Management Branch (address above) for public review and comment. Interested persons may, on or before January 13, 1997, submit to the Dockets Management Branch (address above) written comments. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. FDA will also place on public display any amendments to, or comments on, the petitioner's environmental assessment without further announcement in the Federal Register. If, based on its review, the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the Federal Register in accordance with 21 CFR 25.40(c).

Dated: November 25, 1996.

George H. Pauli,

Acting Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 96–31574 Filed 12–11–96; 8:45 am]

BILLING CODE 4160–01–F

Health Resources and Services Administration

Manufacturer Audit Guidelines and Dispute Resolution Process 0905–ZA–19

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Final notice.

INFORMATION: Section 602 of Public Law 102–585, the ''Veterans Health Care Act of 1992,'' enacted section 340B of the Public Health Service Act (the ''PHS Act''), ''Limitation on Prices of Drugs Purchased by Covered Entities.'' Section 340B provides that a manufacturer who sells covered outpatient drugs to eligible (covered) entities must sign a pharmaceutical pricing agreement with the Secretary of Health and Human Services (''HHS'') in which the manufacturer agrees to charge a price for covered outpatient drugs that will not exceed the 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 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, acting through the Health Resources and Services Administration, Bureau of Primary Health Care, the Office of Drug Pricing (the ''Department''). Section 340B(a)(5)(C) states that the Secretary shall establish guidelines relating to the number, scope and duration of the audits. The Department has defined these terms and provided suggested audit steps.

Further, the Department 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 Department has developed a voluntary dispute resolution process.

The purpose of this notice is to inform interested parties of final program guidelines concerning manufacturer audit guidelines and the dispute resolution process.

FOR FURTHER INFORMATION CONTACT: Director, Office of Drug Pricing, Bureau of Primary Health Care, Health Resources and Services Administration, 4350 East-West Highway, West Towers, 10th Floor, Bethesda, Maryland 20814, Phone: (301) 594–4353.

EFFECTIVE DATE: January 13, 1997.

SUPPLEMENTARY INFORMATION:

(A) Background

Proposed manufacturer audit guidelines and the proposed informal dispute process were announced in the Federal Register at 59 FR 30021 on June 10, 1994. A comment period of 30 days was established to allow interested parties to submit comments. The ODP received comments from 12 sources including pharmaceutical manufacturers, a covered entity, organizations representing pharmaceutical manufacturers or covered entities, and the American Institute of Certified Public Accountants.

The following section presents a summary of all major comments, grouped by subject, and a response to each comment. All comments were considered in developing this final notice. Changes were also made to increase clarity and readability.

(B) Comments and Responses—Manufacturer Audit Guidelines

Comment: A number of commenters addressed the requirement that a manufacturer establish reasonable cause and obtain approval from the Department before conducting an audit. While some commenters believe that the statute gives manufacturers the right to routinely conduct an audit as a normal business practice without the need for Departmental approval, other commenters indicated that manufacturers should be required to provide objective documentation that a violation has occurred before being granted permission to audit.

Response: Section 340B(a)(5)(C) provides that audits will be performed in accordance with procedures established by the Secretary relating to the number, duration, and scope of the audits. These audits must pertain directly to the entity's compliance with the prohibitions against drug diversion and the generation of duplicate drug rebates and discounts with respect to drugs of the manufacturer. See Section 340B(a)(5)(A) & (B). In order to ensure that the audits pertain to compliance with the prohibitions in the aforementioned subparagraphs, it is appropriate to require manufacturers to submit an audit work plan for the Department's review and to establish reasonable cause. Although the Department will not require pre-approval of the plan, this will ensure that the audits are performed where there are valid business concerns and are conducted with the least possible disruption to the covered entity. Significant changes in quantities of specific drugs ordered by a covered entity and complaints from patients/other manufacturers about activities of a covered entity may be a basis for establishing reasonable cause.

Comment: Omit the requirement to submit an audit plan for the Department's approval.

Response: The requirement for approval of an audit plan has been dropped. The Department's review of the audit workplan is necessary to ensure that audit work performed is relevant to the audit objectives while protecting patient confidentiality and information of the covered entity which is considered proprietary. If after this review the Department has concerns regarding the audit plan it will work with the manufacturer to incorporate mutually agreed-upon revisions to the plan.

