exclude certain settings (e.g., such services as emergency room, hospice, dental, physician, nursing facilities, x-ray, lab, and renal dialysis) in some instances. In these settings, if a covered drug is included in the per diem rate (i.e., bundled with other payments in an all-inclusive, per visit, or an encounter rate), it will not be included in the section 340B discount program. However, if a covered drug is billed and paid for instead as a separate line item as an outpatient drug in a cost basis billing system, this drug will be included in the program.

(X). Dealing Direct or Through a Wholesaler

Under the PHS Agreement signed by each manufacturer participating in the Medicaid program, the manufacturer has the option of dealing either directly with the covered entity or through a wholesaler (the Agreement, section II(a)(3)). If purchasing through a wholesaler, the entity will be required to provide the manufacturer with information necessary to arrange for such purchases consistent with the terms of the Agreement.

The purpose of the option for direct or wholesaler purchases was to allow manufacturers, when dealing with covered entities, to continue their usual business practices. If a manufacturer has customarily dealt directly with a particular covered entity, "then requiring the continuation of this form of purchasing with the covered entity is reasonable. When dealing directly with a covered entity, manufacturers must offer covered outpatient drugs at or below the section 340B discount prices. If a manufacturer customarily uses a wholesaler as a means of distribution, then it may continue this practice. If the manufacturer's drugs are available to covered entities through wholesalers, the discount must be made available through that avenue.

Manufacturers may not single out covered entities from their other customers for restrictive conditions that would undermine the statutory objective. Manufacturers must not place limitations on the transactions (e.g., minimum purchase amounts) which would have the effect of discouraging entities from participating in the discount program.

(XI) Manufacturer's Contracts Requiring Entity Compliance

A manufacturer may not condition the offer of statutory discounts upon an entity's assurance of compliance with section 340B provisions. The enforcement of section 340B provisions is a Federal responsibility. Covered entity assurances regarding the following activities may not be required: (1) Eligibility to participate in the program; (2) utilization of covered outpatient drugs only in authorized services; (3) maintaining the confidentiality of the drug pricing information; (4) permitting the manufacturers to audit purchase, inventory, and related records prior to the publication of approved PHS guidelines; and (5) submitting information related to drug acquisition, purchase, and inventory systems. Entities are not required to sign agreements assuring manufacturers of their compliance with section 340B provisions. (If a manufacturer asks a covered entity whether the entity is in fact participating in the section 340B discount program, the entity must supply the manufacturer with this information).

Dated: December 21, 1993.

William A. Robinson,
Acting Administrator, Health Resources and Services Administration.

[FR Doc. 93-31791 Filed 12-28-93; 8:45 am]

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DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Assistant Secretary for Community Planning and Development

[Docket No. N-93-3686; FR-3584-N-01]

Community Development Work Study Program

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice of funding availability.

SUMMARY: This notice invites applications from institutions of higher education, area-wide planning organizations, and States for grants under the Community Development Work Study Program (CDWSP). The CDWSP, authorized by the Housing and Community Development Act of 1974, as amended, assists economically disadvantaged and minority students participating in work study programs in such institutions. This notice announces HUD's intention to award up to \$3 million from FY 1994 appropriations (plus any additional funds recaptured from prior appropriations) to fund work study programs to be carried out from August, 1994 to September, 1996.

DATES: Applications may be requested beginning on January 8, 1994. The application submission deadline date and time will be in the application kit.

FOR FURTHER INFORMATION CONTACT: James H. Turk, Technical Assistance Division, Office of Technical Assistance, Department of Housing and Urban Development, 451 Seventh Street SW., Washington, DC 20410, Telephone (202) 708-3176 (Voice). The TDD number for the hearing impaired is (202) 708-2564. These are not toll-free numbers. Application packages (requests for grant application) may be obtained by written request from the following address: Processing and Control Branch, Office of Community Planning and Development, Department of Housing and Urban Development, 451 Seventh Street SW., room 7255, Washington, DC 20410.

SUPPLEMENTARY INFORMATION:

A. Background

Section 107(c) of the Housing and Community Development Act of 1974, as amended, (the Act) authorizes the CDWSP. Under this section, HUD is authorized to provide grants to institutions of higher education, either directly or through area-wide planning organizations or States, for the purpose of providing assistance to economically disadvantaged and minority students,

including students with disabilities, who participate in community development work study programs and are enrolled in full-time graduate or undergraduate programs in community or economic development, community planning, or community management. Two-year institutions are not eligible applicants for funding under this program. This notice announces HUD's intention to award up to \$3 million from FY 1994 appropriations (plus any additional funds recaptured from prior appropriations). Awards will be made under the HUD implementing regulations at 24 CFR 570.400 and 570.415 and the provisions of this Notice.

B. Eligible Applicants

The following are eligible to apply for assistance under the program subject to the conditions noted below:

1. Institutions of higher education offering graduate degrees in a community development academic program.
2. Institutions of higher education offering undergraduate degrees in a community development academic program if no institutions of higher education in the standard metropolitan statistical area (SMSA) or non-SMSA area in which they are located offer graduate degrees in a community development academic program. (Note: Two-year institutions of higher education are not eligible applicants for funding under this program.)
3. Area-wide planning organizations (APOs) which apply on behalf of two or more institutions of higher education located in the same SMSA or non-SMSA area as the APO.
4. States which apply on behalf of two or more institutions of higher education located in the State. If a State is approved for funding, institutions of higher education located in the State are not eligible recipients. If an APO is approved for funding, institutions of higher education located in the SMSA or non-SMSA non-metropolitan area served by the APO are not eligible recipients.

C. Threshold Requirements

To be eligible for ranking, applications must meet each of the following threshold requirements:

1. The application must be filed in the application form prescribed by HUD, and within the required time prescribed by the Request For Grant Application (RFGA) released pursuant to this notice.
2. The application must demonstrate that the applicant is eligible to participate.