of funds in relation to the objective review panel's recommendations. Approximately $600,000 is available in FY 1994 for this Center. The budget and project periods for approved and funded projects will begin October 1, 1994.

Project periods may be requested for up to five years. However, recommended support beyond the third year is subject to a determination by an objective review panel in conjunction with an assessment by the SPNS staff of the project's progress to date. All grants to support projects beyond the first budget year will be contingent upon the availability of funds, Congressional reauthorization of Ryan White CARE Act funding within the second project year, and satisfactory progress each year in meeting the project's objectives.

All grantees funded to support HIV service delivery model demonstration projects under this Notice are encouraged to secure and show evidence of non-SPNS funding support equal to 20 percent of the approved project budget by the fourth project year, and equal to 40 percent of the approved project budget by the fifth year. Applicants are required to submit, in the initial application, budgets for each proposed project year.

Eligible Applicants

The statute, Section 2618 (a) (1), specifies that grants may be awarded to public and non-profit private entities to fund special programs for the care and treatment of people with HIV disease. Eligible entities may include, but are not limited to, State, local, or tribal public health, mental health, or substance abuse departments; public or non-profit hospitals; community-based service organizations (e.g., AIDS service organizations, primary health care clinics, family planning centers, AIDS discrimination and advocacy organizations, hemophilia centers, community mental health centers, substance abuse treatment centers, urban Indian health centers, migrant health centers, Ryan White CARE Act Title IIIb clinics, etc.); institutions of higher education; and national service provider and/or policy development associations/organizations.

Allowable Costs

The basis for determining allocable and allowable costs to be charged to PHS grants is set forth in 45 CFR part 74, Subpart Q and 45 CFR part 92 for State, local or tribal governments. The four separate sets of cost principles prescribed for public and private non-profit recipients are: OMB Circular A-87 for State, local or tribal governments; OMB Circular A-21 for institutions of higher education; 45 CFR part 74, Appendix E for hospitals; and OMB Circular A-122 for nonprofit organizations.

Reporting and Other Requirements

A successful applicant under this notice will submit semi-annual activity summary reports in accordance with provisions of the general regulations which apply under 45 CFR Part 74, Subpart J, "Monitoring and Reporting of Program Performance," with the exception of State and local governments to which 45 CFR Part 92, Subpart C reporting requirements apply. As a condition of all awards funded under this Notice, grantees will be required to cooperate with HRSA and the SPNS Evaluation and Dissemination center(s) in any multi-site evaluation studies sponsored by the SPNS Program.

Healthy People 2000 Objectives

The Public Health Service urges applicants to address a specific objective of the *Healthy People 2000* in their work plans. Potential applicants may obtain a copy of *Healthy People 2000* (Full Report; Stock No. 017-001-00473-0) or *Healthy People 2000* (Summary Report; Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (Telephone: (202) 783-3238).

Federal Smoke-Free Compliance

The Public Health Service strongly encourages all grant recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

Public Health System Reporting Requirements

This program is subject to the Public Health System Reporting Requirements which have been approved by the Office of Management and Budget under No. 937-0195. Under these requirements, any community-based, non-governmental applicant must prepare and submit a Public Health System Impact Statement (PHSIS). The PHSIS is intended to keep State and local health officials apprised of proposed health services grant applications submitted from within their jurisdictions.

Community-based, non-governmental applicants are required to submit, no later than the Federal due date for receipt of the application, the following information to the administrator of the State and local health agencies and to the State and local AIDS program director in the area(s) to be impacted by the proposal: (1) a copy of the face page of the application (SF 424); and, (2) a summary of the project, not to exceed one page, which provides: (a) a description of the population to be served; (b) a summary of the services to be provided; and, (c) a description of the coordination planned with the appropriate State or local health agencies. Copies of the letters forwarding the PHSIS to these authorities must be contained in the application materials submitted to this program.

Executive Order 12372

The Special Projects of National Significance Grant Program has been determined to be a program subject to the provisions of Executive Order 12372, concerning intergovernmental review of Federal Programs, as implemented by 45 CFR Part 100. Under urgent conditions, the Secretary may waive any provision of this regulation. (See 45 CFR part 100.13.) The Secretary has waived 45 CFR Part 100 due to the compelling need to get funds to grantees.

The OMB *Catalog of Federal Domestic Assistance* number for the Special Projects of National Significance is 93.928.

Dated: May 3, 1994.

John H. Kelso,

Acting Administrator.

