

underserved communities (high rate for placing graduates in practice settings having the principal focus of serving residents of medically underserved communities); OR

(C) During the 2-year period preceding the fiscal year for which such an award is sought, has achieved a significant increase in the rate of placing graduates in such settings.

Additional information concerning the implementation of the preference identified in section 791(a) of the PHS Act has been published in the Federal Register at 58 FR 9570, dated February 22, 1993. The burden for collection of information to request this preference is under review by the Office of Management and Budget in accordance with the Paperwork Reduction Act.

It is not required that applicants request consideration for this funding preference. Applications which do not request consideration for the funding preference will be reviewed and given full consideration for funding.

Information Requirements Provision

Under section 791(b) of the PHS Act, the Secretary may make an award under the Allied Health Project Grants Program only if the applicant for the award submits to the Secretary information regarding the programs of the applicant. These requirements will be provided in the application materials. The burden for collection of this information is under review by the Office of Management and Budget in accordance with the Paperwork Reduction Act.

Questions regarding programmatic information should be directed to: Dr. Norman Clark, Program Officer, Associated Health Professions Branch, Division of Associated, Dental and Public Health Professions, Bureau of Health Professions, Health Resources and Services Administration, Parklawn Building, Room 8C-02, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443-6763.

The *Catalog of Federal Domestic Assistance* number for this program is 93.191. This program is not subject to the provisions of Executive Order 12372, Intergovernmental Review of Federal Programs (as implemented through 45 CFR part 100). This program is not subject to the Public Health System Reporting Requirements.

Dated: April 30, 1993.

Robert G. Harmon,
Administrator.

[FR Doc. 93-10766 Filed 5-6-93; 8:45 am]

BILLING CODE 4100-15-P

Advisory Council; Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92-463), announcement is made of the following National Advisory body scheduled to meet during the month of June 1993:

Name: Council on Graduate Medical Education.

Time: June 2-3, 1993, 8:30 a.m.

Place: Conference Room G&H, Parklawn Conference Center, 5600 Fishers Lane, Rockville, MD 20857.

Open for entire meeting.

Purpose: Provides advice and recommendations to the Secretary and to the Committees on Labor and Human Resources, and Finance of the Senate and the Committees on Energy and Commerce and Ways and Means of the House of Representatives, with respect to (A) the supply and distribution of physicians in the United States; (B) current and future shortages of physicians in medical and surgical specialties and subspecialties; (C) issues relating to foreign medical graduates; (D) appropriate Federal policies regarding (A), (B), and (C) above; (E) appropriate efforts to be carried out by medical and osteopathic schools, public and private hospitals and accrediting bodies regarding matters in (A), (B), and (C) above; (F) deficiencies in the needs for improvements in, existing data bases concerning supply and distribution of, and training programs for physicians in the United States.

Agenda: There will be presentations and discussions regarding the need to refine the Third Report recommendations in view of the Administrations proposed health care reform initiative and other developments. Status reports will be given and discussions will be held on Council on Graduate Medical Education initiatives such as Managed Care, Women in Medicine, etc. Also a period of public comment on the Third Report and status reports of the Council will be provided.

Anyone requiring information regarding the subject Council should contact Marc L. Rivo, M.D., M.P.H., Executive Secretary, telephone (301) 443-6190; or F. Lawrence Clare, M.D., M.P.H., Deputy Executive Secretary, telephone (301) 443-6326, Council on Graduate Medical Education, Division of Medicine, Bureau of Health Professions, Health Resources and Services Administration, room 4C-25, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857.

Agenda items are subject to change as priorities dictate.

Dated: May 3, 1993.

Jackie E. Baum,
Advisory Committee Management Officer,
HRSA.