Comment: Commenters indicated that audits would not be meaningful without

a clear definition of a ''patient of the entity.''

Response: Because sufficient criteria must be provided by which auditors (and others) can determine if consumers of drugs purchased at the mandated prices are eligible to receive covered drugs, a definition of ''patient of the entity'' is necessary. ODP has addressed this issue by means of Federal Register final notice dated October 24, 1996 (61 FR 55156)

Comment: Establish a timeframe or deadline for the various steps in the process. The commenters are concerned that the process could be unreasonably delayed should the Department, the covered entity, or the dispute resolution committee not act in a timely manner. For example, an audit cannot begin until the Department grants permission and approves the audit workplan, while a covered entity's refusal to respond to an audit report would preclude the next step in the process from taking place. The suggestions for timeframes included to shorten from 60 to 30 days the timeframe for covered entities to respond to a manufacturer's audit findings and apply a 30-day timeframe for each step except for the act of performing the actual audit.

Response: There should be timeframes applicable to the actions required by the covered entities and the Department. The following timeframes have been incorporated into the guidelines:

- The Department will review an audit work plan submitted by a manufacturer within 15 days of submission;
- The requirement for covered entities to respond to audit findings and recommendations within 60 days has been reduced to 30 days;

Comment: Access to records should include the records of any organization employed by the covered entity to purchase or dispense drugs or file Title XIX claims on the entity's behalf.

Response: The auditors must have access to all records necessary for identifying and determining the eligibility of the ultimate consumer of drugs purchased at the discount price and whether Medicaid rebates were also claimed for those drugs. The guidelines have been revised to indicate that any organization purchasing or dispensing covered drugs or filing Title XIX claims on behalf of a covered entity is subject to the same audit requirements as the covered entity.

Comment: There were concerns with the Department's March 1994 Guideline Letter concerning the contracted pharmacy mechanism. These commenters believe that unforeseen business relationships and activities by covered entities under these guidelines could result in new patterns of fraud and abuse.

Response: The Department has addressed the contracted pharmacy mechanism in a separate Federal Register final notice on August 23, 1996 at 61 FR 43549.

Comment: Compliance with the requirements outlined in the Government Auditing Standards will significantly increase the cost of performing audits and require the use of independent accountants rather than internal audit staff. It was suggested that manufacturers use their own internal auditing standards or those of the Institute of Internal Auditors.

Response: Conducting audits in accordance with the Government Auditing Standards will provide assurances that audits will be performed in accordance with generally accepted auditing standards relating to professional qualifications of the auditors, independence, due professional care, field work, and reporting of the audit findings. Compliance with these standards will also ensure audit uniformity and consistency and adequacy of documentation to permit independent review in cases where disputes arise.

Comment: The guidelines should stipulate the record retention requirements for covered entities (i.e., indicate how long records must be maintained for possible audit).

Response: Covered entities should maintain records to demonstrate the distribution and use of covered drugs for a period of not less than 3 years.

Comment: There should be greater audit latitude and cooperation between manufacturers and entities as allowed by the ''Medicaid Agreement.''

Response: The ''Medicaid Agreement'' permits manufacturers to audit the Medicaid utilization information reported by the State. In this instance, manufacturers are auditing information received by the State and are permitted to develop mutually beneficial procedures with the State. This is a very different situation from the audits permitted by section 340B. Pursuant to section 340B authority, a manufacturer may audit an entity whose only connection to the State or Federal government is in the form of a grant or reimbursement that it receives. In this instance, the manufacturer is permitted to audit only pursuant to guidelines established by the Secretary.

Comment: In order to maximize profits, covered entities could require patients to purchase covered drugs from them, thus infringing on patients' rights to choose their own providers.

Response: Patients of covered entities have the right to fill their prescriptions at the pharmacy of their choice. Of course, if the patient chooses to have the prescription filled at a location other than with the covered entity, discount pricing cannot be guaranteed.

Comment: The guidelines should focus only on the number, duration, and scope of audits.

Response: The guidelines stipulate that (1) audits are to be performed only when there is a reasonable cause to believe that there has been a violation of section 340B(a)(5) (A) or (B); (2) audits are to be conducted with the least possible disruption to the operations of the covered entity with only one audit being permitted during the same time period; and (3) the scope of the audits must be sufficient to evaluate the covered entity's compliance with the aforementioned statutory prohibitions.