[FR Doc. 94-14088 Filed 6-9-94; 8:45 am]

BILLING CODE 4160-15-P

Public Health Service

Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Manufacturer Audit Guidelines and Informal Dispute Resolution

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 (the "Secretary") in which the manufacturer agrees to charge a price for covered outpatient drugs that will not exceed an amount determined under a statutory formula.

Section 340B(a)(5) of the PHS Act identifies certain requirements for covered entities concerning potential double price reductions and drug diversion. A covered entity must permit the manufacturer of a covered outpatient drug that has signed the Agreement, to audit the records of the covered entity directly pertaining to the entity's compliance with the requirements of section 340B(a)(5) (A) and (B) as to drugs purchased from the manufacturer. These audits must be conducted in accordance with guidelines established by the Secretary, as stated in section 340B(a)(5)(C).

Further, the Office of Drug Pricing anticipates that disputes may arise between covered entities and participating manufacturers regarding implementation of the provisions of section 340B. To resolve these disputes in an expeditious manner, the Office of Drug Pricing has developed a proposed informal dispute resolution process.

The purpose of this notice is to invite public comment on the proposed manufacturer audit guidelines and the proposed informal dispute resolution process.

DATES: The public is invited to submit comments on the proposed audit guidelines and dispute resolution process by July 11, 1994. After consideration of the comments submitted, PHS will issue the final audit guidelines and the dispute resolution process.

ADDRESSES: Submit comments to Ms. Alvarez at the address noted below.

FOR FURTHER INFORMATION CONTACT: Marsha Alvarez, R. Ph., Director, Office of Drug Pricing, Bureau of Primary Health Care, 4350 East West Highway, West Towers, 10th Floor, Bethesda, MD 20814, Tel: (301) 594–4354.

SUPPLEMENTARY INFORMATION:

Manufacturer Audit Guidelines

Covered entities which choose to participate in the section 340B drug discount program must comply with the requirements of section 340B(a)(5) of the PHS Act. Section 340B(a)(5)(A) prohibits a covered entity from accepting a discount for a drug that would also generate a Medicaid rebate. Further, section 340B(a)(5)(B) prohibits a covered entity from reselling or otherwise transferring a discounted drug to a person who is not a patient of the entity. The participating entity must permit the manufacturer of a covered outpatient drug who has signed the Agreement with the Secretary to audit its records that directly pertain to the entity's compliance with section 340B(a)(5) (A) and (B) requirements with respect to drugs of the manufacturer. Manufacturer audits must be conducted in accordance with guidelines developed by the Secretary as required by section 340B(a)(5)(C). This notice does not include the audit guidelines to be used by Government auditors where the Government performs the audit of the records of the covered entity's compliance with the requirements of section 340B(a)(5) (A) and (B).

The following is the proposed "Compliance Audit Guide" concerning manufacturer audit guidelines as developed by the Secretary pursuant to section 340B(a)(5)(C):

I. General Guidelines

A manufacturer shall conduct an audit only when the Office of Drug Pricing determines that there is reasonable cause to believe a violation of section 340B(a)(5) (A) or (B) has occurred. The manufacturer must submit a request for an audit of a covered entity to the Office of Drug Pricing. [See section II for audit steps]. Auditors have an ethical and legal responsibility to perform quality audits conducted in accordance with Government Auditing Standards, Current revision, developed by the Comptroller General of the United States. Patient confidentiality requirements must also be observed. Audit reports must be prepared at the completion of the audit. Copies of the audit report shall be prepared in accordance with the reporting standards for performance audits in Government Auditing Standards, Current Revision. The cost of a manufacturer audit will be borne by the manufacturer, as provided by section 340B(a)(5)(C) of the PHS Act.

(a) Number of Audits

Consistent with Government auditing standards, the organization performing the audit shall coordinate with other auditors, when appropriate, to avoid duplicating work already completed or that may be planned. Only one audit will be permitted at any one time. When specific allegations involving the drugs of more than one manufacturer have been made concerning an entity's failure to comply with section 340B(a)(5) (A) and (B), the Office of Drug Pricing will determine whether an audit should be performed by the (1) Government or (2) the manufacturer.

(b) Scope of Audits

The manufacturer must submit an audit workplan describing the audit to the Office of Drug Pricing for review. The workplan will be reviewed for reasonable purpose and scope. Further, a determination will be made that only those records of the covered entity that directly pertain to the potential violation(s) will be accessed including those systems and processes (e.g., purchasing, distribution, dispensing, and billing) that would assist in identifying a violation.