[FR Doc. 93-10815 Filed 5-6-93; 8:45 am]

BILLING CODE 4100-15-P

Guidance Regarding Section 602 of the Veterans Health Care Act of 1992; Limitation on Prices of Drugs Purchased by Covered Entities

AGENCY: Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The Secretary of Health and Human Services provides the following guidance regarding section 602 of Public Law 102-585, the "Veterans Health Care Act of 1992" (the "Act"), which enacted section 340B of the Public Health Service (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 the average manufacturer price ("AMP") decreased by a rebate percentage. This notice advises manufacturers and covered entities of the terms of the Agreement, describes the criteria for the certification process required of certain entities, and alerts manufacturers who have not received an Agreement by mail of the manner in which to request one.

DATES: Section 340B was effective with respect to drug purchases on or after December 1, 1992. Agreements signed after that date are effective for purchases of covered outpatient drugs retroactive to December 1, 1992, for those entities included on the initial list of covered entities mailed to each manufacturer. For manufacturers that have not received an Agreement by mail, a written request for an Agreement should be submitted to the Drug Pricing Program within 30 days from the date of publication of this notice.

FOR FURTHER INFORMATION CONTACT: Marsha Alvarez, R. Ph. Chief Pharmacy Officer, Attn: Drug Pricing Program, Health Resources and Services Administration, Bureau of Primary Health Care, Rm 7A-55 Parklawn Bldg., 5600 Fishers Lane, Rockville, Maryland 20857, Phone: (301) 443-0004-6.

SUPPLEMENTARY INFORMATION:

I. Introduction

The Act was designed to establish price controls to limit the cost of drugs to Federal purchasers and to certain grantees of Federal agencies. In 1990, Congress identified a problem with increasing drug prices and enacted the Omnibus Budget Reconciliation Act of 1990. This attempt at drug price control focused only on the Medicaid program

and established a best-price policy. Under the Medicaid drug rebate program, pharmaceutical manufacturers initially gave State Medicaid agencies the greater of a minimum 12.5 percent flat rebate of the average manufacturer price (AMP) or the difference between the AMP and the best price paid by the customer for single source or innovator multiple source drugs. To provide a phase-in period, the rebate amount was capped at a specific percentage of the AMP which increased from 1991 through 1993. Generic manufacturers gave States a ten percent of AMP flat rebate which will increase to 11 percent in 1994.

The Veterans Health Care Act is an attempt to provide Federal purchasers with a process whereby they will receive drug discounts or rebates. Section 601 of Public Law 102-585 amends the Medicaid rebate program, section 602 provides drug discounts primarily to certain grantees of the Public Health Service, and section 603 enacts a drug discounting process administered by the Department of Veterans Affairs for the benefit of several Federal agencies. This guidance addresses the program enacted by section 602.

II. Covered Entities

(a) Current Covered Entities

Section 602 of Public Law 102-585 enacted a new section 340B of the PHS Act. Pursuant to this new section, eligible entities are as follows (except as otherwise indicated, references are to sections of the Public Health Service Act):

1. Federally-qualified health centers (migrant, community and homeless health centers) as defined in section 1905(l)(2)(B) of the Social Security Act, 42 U.S.C. 1396d.
2. Health centers for residents of public housing funded under section 340A, 42 U.S.C. 256a.
3. Family planning projects receiving grants or contracts under section 1001, 42 U.S.C. 300.
4. An entity receiving a grant for outpatient early intervention services for HIV disease under subpart II of part C of title XXVI, 42 U.S.C. 300ff-51 *et seq.*
5. A State-operated AIDS drug purchasing assistance program receiving financial assistance under section 2616 of the Act, 42 U.S.C. 300ff-26.
6. A black lung clinic receiving funds under section 427(a) of the Black Lung Benefits Act, 30 U.S.C. 937(a).
7. A comprehensive hemophilia diagnostic treatment center receiving a grant under section 501(a)(2) of the Social Security Act, 42 U.S.C. 701(a)(2).

8. A Native Hawaiian Health Center receiving funds under the Native Hawaiian Health Care Act of 1988, 42 U.S.C. 11701 *et seq.*

9. An urban Indian organization receiving funds under title V of the Indian Health Care Improvement Act, 25 U.S.C. 1651 *et seq.*

10. Any entity, certified by the Secretary, receiving assistance under title XXVI of the Act, 42 U.S.C. 300ff *et seq.*, (other than a State or unit of local government or an entity described in #4).