Comment: The guidelines are unfairly burdensome and shift the Secretary's responsibility for enforcing the statute to the manufacturers.

Response: In accordance with the intent of the statute, the audits should be performed only when there is reasonable cause for their performance. Further, the statute also states that the audits should be conducted at the expense of the Government or the manufacturer. We believe that the party which demonstrates a reasonable cause for the audit should commission the audit. However, in cases where more than one manufacturer has demonstrated reasonable cause for an audit, then the Government may perform the audit in order to protect the confidentiality of the manufacturers' proprietary information.

Comment: Some of the proposed audit steps are duplicative; therefore, the proposed audit steps at section II b, c, e, f, g should be excised or moved to streamline the proposed guidelines.

Response: The guidelines have been reorganized to provide a section on ''Procedures To Be Followed'' and a section on ''Suggested Audit Steps.'' This clearly distinguishes the procedures to be followed by the manufacturer from the suggested procedures to be performed by the manufacturer's auditors.

Comment: In cases where the Government elects to perform its own audit, the resulting audit report should be made available to the manufacturers.

Response: Audit reports prepared by Government auditors are public documents. A copy of the audit report will be made available to the manufacturers upon request. Requests

should be addressed to: Director, HRSA, Office of Drug Pricing, Bureau of Primary Health Care, 4350 East West Highway, West Towers, 10th Floor, Bethesda, MD 20814.

Comment: Because audits will be permitted only when the manufacturer can demonstrate that there is ''reasonable cause'' to believe that a violation of section 340B(a)(5) has occurred, ''reasonable cause'' should be defined.

Response: The guidelines have been revised to provide a definition of ''reasonable cause.''

Comment: A covered entity should be given an opportunity to respond to a manufacturer's request for an audit before the Department determines whether an audit may be performed and should be permitted to review and comment on the manufacturer's proposed audit workplan before it is approved by the Department.

Response: The guidelines provide for a 30 day period before the manufacturer submits to the Department an audit work plan in which the manufacturer and the covered entity must attempt in good faith to resolve the matter. When the manufacturer submits its audit work plan, it has already discussed the matter with the covered entity; therefore, we do not believe there is a need for the covered entity to comment on a manufacturer's submission of an audit workplan. The Department, at its discretion, may contact the covered entity as part of the review process of the proposed manufacturer's audit. Likewise, we do not believe that there is a need for the covered entity to review and comment on the manufacturer's proposed workplan once it has been reviewed by the Department.

Comment: The guidelines should be clarified to indicate that the manufacturer's independent public accountant should perform the audit. This is necessary to comply with the ''independence standard'' contained in the Government Auditing Standards.

Response: The guidelines have been modified to indicate that a manufacturer's auditor shall be an independent public accountant employed by a manufacturer to perform the audit.

Comment: Refer to reviews as ''attestation engagements'' rather than ''audits,'' and perform them as agreed-upon procedures in accordance with the Statement on Standards for Attestation Engagements No. 3, Compliance Attestation. The procedures to be performed could be jointly developed and agreed upon by the Department, the covered entity, manufacturer, and the independent accountant.

Response: Although some of the work to be performed by the independent public accountant or government auditor may involve some attestation procedures, the statute calls for an audit of the covered entity's records. Therefore, the term audit has been used in the preparation of the guidelines. Further, we agree that the opinions and views of all interested parties should be considered in the preparation of the guidelines. This has been achieved through the publication of the proposed guidelines in the Federal Register, requesting public comment.

Comment: The notice should include the guidelines to be followed by Federal auditors.

Response: Federal auditors will perform audits in accordance with the Government Auditing Standards. The Notice has been clarified.

Comment: Covered entities should have the right to submit newly compiled or discovered information following the manufacturer's audit for consideration by the review committee.

Response: The guidelines provide that when a covered entity disagrees with the audit report's findings and recommendations, the covered entity should provide its rationale for the disagreement to the manufacturer. The manufacturer and the covered entity must make a good faith effort to resolve the issue before requesting review using the dispute resolution process. Newly compiled or discovered information can be provided to the manufacturer during this period of good faith effort. If the parties are still unable to reach agreement, the newly compiled or discovered information can be submitted to the Department along with the other information that was developed as part of the audit. The Department will consider the auditor's findings and recommendations as well as the covered entity's rationale for disagreeing during the review process.