(c) Duration of Audits

Audits shall be performed in the minimum time necessary with the minimum intrusion on the covered entity's operations.

II. Audit Steps

(a) The manufacturer shall notify the covered entity in writing when it believes the covered entity has violated provisions of section 340B. The manufacturer and the covered entity shall have at least 30 days from the date of notification to attempt in good faith to resolve the matter.

(b) The manufacturer has the option to proceed to the informal dispute resolution process described later in the notice without an audit, if it believes it has sufficient evidence of a violation absent an audit. If the matter is not resolved and the manufacturer desires to perform an audit, the manufacturer must file a request for a covered entity audit with the Office of Drug Pricing. [See section "FOR FURTHER INFORMATION" for address.] The request must set forth a clear description of the reasonable cause to believe that a violation of section 340B(a)(5) (A) or (B) has occurred, along with sufficient facts and evidence in support of the request. In addition, the manufacturer shall provide copies of any documents supporting its claims.

(c) The Office of Drug Pricing will conduct a preliminary review of the documentation submitted to determine if reasonable cause exists. If the Office of Drug Pricing finds that there is reasonable cause to believe that a violation of section 340B(a)(5) (A) or (B) has occurred, the audit will be permitted, and the manufacturer will be notified accordingly. In cases where the Office of Drug Pricing determines that the audit shall be performed by the Government, the Office of Drug Pricing will so advise the manufacturer and the covered entity.

(d) The filing of a request for an audit does not affect any statutory obligations of the parties as defined in section 340B of the PHS Act. During the audit process, a manufacturer must continue to sell covered outpatient drugs at or below the section 340B ceiling price to the covered entity being audited.

(e) Upon approval of the request for a covered entity audit, the manufacturer

shall then submit an audit workplan to the Office of Drug Pricing for approval. The Office of Drug Pricing, after consultation with the PHS Office of Cost and Audit Management, will evaluate the manufacturer's workplan, and approval will be based on criteria set forth in the Audit Program section, Field Work Standards for Performance Audits, Government Audit Standards, Current Revision. The audit workplan shall describe in detail the following:

(1) Audit objectives (what the audit is to accomplish), scope (type of data to be reviewed, systems and procedures to be examined, officials of the covered entity to be interviewed, and expected time frame for the audit), and methodology (processes used to gather and analyze data and to provide evidence to reach conclusions and recommendations);

(2) Skill and knowledge of the audit organization's personnel to staff the assignment, their supervision, and the intended use of consultants, experts, and specialists;

(3) Tests and procedures to be used to assess the covered entity's system of internal controls;

(4) Procedures to be used to determine the amounts to be questioned should violations of section 340B(a)(5) (A) and (B) be discovered; and

(5) Procedures to be used to protect patient confidentiality.

(f) When the audit workplan has been approved, the Office of Drug Pricing shall notify the: (1) Manufacturer of the approval of the audit, and (2) covered entity of a pending manufacturer audit. The covered entity will have at least 15 days from the date of receipt of the notice to prepare for the audit.

(g) Suggested audit procedures include the following:

(1) Review the covered entity's policies and procedures regarding the procurement, inventory, distribution, dispensing, and billing for covered outpatient drugs.

(2) Assess internal controls applicable to the policies and procedures identified above (#1) when necessary to satisfy the audit objectives.

(3) Review the covered entity's policies and procedures to prevent the resale or transfer of drugs to a person or persons who are not patients of the covered entity.

(4) Test compliance with the policies and procedures identified above (#3) when necessary to satisfy the audit objectives.

(5) Review the covered entity's records of drug procurement and distribution and determine whether the covered entity obtained a discount only for those programs authorized to receive discounts by section 340B of the PHS Act.

(6) If a covered entity does not use an all inclusive billing system (per encounter or visit), but instead bills outpatient drugs using a cost based billing system, determine whether the covered entity has provided its Medicaid provider number to the Office of Drug Pricing and billed Medicaid at the actual acquisition cost.

(h) Where the manufacturer's auditors conclude that there has been a violation of the requirements of section 340B(a)(5) (A) or (B), the manufacturer's auditors shall identify (1) the procedures or lack of adherence to existing procedures which caused the violation, and (2) the dollar amounts involved.

(i) Following completion of the audit field work, the manufacturer's auditors shall provide a verbal briefing of the audit findings to the covered entity to ensure a full understanding of the facts.