11. Any entity, certified by the Secretary, receiving funds relating to the treatment of sexually transmitted diseases under section 318, 42 U.S.C. 247c, or relating to the treatment of tuberculosis under section 317(j)(2), 42 U.S.C. 247b, through a State or unit of the local government.

12. A "disproportionate share" hospital as defined in section 1886(d)(1)(B) of the Social Security Act, which (for the most recent cost reporting period that ended before the calendar quarter involved) had a disproportionate share adjustment greater than 11.75 percent, and which is (1) owned or operated by a State or local government, (2) a public or private nonprofit corporation formally granted governmental powers by a State or local government, or (3) a private nonprofit hospital with a State or local government contract to provide health services to low income individuals who are not entitled to benefits under Medicare or eligible for assistance under the State plan. The discount need not be provided for drugs which the hospital obtains through a group purchasing arrangement.

In the case of a covered entity that is a distinct part of a hospital, the hospital shall not be considered a covered entity unless the hospital is otherwise a covered entity, i.e., it meets the requirements of a disproportionate share hospital as determined by the Secretary under section 340B(a)(4)(L).

(b) Certification

Certain covered entities must be certified by the Secretary before they become eligible for the discount drug prices, section 340B(a)(7) of the PHS Act. The entities requiring certification are those that—

(a) receive grant funds related to the treatment of sexually transmitted diseases through a state or local government under section 318 of the PHS Act, 42 U.S.C. 247c,

(b) receive grant funds related to the treatment of tuberculosis through a state or local government under section

317(j)(2) of the PHS Act, 42 U.S.C. 247b, and

(c) are receiving assistance under title XXVI of the PHS Act, 42 U.S.C. 300ff *et seq.*, other than a State or unit of local government or grantees for HIV outpatient early intervention services (subpart II of part C of title XXVI of the PHS Act).

The criteria for eligibility include State certification that the entity does receive Federal grant funds and is an entity described in (a), (b), or (c) above. Information concerning the amount each entity expended for outpatient drugs in the preceding fiscal year (October 1, 1991, to September 30, 1992) is also required. These amounts are necessary to assist the Secretary in evaluating the validity of subsequent purchases of outpatient drugs at the discounted prices.

The respective PHS program directors for these entities have been asked to compile a list of the covered entities in their programs and include for each entity the estimated amount of outpatient drug purchases in the preceding year. They are asked to send this list and a form certification letter to the respective State program directors so that the State may certify the accuracy of the list.

The States are asked to return the certification letters to the respective PHS program directors. These letters, along with the drug purchasing information, will be kept on file so that they can be used for audit purposes.

In addition, section 340B(a)(7)(E) of the PHS Act requires a recertification process of these same entities. The respective PHS program directors will compile, on an annual basis, a list of eligible entities for the above categories (a), (b), and (c), will estimate the amount of outpatient drug purchases for each listed entity during the preceding fiscal year, and will include a recertification letter and the newly compiled list of entities in the grant renewal package for each State program director to complete and return.

(c) Possible Future Covered Entities

Section 340B also requires the Secretary to conduct a study concerning entities that receive funds from a State for mental health and substance abuse treatment services under subparts I or II of part B of title XIX of the PHS Act or under title V of such Act; or receive funds from a State under title V of the Social Security Act for outpatient maternal and child health services. The Secretary is directed to determine the feasibility of awarding these entities eligibility status and to submit this report to Congress by November 4, 1993.