Comment: All covered entity records and information identified in the audit process should be held in strict confidence by the manufacturer.

Response: Confidential patient information and proprietary information will be protected.

Comment: Manufacturers should not be required to continue to sell to a covered entity at the mandated price once an audit has been initiated, particularly since reasonable cause has already been demonstrated.

Response: Manufacturers must continue to sell at the statutory price during the audit process. Once the audit has been completed and the manufacturer believes that there is sufficient evidence to indicate prohibited entity activity, then the manufacturer may bring the claim to the Department through the informal dispute process. Not until the entity is found guilty of prohibited activity and a decision is made to remove the entity from the covered entity list, will the manufacturers no longer be required to extend the discount.

Comment: Each manufacturer, wronged by the same business practices of the same entity, must wait its turn to audit the entity and pursue its case through the dispute process in order to recover. This could result in a failure to enforce the statute.

Response: The guidelines have been revised to permit the Department, if deemed necessary, to provide for corrective action as to other manufacturers wronged by prohibited entity activity.

Comment: Include the hospital prohibition against participation in any group purchasing arrangement as a permissible audit subject.

Response: The statute clearly limits the audit subjects to potential entity diversion (section 340B(a)(5)(B)) and entity activity that could generate a rebate on a drug that was discounted under the Act (section 340B(a)(5)(A)).

Comment: Provide for access to different records depending upon the record keeping system of the entity.

Response: The notice has been revised to permit access to primary records which would be included in a reasonable audit trail.

Comment: There is a requirement that an informational copy of the audit be provided to the Department and the Inspector General. Why cannot the entire report be provided to these offices?

Response: The guidelines have been revised to require that the entire report be submitted to the Department and the Office of the Inspector General.

Comment: The guidelines should not preclude the entity and the manufacturer from both voluntarily developing mutually beneficial audit procedures.

Response: The guidelines have been revised to include a statement that the guidelines do not preclude the entity and the manufacturer from both voluntarily developing mutually beneficial audit procedures.

Comment: The auditor should be able to confirm with the Department that the entity has provided its Medicaid provider number.

Response: The guidelines have been revised to permit the auditor to confirm with the Department that the entity being audited does not generate a Medicaid rebate while accepting 340B

discounts (e.g., has provided its Medicaid provider number, does not bill Medicaid, or utilizes an all-inclusive rate billing system). Manufacturers are free to challenge a hospital's eligibility as a covered entity by corresponding with the Department.

Comment: The Department must act independently to assure compliance.

Response: The Department will investigate all documentation submitted regarding both entity and manufacturer noncompliance and, when appropriate, take the necessary steps to remove the entity from ''covered entity'' status or terminate the Pharmaceutical Pricing Agreement which the manufacturer signed with HHS, thus preventing further participation in the program.

Comment: Set a specific time limit for a manufacturer to have audit personnel at the entity facility with the possibility of an extension for good cause.

Response: Because of the many variables (e.g., size of the covered entity and scope of the audit), it would be impossible to set specific time limits. However, if an entity believes that auditors are exceeding a reasonable time period, it may notify the Department for assistance.

Comment: You fail to require entities to allow audits.

Response: Please refer to the section entitled, ''Supplemental Information, Manufacturer Audit Guidelines,'' where we begin the discussion with the statement, ''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)(C) provides that a covered entity shall permit the manufacturer of a covered outpatient drug to audit the records of the entity that pertain to the entity's compliance with section 340B(a)(5).

Comment: Guidelines regarding scope should be expanded to include procedures to assure that manufacturers not have access to information that identifies specific patients or transaction records concerning the products of other manufacturers.

Response: The guidelines require that audits be performed in accordance with the *Government Auditing Standards* (GAS) developed by the Comptroller General of the United States. These standards require auditors to prepare the audit reports in a manner that protects privileged and confidential information. Confidential patient information and/or proprietary information which auditors may access in the performance of an audit will not be disclosed to the manufacturer.

Comment: In the new section III(b), change the word ''access'' to ''obtain an understanding of,'' and in section III(e) change the word ''determine'' to ''test.''

Response: We have revised the notice accordingly.

(C) Revised Manufacturer Audit Guidelines

Set forth below are the final manufacturer audit guidelines, revised based upon an analysis of the comments above.