(j) An audit report must be prepared at the completion of the audit in accordance with reporting standards for performance audits of the Government Auditing Standards, Current Revision. The manufacturer shall submit a copy of the audit report to the covered entity. The covered entity shall provide its response to the manufacturer on the audit report's findings and recommendations within 60 days from the date of receipt of the audit report. When the covered entity agrees with the audit report's findings and recommendations either in full or in part, the covered entity shall include in its response to the manufacturer a description of the actions planned or taken to address the audit findings and recommendations. When the covered entity does not agree with the audit report's findings and recommendations, the covered entity shall provide its rationale for the disagreement to the manufacturer.

(k) Informational copies of the audit report shall also be submitted to the Office of Drug Pricing (see section **For Further Information Contact** for the address), the Office of Inspector General, Office of Audit Services, PHS Audits Division at room 1–30, Park Building, 12420 Parklawn Drive, Rockville, MD 20857, and the PHS Cost and Audit Management Branch, room 17A–50, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

(l) If a dispute concerning the audit findings and recommendations arises, the parties may file a request for informal dispute resolution with the Office of Drug Pricing. All dispute resolution procedures developed by the Office of Drug Pricing shall be followed.

Informal Dispute Resolution

The Office of Drug Pricing is proposing an informal process for the resolution of certain disputes between manufacturers, covered entities, and PHS concerning compliance with the provisions of section 340B of the PHS Act. PHS expects parties to utilize this informal process before resorting to other remedies which may be available.

I. Types of Disputes Covered

Disputes resolved by these procedures include:

(a) A manufacturer believes a covered entity is in violation of the prohibition against resale or transfer of a covered outpatient drug provided in section 340B(a)(5)(B) of the PHS Act, or the prohibition against duplicate discounts or rebates provided in section 340B(a)(5)(A) of the PHS Act;

(b) A covered entity believes that a manufacturer is charging a price for a covered outpatient drug that exceeds the ceiling price as determined by section 340B(a)(1) of the PHS Act;

(c) A manufacturer is conditioning the sale of covered outpatient drugs to a covered entity on the entity's provision of assurances or other compliance with the manufacturer's requirements that are based upon section 340B provisions;

(d) A manufacturer has refused to sell a covered outpatient drug to a covered entity at or below the ceiling price as determined by section 340B(a)(1) of the PHS Act;

(e) A manufacturer believes that a covered entity is dispensing a covered outpatient drug in an unauthorized service (e.g., inpatient services or ineligible clinics within the same health system);

(f) A manufacturer believes that a covered entity has not complied with the audit requirements under section 340B(a)(5)(C) of the PHS Act, or the auditors of the manufacturer have not abided by the approved workplan or audit guidelines.

II. Review Process

Prior to the filing of a request for review with the Office of Drug Pricing, the parties must attempt, in good faith, to resolve the dispute. All parties involved in the dispute must maintain written documentation as evidence of a good faith attempt to resolve the dispute. Such evidence includes documentation of meetings, letters, or telephone calls between the disputing parties that concern the dispute.

If the dispute has not been resolved after a good faith attempt, a party may submit a written request for a review of the dispute to the Director of the Office of Drug Pricing. [See address in "For Further Information Contact" section].

The party requesting the review may not rely only upon allegations but is required to set forth specific facts showing that there is a genuine and substantial issue of material fact in dispute that requires a review.

The request for review shall include a clear description of the dispute, shall identify all the issues in the dispute, and shall contain a full statement of the party's position with respect to such issue(s) and the pertinent facts and reasons in support of the party's position. In addition to the required statement, the party shall provide copies of any documents supporting its claim and evidence that a good faith effort was made to resolve the dispute. These materials must be tabbed and organized chronologically and accompanied by an indexed list identifying each document.

The filing of the dispute does not affect any statutory obligations of the parties as defined in section 340B of the PHS Act. During the review process, for example, a manufacturer must continue to sell covered outpatient drugs at or below the section 340B ceiling price to all covered entities, including the covered entity involved in the dispute.

The Director, Bureau of Primary Health Care, shall appoint a committee to review the documentation submitted by the disputing parties and to make a proposed determination. A minimum of three individuals shall be appointed (one of whom shall be designated as a chairperson) either on an ad hoc, case-by-case basis, or as regular members of the review committee. The chairperson shall be from the Office of Drug Pricing and the committee members shall be from other sections of PHS (e.g., chief pharmacist, auditor).