Covered drugs are outpatient drugs as defined in section 1927(k) of the Social Security Act. Section 1927(k)(2) generally includes within this term (a) a drug which can only be dispensed upon prescription, and (1) which has been approved for safety and effectiveness under section 505 or 507 of the Federal Food, Drug, and Cosmetic Act, or (2) which was used or sold commercially in the United States before the enactment of the Drug Amendments of 1962 (or identical, related, or similar to such a drug) and which has not been the subject of a final determination by the Secretary that it is a "new drug," or (3) which is described in section 107(c)(3) of the Drug Amendments of 1962 and for which the Secretary has determined that there is a compelling justification of its medical need and for which the Secretary has not issued a notice of opportunity for hearing on a proposed order to withdraw approval of an application for such a drug because the drug is less than effective for some or all of its labelled indications; (b) a prescribed biological product other than a vaccine, licensed under section 351 of the PHS Act, and produced at an establishment licensed under such section to produce such a product; (c) insulin, certified under section 506 of the Federal Food, Drug, and Cosmetic Act; and (d) an over-the-counter drug, if it is prescribed by a person authorized to prescribe such a drug under State law.

Pursuant to the limiting definition of section 1927(k)(3) of the Social Security Act, a covered outpatient drug does not include any drug, biological product, or insulin provided as part of, or incident to and in the same setting as, any of the following (and for which payment is made as part of payment for the following and not as direct reimbursement for the drug): (a) Inpatient hospital services; (b) hospice services; (c) dental services, except drugs for which the State Medicaid plan authorizes direct reimbursement to the dispensing dentist; (d) physicians' services; (e) outpatient hospital service emergency room visits; (f) nursing facility services; (g) other laboratory and x-ray services; and (h) renal dialysis. A covered outpatient drug does not include any such drug or product which is used when there is no medically accepted indication.

IV. Calculation of the Drug Price.

To determine the price for a covered outpatient drug, the manufacturer shall calculate the average manufacturer price (AMP) for the drug and reduce it by the rebate percentage. Average manufacturer price is the average price

paid to the manufacturer for the drug in the United States by wholesalers for the drug distributed to the retail pharmacy class of trade in the calendar quarter. The rebate percentage is the total per unit Medicaid rebate amount, section 1927(c)(1) and (2) of the Social Security Act, for the particular drug divided by the AMP. The Medicaid rebate calculation utilizes Best Price information which considers the lowest price available at which the manufacturer sells the covered outpatient drug to any wholesaler, retailer, nonprofit entity, or governmental entity within the United States in any pricing structure (as defined in section I(b) of the Pharmaceutical Pricing Agreement).¹

To calculate the price for an over-the-counter or generic drug, the rebate percentage will be determined as if the rebate required under 1927(c) of the Social Security Act is based upon the percentages provided in section 1927(c)(4) of the same Act (i.e., calendar quarters between January 1, 1991 and December 31, 1993=10% and calendar quarters beginning on or after January 1, 1994=11%).

V. Manufacturers' Information.

(a) Effective Date of Implementation

Because the effective date of section 340B of the PHS Act with respect to drug purchases is December 1, 1992, and all Agreements signed with entities included on the initial list of covered entities are effective retroactive to that date, manufacturers should incorporate these pricing limitations in dealings with covered entities as of that date. If the manufacturer finds that a price adjustment is required, the manufacturer shall calculate any rebate (or credit) necessary to account for sales between December 1, 1992, and the date of the Agreement and shall either remit the rebate to the entity (or provide for the credit). Additional eligible entities, later included in the updated lists, will be eligible for drug discounts only for

¹ For those drug manufacturers who are participating in the Medicaid Drug Rebate Program, calculation of the Medicaid unit rebate amount is based on the same formulas (per unit basic rebate amount and additional rebate amount for single source and innovator multiple source drugs or the per unit rebate amount for noninnovator multiple source or over-the-counter drugs) as used by Medicaid. Those drug manufacturers who are not participating in the Medicaid Drug Rebate Program should contact Ms. Marsha Alvarez at the address or telephone number listed in the "For Further Information Contact" section for information concerning rebate calculations. Sample calculations of a section 1927(c) rebate included in Enclosure C of the letter dated December 11, 1992, from the Administrator, Health Resources and Services Administration, should be disregarded.

purchases on and after the date of their inclusion on the list.

(b) Definition of Manufacturer

The term "Manufacturer" has the meaning as set forth in section 1927(k)(5) of the Social Security Act and includes all entities engaged in—

(1) the production, preparation, propagation, compounding, conversion, or processing of prescription drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, or (2) the packaging, repackaging, labeling, relabeling, or distribution of prescription drug products.