Manufacturer Audit Guidelines

Covered entities which choose to participate in the section 340B drug discount program shall 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 shall permit the manufacturer of a covered outpatient drug 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 shall be conducted in accordance with guidelines developed by the Secretary, as required by section 340B(a)(5)(C). Not only will the records of any organization working with a covered entity to purchase or dispense covered drugs, or to prepare Medicaid reimbursement claims for the covered entity be subject to the same audit requirement, but also any primary record that could be part of a reasonable audit trail.

This notice does not include the complete audit guidelines to be used by Government auditors in cases where the Government performs its own audit. Federal auditors shall perform audits in accordance with the Government Auditing Standards. The Government auditors' authority to audit the covered entity's compliance with the requirements of section 340B(a)(5) (A) and (B) shall not be limited by the manufacturer's audit guidelines.

The following is the ''Compliance Audit Guide'' concerning manufacturer audit guidelines as developed by the Secretary pursuant to section 340B(a)(5)(C): (These guidelines do not preclude the entity and the manufacturer from voluntarily developing mutually beneficial audit procedures.)

I. General Guidelines

The manufacturer shall submit a work plan for an audit which it plans to conduct of a covered entity to the Department. (See section III for suggested audit steps.) The manufacturer's auditor shall be an independent public accountant employed by the manufacturer to perform the audit. The auditor has an ethical and legal responsibility to perform a quality audit in accordance with Government Auditing Standards, Current Revision, developed by the Comptroller General of the United States. Patient confidentiality requirements also must be observed. At the completion of the audit, the auditors must prepare an audit report in accordance with the reporting standards for performance audits in Government Auditing Standards, Current Revision. The cost of a manufacturer audit shall be borne by the manufacturer, as provided by section 340B(a)(5)(C) of the PHS Act.

(a). Number of Audits

A manufacturer shall conduct an audit only when it has documentation which indicates that there is reasonable cause. ''Reasonable cause'' means that a reasonable person could believe that a covered entity may have violated a requirement of section 340B(a)(5) (A) or (B) of the PHS Act (i.e., accepting a 340B discount on a covered outpatient drug at a time when the covered entity has not submitted its Medicaid billing status to the Department or transferring or otherwise reselling section 340B discounted covered drugs to ineligible recipients).

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 of a covered entity 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 compliance with section 340B(a)(5) (A) and (B), the Department will determine whether an audit should be performed by the (1) Government or (2) the manufacturer.

(b). Scope of Audits

The manufacturer shall submit an audit workplan describing the audit to the Department for review. The Department will review the workplan for reasonable purpose and scope. Only those records of the covered entity (or the records of any organization that works with the covered entity to

purchase, dispense, or obtain Title XIX reimbursement for the covered drug) that directly pertain to the potential 340B violation(s) may be accessed, including those systems and processes (e.g., purchasing, distribution, dispensing, and billing) that would assist in determining whether a 340B violation has occurred.

(c). Duration of Audits

Normally, audits shall be limited to an audit period of one year and shall be performed in the minimum time necessary with the minimum intrusion on the covered entity's operations.

II. Procedures To Be Followed

(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 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 an audit work plan with the Department. (See section **FOR FURTHER INFORMATION** for address.) The manufacturer must set forth a clear description of why it has 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 belief. In addition, the manufacturer shall provide copies of any documents supporting its claims.

(c). The Department will review the documentation submitted to determine if reasonable cause exists. If the Department finds that there is reasonable cause to believe that a violation of section 340B(a)(5) (A) or (B) has occurred, the Department will not intervene. In cases where the Department determines that the audit shall be performed by the Government, the Department will so advise the manufacturer and the covered entity within 15 days of receipt of the audit work plan.

(d). The filing of a audit work plan does not affect the statutory obligations of the parties as defined in section 340B of the PHS Act. During the audit process, the manufacturer must continue to sell covered outpatient drugs at the section 340B ceiling price to the covered entity being audited, and the covered entity must continue to comply with the requirements of section 340B(a)(5).

(e). Upon receipt of the manufacturer's audit work plan, the Department, in consultation with an appropriate audit component, will review the manufacturer's proposed workplan. As requested by GAS, 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 and proprietary information.

(f). Within 15 days of receipt of the proposed audit workplan, the Department shall review the work plan. If after this review the Department has concerns about the work plan, it will work with the manufacturer to incorporate mutually agreed-upon revisions to the plan. The covered entity will have at least 15 days to prepare for the audit.