Upon receipt of a request for a review, the chairperson of the review committee will send a letter to the party alleged to have committed a violation. The letter will include (1) the name of the party making the allegation(s), (2) the allegation(s), (3) documentation supporting the party's position, and (4) a request for a response to or rebuttal of the allegations within 30 calendar days of the receipt of the letter. 7 days from the date of the postmark of the letter will be allowed for mailing and processing through the organization.

Upon receipt of the response or rebuttal, the review committee chairperson will review all documentation. The request and rebuttal information will be reviewed for (1) evidence that a good faith effort was made to resolve the dispute, (2) completeness, (3) adequate documentation supporting the issues, and (4) the reasonableness of the allegations. If the documentation is adequate, the review committee will be convened to consider the matter.

The reviewing committee may, at its discretion, invite parties to discuss the pertinent issues with the committee and to submit such additional information as the committee deems appropriate.

The reviewing committee will propose to dismiss the dispute, if it conclusively appears from the data, information, and factual analyses contained in the request for a review and rebuttal documents that there is no genuine and substantial issue of fact in dispute. This proposed finding of the committee will be submitted to the Director of the Office of Drug Pricing for consideration and approval. A written decision of dismissal will be sent to each party and will contain the Director's findings and conclusions in detail and reasons why the request for a review did not raise a genuine and substantial issue of fact.

With all other proposed findings, the review committee will prepare a written document containing the findings and detailed reasons supporting the proposed decision. The document is to be signed by the chairperson and each of the other committee members. The chairperson will submit the proposed findings to the Director of the Office of Drug Pricing for consideration and approval. The Director's written decision will be sent with a transmittal letter to both parties.

If the covered entity or the manufacturer does not agree with the Office of Drug Pricing's determination, the covered entity or the manufacturer may appeal within 30 days after receiving such a determination to the Administrator of the Health Resources and Services Administration who will appoint a review official or committee.

III. Penalties

If the final determination is that a manufacturer has violated the provisions of section 340B of the PHS Act or the PHS pharmaceutical pricing agreement, the manufacturer's agreement with PHS could be terminated or other actions taken as deemed appropriate. If the final determination is that an entity has violated section 340B prohibitions against resale or transfer of covered outpatient drugs, the prohibition against duplicate discounts and rebates (or billing Medicaid more than the actual acquisition cost of the drug), or other statutory prohibitions, the entity shall be liable to the manufacturer of the covered outpatient drug that is the subject of the violation in an amount equal to the reduction in the price of the drug for the period of the violation, as provided by section 340B(a)(5)(D) of the PHS Act. The entity may also be excluded from the drug discount program, if the conduct warrants such a sanction.

After the dispute is resolved, any disputed amounts plus the rate of interest must be paid or credited to an account balance no later than 30 days following a final determination. Interest will begin to accrue from the time the manufacturer is deemed to have been out of compliance with section 340B (or provisions of the PHS Pharmaceutical Pricing Agreement) or the entity is deemed to have violated prohibitions of section 340B. The interest rate will be based upon an annual rate established by the Secretary of the Treasury after considering private consumer rates of interest prevailing at the time of the violation. This rate, utilized by the Department of Health and Human Services (HHS) in the collection of debts owed to the United States, may be revised quarterly by the Secretary of the Treasury and is published by the HHS Assistant Secretary for Management and Budget in the **Federal Register**. See 45 CFR 30.13 Parties will apply the interest rate for the quarter in which the violation occurred, and this rate will remain fixed for the duration of the time in which interest accrues.

(The reporting requirements of this document are subject to Office of Management and Budget (OMB) clearance under the Paperwork Reduction Act of 1980, 44 U.S.C. 3501–3520, and will not be implemented until such clearance has been obtained)

Dated: June 6, 1994.

Ciro V. Sumaya,

Administrator, Health Resources and Services Administration.

[FR Doc. 94–14089 Filed 6–9–94; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Assistant Secretary for Community Planning and Development

[Docket No. N–94–1917; FR–3350–N–87]

Federal Property Suitable as Facilities To Assist the Homeless

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

ACTION: Notice.

SUMMARY: This Notice identifies unutilized, underutilized, excess, and surplus Federal property reviewed by HUD for suitability for possible use to assist the homeless.

ADDRESSES: For further information, contact Barbara Richards, room 7262, Department of Housing and Urban Development, 451 Seventh Street SW.,