A manufacturer must hold legal title to or possession of the NDC number for the covered outpatient drug. Such term does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law.

"Manufacturer" also includes an entity, described in (1) or (2) above, that sells outpatient drugs to covered entities, whether or not the manufacturer participates in the Medicaid rebate program. Furthermore, the Pharmaceutical Pricing Agreement provides that the term also includes any contractor who fulfills the responsibilities pursuant to the PHS drug pricing agreement.

The Department is aware that many covered entities purchase drugs from wholesalers, rather than directly from manufacturers. Manufacturers shall take the steps necessary to assure that the discounts required by this legislation are passed through the wholesalers to the covered entities.

(c) Pharmaceutical Pricing Agreement

A manufacturer must sign an Agreement with the Department agreeing not to charge a covered entity a price for a covered outpatient drug exceeding the AMP of the drug decreased by the rebate percentage. Signing the Agreement does not prohibit a manufacturer from charging a price for a covered outpatient drug that is lower than the maximum price that can be charged.

The Department mailed the Agreements December 15, 1992, priority mail, and requested, for participation in the discount program, a return of the signed agreement by January 6, 1993. If a manufacturer did not receive a copy of the Agreement, it must contact Ms. Alvarez at the address specified in the "Further Information" section of this notice within 30 days from the date of publication of this notice.

(d) List of Eligible Covered Entities

A list of eligible covered entities has been mailed to each manufacturer along with the Agreement, and this list will be updated at least annually. Timely notification of additions to and deletions from the list of eligible covered entities will also be provided. A list of eligible subgrantees will be made available at a later date. The requirement for retroactive adjustments to December 1, 1992, will not apply to covered entities not included on the initial list.

(e) Drug Pricing Information Access

Those manufacturers that do not have a reporting requirement under section 1927(b)(3) of the Social Security Act for covered outpatient drugs must agree to submit, upon request, to the Department a list of all covered outpatient drugs purchased by covered entities, the average manufacturer prices (AMP), baseline AMP, Best Price calculations (if relevant), and information concerning the prices of the covered outpatient drugs distributed through a wholesaler. The manufacturer must further maintain all records relevant to the generation of these reports for a period of three years from the date of their creation. The Department will have reasonable access to the records of all participating manufacturers relevant to the manufacturer's compliance with the terms of the Agreement. Upon request the Health Care Financing Administration (HCFA) will share AMP and (if relevant) Best Price information submitted under the Medicaid Rebate Agreement on covered drugs with the Secretary or her designee for the purposes of carrying out the agreement.

(The reporting and record-keeping requirements of this section are subject to the 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.)

(f) Drug Utilization Information Access

A manufacturer will be permitted to audit the records of covered entities that directly pertain to a prohibition on the resale of drugs to persons not patients of the entity and a prohibition on possible duplicate discounts (i.e., Medicaid rebates, coupled with discounts allowable under the Act). This audit must be in accordance with procedures established by the Department relating to number, duration, and scope of audits and will be at the manufacturer's expense.

(g) Penalty Provisions

Pursuant to section 1927(a)(5)(A) of the Social Security Act, a manufacturer who does not sign, and keep in effect, an Agreement will not have met the requirements of section 1927(a)(5)(A).

If the Department finds, after notice and a hearing, that a manufacturer has failed to comply with the pricing requirement of section II(a) of this Agreement, has refused to submit drug pricing information requested by the Department, or has submitted false information, the Agreement will be terminated. As applicable, other penalties will be imposed.

VI. Covered Entities' Information**(a) Effective Date of Implementation**

Covered outpatient drugs purchased on or after December 1, 1992, by a covered entity included on the initial list must be discounted pursuant to the formula in section 340B(a)(1) and (2) of the PHS Act. Agreements with manufacturers signed after December 1, 1992, will be effective retroactive to that date for covered entities included on the initial list; therefore, the manufacturer must calculate any price adjustments necessary and remit a rebate directly to the covered entity (or provide for a credit).