(g). At the completion of the audit, the auditors must prepare an audit report in accordance with reporting standards for performance audits of the GAS. The manufacturer shall submit 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 30 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.

(h). The manufacturer shall also submit copies of the audit report to the Department (see section **FOR FURTHER INFORMATION CONTACT** for the address) and the Office of Inspector General, Office of Audit Services, PHS Audits Division at Room 1–30, Park Building, 12420 Parklawn Drive, Rockville, MD 20857.

(i). If a dispute concerning the audit findings and recommendations arises, the parties may file a request for dispute resolution with the Department. All dispute resolution procedures developed by the Department shall be followed.

III. Suggested Audit Steps

Suggested audit steps include the following:

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

(b). Obtain an understanding of internal controls applicable to the policies and procedures identified above (step a) when necessary to satisfy the audit objectives.

(c). 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.

(d). Test compliance with the policies and procedures identified above (step c) when necessary to satisfy the audit objectives.

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

(f). 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 pharmacy Medicaid provider number to the Department and test whether the covered entity billed Medicaid at the actual acquisition cost. The auditor is permitted to contact the ODP (at the number in the **FOR FURTHER INFORMATION CONTACT** section) to determine if the entity—(1) has provided its pharmacy Medicaid provider number, (2) does not bill Medicaid for covered outpatient drugs, (3) uses an all-inclusive rate billing system, or (4) is an entity clinic eligible for the discount pricing but located within a larger medical facility not eligible for the drug discounts and has provided the ODP a separate pharmacy Medicaid provider number or an agreement with the State Medicaid Agency regarding an operating mechanism to prevent duplicate discounting.

(g). Where the manufacturer's auditors conclude that there has been a violation of the requirements of section 340B(a)(5)(A) or (B), identify (1) the procedures or lack of adherence to existing procedures which caused the violation, (2) the dollar amounts involved, and (3) the time period in which the violation occurred.

(h). Following completion of the audit field work, provide an oral briefing of the audit findings to the covered entity to ensure a full understanding of the facts.

(D) Comment and Responses—Informal Dispute Resolution

Comment: The guidelines should include a mechanism to verify or ''dispute'' the accuracy of the Department's list of covered entities.

Response: The notice has been revised to include, as a type of dispute covered by the informal dispute mechanism, the accuracy of the master list of covered entities.

Comment: A dispute review committee consisting of only ODP and other PHS employees could result in conflict-of-interest concerns. The dispute review committee should be an independent body (e.g., an administrative law judge), and there should be a mechanism to provide for non-PHS members in cases where the dispute involved ODP.

Response: The Department is overseeing the implementation of section 340B of the PHS Act, and as such, is offering a voluntary dispute resolution mechanism to expedite this process. No manufacturer or covered entity is required to avail itself of this process before resorting to other available measures. Further, parties which do participate in the dispute resolution process will have an appeal opportunity with a HRSA review official or committee.

Comment: The penalties for covered entities that violate section 340B(a)(5) requirements are not adequate. For entities to merely repay discounts (plus interest) which they obtained and to which they were not entitled is not an effective deterrent. It was suggested that entities that have violated statutory requirements pay the cost of the audits, pay various amounts up to 150 percent of the improperly obtained discount (plus interest) and/or be banned from continued participation in the program. Further, it was suggested that an entity's failure to respond in a timely basis to a manufacturer's audit findings should result in a ''summary judgment'' against the entity.

Response: Section 340B(a) is clear concerning entity penalties for reselling or transferring discounted drugs, for generating duplicate discounts and rebates and who must bear the cost of auditing. Section 340B(a)(4) defines ''covered entity'' as one which meets the requirements of paragraph (5). This paragraph prohibits drug diversion and double price reductions. If an entity is found guilty of either of these activities, the entities may be found by the Department no longer to be covered under section 340B. Section 340B(a)(5)(D) outlines the monetary penalty for violations of these prohibitions and provides that entities must pay to the manufacturer the amount of discount received. Although section 340B provides for no other penalty, copies of the audit results will be submitted to the Office of Inspector General for review and possible further investigation. Section 340B(a)(5)(C) clearly provides that manufacturer audits are performed at the manufacturer expense. We agree that some type of penalty is necessary for an entity which does not respond in a timely fashion to a manufacturer audit results. We have revised the audit guidelines to allow for the manufacturer to submit to the Department a request for dispute resolution for entity non-response within given timeframes.