(b) Eligibility

The Department has provided a list of eligible entities to each manufacturer along with a copy of the Agreement and is notifying each covered entity of its eligibility to purchase drugs at the discounted prices. Each covered entity is encouraged to begin discussing the pricing provisions of section 340B of the PHS Act with manufacturers so that potential problems can be identified early and resolved.

(c) Drug Price Negotiation

Although the Department signs the Agreement with each manufacturer, the entity itself may continue to negotiate individual drug pricing agreements with each manufacturer. Nothing in the statute precludes group purchasing agreements or other arrangements not inconsistent with the Agreement, except for disproportionate share hospitals.

(d) Penalty Provisions

A covered entity is prohibited from reselling or otherwise transferring a covered drug to a person who is not the patient of the entity (section 340B(a)(5)(B) of the PHS Act). The statute provides further the drug purchases will not be subject to both the discount under section 340B and the Medicaid rebate under section 1927 of

the Social Security Act (section 340B(a)(5)(A) of the PHS Act). The Secretary has decided to establish a mechanism within 120 days after the effective date of the Agreement to assure that covered entities comply with the prohibition on duplicate discounts and rebates. If the Secretary does not establish a mechanism within 120 days, the Secretary will apply the provisions of section 1927(a)(5)(C) of the Social Security Act.² If the Secretary finds, after notice and hearing, that a covered entity has violated either of these prohibitions, the covered entity shall be liable to the manufacturer of the covered drug that is the subject of the violation in an amount equal to the reduction in the price of the drug as described in section 340B of the PHS Act.

(e) Audit Provision

Each covered entity will be required to retain records of purchases of covered outpatient drugs under the Agreement and of any claims for reimbursement submitted for such drugs under title XIX of the Social Security Act. When a covered entity is making purchases through a wholesaler, it will be required to provide the manufacturer with information necessary to arrange for such purchases consistent with the terms of the Agreement.

A covered entity shall permit the Secretary and the manufacturer of a covered outpatient drug that is the subject of an Agreement to audit, at the Secretary's or manufacturer's expense, the records of the entity that directly pertain to the entity's compliance with the resale or duplicate discount prohibition.

VII. Confidentiality Provisions

Information disclosed by the manufacturer in connection with a request by the Department is confidential and, except as otherwise required, will not be disclosed by the Department in a form that reveals the manufacturer, or the prices charged by the manufacturer, except as necessary by the Department to carry out the provisions of the Act or to permit review by the Comptroller General.

The manufacturer shall hold audit information obtained from the covered entities confidential.

The Department shall require, under a reasonable schedule of implementation,

² Depending upon the type of mechanism developed, some covered entities may be required to refund a portion of the discount received from drug manufacturers prior to the establishment of the mechanism (e.g., discounts for covered outpatient drugs for which Medicaid reimbursement claims were submitted to State Medicaid agencies).

that covered entities not reveal confidential drug pricing information.

VIII. Nonrenewal and Termination Provisions

Unless otherwise terminated by either party, the Agreement will be effective for a period of one year and will be renewed automatically for additional successive terms of one year, unless the manufacturer gives written notice of intent not to renew. The manufacturer may terminate the Agreement for any reason, and the Secretary, after notice and hearing, may terminate the Agreement for good cause or a violation of the Agreement.

Dated: February 11, 1993.

Robert G. Harmon,
Administrator, Health Resources and Services Administration.

[FR Doc. 93-10816 Filed 5-6-93; 8:45 am]
BILLING CODE 4160-15-M

Notice Regarding Section 602 of the Veterans Health Care Act of 1992, Duplicate Discounts and Rebates on Drug Purchases

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 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.

Section 340B(a)(5)(A) of the PHS Act provides that a drug purchase shall not be subject to both the discount under section 340B and a Medicaid rebate under section 1927 of the Social Security Act. The Department is directed to establish a mechanism to assure that covered entities comply with this prohibition. The purpose of this notice is to announce the mechanism that the Department is proposing and to invite public comment on the proposal.