Comment: Please clarify the meaning of ''final determination'' as used in Part III of the Notice entitled, ''Penalties.''

Response: A ''final determination'' under the Dispute Resolution procedure is reached when review by the Administrator of the Health Resources and Services Administration (HRSA) is completed and the HRSA Administrator or appointee has made a decision on the issue(s) involved.

Comment: It is not clear when an administrative decision can be appealed by a covered entity to the Federal courts.

Response: Covered entities or manufacturers are encouraged to participate in this voluntary process for the resolution of disputes regarding section 340B. It is expected that once a covered entity or a manufacturer submits a request for informal dispute resolution, the process will be completed before pursuing other remedies which may be available under applicable principles of law. Entities may wish to seek legal advice concerning the exhaustion of administrative remedies regarding a voluntary administrative process. Section III of the Guidelines has been clarified.

Comment: Additional appeal procedures may be problematic for covered entities or manufacturers who must exhaust their administrative remedies before seeking remedies in a court of law.

Response: The dispute resolution process is a voluntary process. Manufacturers or entities are only encouraged to participate in the process before seeking other remedies.

Comment: The term ''PHS'' is not defined. It is unclear whether this means the ODP or some other office within the PHS.

Response: The term ''PHS'' means the Public Health Service in its entirety. The guidelines have been revised to reflect that the Department will be implementing these guidelines through the ODP.

Comment: A party who is unable to resolve a dispute can submit a written request for a review of the dispute. Time deadlines should be included to state when that written request can be submitted.

Response: The guidelines have been changed to include such deadlines.

Comment: Time deadlines and penalties for non-response must be included for various steps in the dispute process. First, upon receipt of a request for a review, the chairperson of the review committee should send a letter to the party alleged to have committed a violation. Time deadlines should be included on when the chairperson must send this letter. Second, the activities of the review committee should also have deadlines. Third, a deadline for the submission of additional information should be included.

Response: The guidelines have been changed to include such deadlines.

Comment: The penalties do not preclude the imposition by the Government of other penalties or remedies under other statutes such as the Federal False Claims Act.

Response: The guidelines have been revised to clarify this issue.

(E) Revised Informal Dispute Resolution Process

Set forth below are the final informal dispute resolution guidelines, revised based upon the analysis of the comments above.

Dispute Resolution Process

The Department, acting through the Office of Drug Pricing (ODP), is proposing a voluntary process for the resolution of certain disputes between manufacturers and covered entities concerning compliance with the provisions of section 340B of the PHS Act. Covered entities or manufacturers are not required to enter this informal process for resolution of disputes regarding section 340B. However, the Department expects parties to utilize the

process before resorting to other remedies which may be available under applicable principles of law.

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 (section 340B(a)(5)(B) of the PHS Act), or the prohibition against duplicate discounts or rebates (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 covered entity believes that a manufacturer has refused to sell a covered outpatient drug 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 audit guidelines as set forth in this notice.

(g) A covered entity believes that the auditors of the manufacturer have not abided by the approved workplan or audit guidelines.

(h) A covered entity is unable to obtain covered outpatient drugs through a wholesaler because the manufacturer will only sell section 340B discounted drugs directly from the manufacturer to the entity.

(i) A manufacturer or covered entity wants to verify the accuracy of the master list of covered entities.

II. Dispute Resolution Process

Prior to the filing of a request for dispute review with the Department, the parties must attempt, in good faith, to resolve the dispute. All parties involved in the dispute must maintain written documentation as evidence of the 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 ODP within 30 days. [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. Only when the entity is found guilty of prohibited activity and a decision is made to remove the entity from the list of covered entities, is the manufacturer no longer required to extend the discount.

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 ODP 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, within 30 days, 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 37 calendar days of the receipt of the letter (7 days from the date of the postmark of the letter being allowed for mailing and processing through the organization).

Upon receipt of the response or rebuttal, the review committee 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) adequacy of the documentation supporting the issues, and (4) the reasonableness of the allegations. If the documentation meets these requirements, the review committee will 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. Within 30 days, a written decision of dismissal will be sent to each party and will contain the committee's findings and conclusions in detail, and, if the committee decided to dismiss, reasons why the request for a review did not raise a genuine and substantial issue of fact.