DATES: The Health Resources and Services Administration is soliciting comments from the public on this proposed mechanism by June 7, 1993.

The Department will consider the comments and issue a final notice of the mechanism to be established. The Department presently intends that State

Medicaid agencies will implement the procedures outlined below for outpatient drug claims paid by Medicaid beginning July 1, 1993, if PHS provides State Medicaid agencies with the Medicaid provider numbers for all covered entities by July 1, 1993.

With a July 1, 1993, effective date, all State Medicaid drug utilization data for the third calendar quarter due to manufacturers by November 30, 1993, would exclude rebates for discounted drugs sold to PHS covered entities. For claims paid by Medicaid prior to July 1, 1993, State agencies will bill manufacturers for rebates on all drugs paid by Medicaid.

ADDRESSES: Comments should be submitted to: Marsha Alvarez, R.Ph., Director, Drug Pricing Program, Bureau of Primary Health Care, Health Resources and Services Administration, Rm. 7A-55, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857, Phone: (301) 443-0004

FOR FURTHER INFORMATION CONTACT: For further information please contact Marsha Alvarez, as cited above.

SUPPLEMENTARY INFORMATION:

Section 1927 of the Social Security Act provides that in order to receive payment under the Medicaid program for covered outpatient drugs, drug manufacturers must enter into and comply with rebate agreements with the Secretary on behalf of States or with States directly. Section 1927 was enacted by the Omnibus Budget Reconciliation Act of 1990 and was amended by section 601 of the Act. Section 602 of the Act creates a program under which drug manufacturers must provide discounts to "covered entities," which consist primarily of certain grantees of the Public Health Service and "disproportionate share" hospitals.

Section 340B(a)(5)(A) of the PHS Act reflects Congress' recognition that there is a potential for drugs purchased by a covered entity with a discount to be subject to a Medicaid rebate, if the drug is reimbursed by the Medicaid program. Accordingly, this section directs the Department to establish a mechanism to avoid the combination of the discount and the Medicaid rebate for the same drug purchases.

The Public Health Service has consulted with the Health Care Financing Administration (HCFA), which is responsible for the Federal administration of the Medicaid program, and proposes the following as the mechanism to comply with section 340B(a)(5)(A).

I. All-Inclusive Rates Per Encounter or Visit

Under "all-inclusive rates" (either per encounter or visit), drug purchases are not billed as separate cost items, and, therefore, there is no opportunity for a Medicaid rebate to be sought for the drugs, even if purchased with a section 340B discount. (See, for example, the reimbursement methodology for Federally Qualified Health Centers, sections 1861(aa) and 1905(l)(2) of the Social Security Act.) Accordingly, to the extent that covered entities develop all-inclusive rates, there is no possibility that the duplicate discount and rebate can occur.

II. Drug Purchases Not Reimbursed Under All-Inclusive Rate

For those drug purchases which are not reimbursed by Medicaid under all-inclusive rates, the Department proposes the following mechanism to avoid the duplicate discount and rebate. PHS has provided manufacturers a list of covered entities eligible for the discounts. (This list will be updated periodically.) PHS will provide the list to State Medicaid agencies with the Medicaid provider numbers for each covered entity in the respective State. The covered entities will provide these numbers to the PHS.

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 shall 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 dispensing fee established by the State Medicaid agency. This will assure that the discount to the covered entity will be passed on to the State Medicaid agency.

Based on the Medicaid provider number information furnished by PHS, the State Medicaid agency will create a separate provider file for claims from covered entities which are billing on a cost basis for drug purchases. The State Medicaid agency will exclude data from these provider files when generating the rebate bills to the manufacturers under the section 1927 program. Thus, the payment of duplicate discounts and rebates by the drug manufacturer will be prevented.

This mechanism is consistent with the Veterans Health Care Act and the limitations established in the Medicaid regulations, 42 CFR sections 447.331-447.334, which limit the amount the Medicaid State agency may reimburse providers. These regulations are designed to give States a certain amount