With all other proposed findings, within 30 days, 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 committee's written decision will be sent with a transmittal letter to both parties. If the committee finds the covered entity guilty of prohibited activity and a decision is made to remove the entity from the covered entity list, then the manufacturers will no longer be required to extend the discount. If the covered entity or the manufacturer does not agree with the committee'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. The review official or committee will respond to appeal requests within 30 days from the receipt of the request.

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 HHS could be terminated or other actions taken, as

deemed appropriate. If the final determination is that an entity has violated section 340B prohibitions against the resale or transfer of covered outpatient drugs or the prohibition against duplicate discounts and rebates (or billing Medicaid more than the actual acquisition cost of the drug), 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. After the dispute is resolved, any disputed amounts must be paid or credited to an account balance no later than 30 days following a final determination. The entity may also be excluded from the drug discount program, if the conduct warrants such a sanction. Such penalties do not preclude the imposition by the Government of other penalties or remedies under other statutes such as the Federal False Claims Act. A copy of the findings may be sent to the Office of the Inspector General for further action. If it is documented that several manufacturers have been wronged by the same prohibited entity behavior, corrective action will be afforded such manufacturers. (The reporting and recordkeeping requirements of this document are subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501–3520, and have OMB clearance through 9/30/97 (OMB Control No. 0915–0176). The Paperwork Reduction Act of 1995 added disclosure requirements to the list of items needing OMB approval. The disclosure requirements in the audit guidelines include: section II(a)—the manufacturer shall notify the covered entity in writing when it believes the covered entity has violated provisions of section 340B; section II(g)—the manufacturer shall submit the audit report to the covered entity, and the covered entity shall provide its response to the manufacturer on the audit report's findings * * *; and section III(h) the manufacturer shall provide an oral briefing of the audit findings to the covered entity. The disclosure requirements in these sections will not be in force until OMB approval has been obtained.

Dated: December 6, 1996.

Ciro V. Sumaya,

Administrator, Health Resources and Services Administration.

[FR Doc. 96–31541 Filed 12–11–96; 8:45 am]

BILLING CODE 4160–15–P

National Institutes of Health

National Institute on Aging; Notice of Closed Meeting

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting:

Name of Committee: National Institute on Aging Special Emphasis Panel (Teleconference).

Date of Meeting: December 19, 1996.

Time of Meeting: 10:30 a.m. to adjournment.

Place of Meeting: Gateway Building, Room 2C212, 7201 Wisconsin Avenue, Bethesda, Maryland 20892.

Purpose/Agenda: To review a grant application.

Contact Person: Dr. James P. Harwood, Scientific Review Administrator, Gateway Building, Room 2C212, National Institutes of Health, Bethesda, Maryland 20892–9205, (301) 496–9666.

This notice is being published less than 15 days prior to the above meeting due to the urgent need to meet timing limitations imposed by the review and funding cycle.

This meeting will be closed in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Program No. 93.866, Aging Research, National Institutes of Health)

Dated: December 6, 1996.

Paula N. Hayes,

Acting Committee Management Officer, NIH.

[FR Doc. 96–31585 Filed 12–11–96; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4086–N–86]

Notice of Proposed Information Collection for Public Comment

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

ACTION: Notice

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: Comments due: February 10, 1997.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Reports Liaison Officer, Shelia E. Jones, Department of Housing & Urban Development, 451—7th Street, SW, Room 7230, Washington, DC 20410.

FOR FURTHER INFORMATION CONTACT: Frank Price, 202–708–2094 ext. 4572 (this is not a toll-free number) for copies of the proposed forms and other available documents.

SUPPLEMENTARY INFORMATION: The Department will submit the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended).

The Notice is soliciting comments from members of the public and affected agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

This Notice also lists the following information:

Title of Proposal: Rental Rehabilitation Program Renewal Application.

OMB Control Number, if applicable: 2506–0080.

Description of the need for the information and proposed use: Although the Rental Rehabilitation Program was terminated October 1, 1991, Public Law 98–181 (97 Stat. 1153), Section 17, that originally authorized the Rental Rehabilitation Program still imposes data collection and reporting requirements upon HUD and grantees. The information will be used by HUD to account for program grant funds and to satisfy statutory reporting requirements.