

As discussed in section V of this notice, findings of failure to attain and reclassification of nonattainment areas under section 188(b)(2) of the Act do not in-and-of-themselves create any new requirements. Therefore, I certify that today's proposed action does not have a significant impact on small entities.

#### VII. Unfunded Mandates

Under sections 202, 203 and 205 of the Unfunded Mandates Reform Act of 1995 (Unfunded Mandates Act), signed into law on March 22, 1995, EPA must assess whether various actions undertaken in association with proposed or final regulations include a Federal mandate that may result in estimated costs of \$100 million or more to the private sector, or to State, local or tribal governments in the aggregate.

EPA believes, as discussed earlier in section V of this notice, that the proposed finding of failure to attain and reclassification of the Liberty Borough nonattainment area are factual determinations based upon air quality considerations and must occur by operation of law and, hence, do not impose any federal intergovernmental mandate, as defined in section 101 of the Unfunded Mandates Act.

#### List of Subjects in 40 CFR Part 81

Environmental protection, Air pollution control, Intergovernmental relations, Particulate matter.

Authority: 42 U.S.C. 7401-7671q.

Dated: September 11, 1995.

W. Michael McCabe,

*Regional Administrator, Region III.*

[FR Doc. 95-23205 Filed 9-18-95; 8:45 am]

BILLING CODE 6560-50-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Care Financing Administration

#### 42 CFR Parts 441 and 447

[MB-046-P]

RIN 0938-AF42

#### Medicaid Program; Payment for Covered Outpatient Drugs Under Drug Rebate Agreements With Manufacturers

**AGENCY:** Health Care Financing Administration (HCFA), HHS.

**ACTION:** Proposed rule.

**SUMMARY:** This proposed rule would specify requirements for State Medicaid agencies and conditions under which Federal payments would be made under Medicaid for covered outpatient

prescription drugs. The rule would also specify the conditions for approval and renewal of rebate agreements with drug manufacturers participating in the Medicaid program.

The proposed rule would interpret sections 1902(a)(54), 1903(i)(10), and 1927 of the Social Security Act, as added by section 4401 of the Omnibus Budget Reconciliation Act of 1990, and amended by section 13602 of the Omnibus Budget Reconciliation Act of 1993, and section 601(b) of the Veterans Health Care Act of 1992. We consider this rule necessary to adequately implement the provisions of section 1927 of the Act.

**DATES:** Written comments will be considered if we receive them at the appropriate address, as provided in the "Addresses" section below, no later than 5:00 p.m. on November 20, 1995.

**ADDRESSES:** Mail written comments (an original and 3 copies) to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: MB-046-P, P.O. Box 7518, Baltimore, MD 21207-0518.

If you prefer, you may deliver your written comments (an original and 3 copies) to one of the following addresses: Room 309-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, D.C., or C5-09-26, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Due to staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code MB-046-P. Written comments received timely will be available for public inspection as they are received, beginning approximately 3 weeks after publication of this document, in room 309-G of the Department's offices at 200 Independence Ave., SW., Washington, D.C., on Monday through Friday of each week from 8:30 a.m. to 5:00 p.m. (telephone: (202) 690-7890).

If you wish to submit comments on the information collection requirements contained in this rule, you may submit written comments to: Office of Information and Regulatory Affairs, Attention: Laura Oliven, Office of Management and Budget, Room 3002, New Executive Office Building, Washington, D.C. 20503.

**FOR FURTHER INFORMATION CONTACT:** Estelle Chisholm, (410) 786-3286.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

##### A. Overview of the Drug Rebate Provisions

Under section 1927 of the Social Security Act (the Act), manufacturers that have entered into a national rebate agreement must provide each State Medicaid program with rebate period payments (or other periodic rebate payments, as determined by the Secretary). The rebate must be calculated in accordance with sections 1927(b) and (c) of the Act, using manufacturing pricing data and State drug utilization information as outlined in the statute.

The requirements concerning rebate agreements apply to drugs dispensed and paid for under Medicaid on or after January 1, 1991. For manufacturers who entered into rebate agreements before March 1, 1991, section 1927(a)(1) of the Act provided for Federal financial participation (FFP) retroactively calculated as if the agreement had been entered into on January 1, 1991. For agreements that are entered into on or after March 1, 1991, Medicaid coverage and FFP begin, as specified in section 1927(a)(1), the first day of the rebate period that begins more than 60 days after the date the agreement is entered into. We are interpreting the term "entered into" to mean the date the agreement is postmarked by the U.S. Postal Service or other common mail carrier. We will not consider the date stamped by a postage meter to be a postmark.

Although the statute provides specific deadlines for manufacturers to sign rebate agreements, section 1927(a)(3) of the Act provides, in part, for payment of drugs not covered under rebate agreements if the Secretary determines that in the first calendar quarter of 1991 there were extenuating circumstances. Therefore, in light of the deadlines imposed by the statute for signing the agreement, and in accordance with the extenuating circumstances clause in section 1927(a)(3) of the Act, HCFA extended through April 30, 1991, the deadline for manufacturers to enter into Medicaid rebate agreements that are retroactive to January 1, 1991. Therefore, rebate agreements entered into on or after May 1, 1991, are effective on the first day of the calendar quarter that begins more than 60 days after the date the agreement is entered into.

The statute does not specify whether the drug provisions are applicable in areas other than the 50 States and the District of Columbia. However, in the

legislative history, the Congress specifically noted that the drug rebate provisions "[r]equire drug manufacturers to comply with the rebate requirements in all States and the District of Columbia." (H. R. Conf. Rep. 964, 101st Cong., 2d Sess. 822 (1990).) Therefore, in accordance with our understanding of Congressional intent, we are applying the drug rebate requirements only to the 50 States and the District of Columbia.

Section 1115 of the Act contains provisions for State demonstration projects that are likely to assist in promoting the objectives of certain Federal programs, including the Medicaid program. Specifically, under the authority of section 1115(a)(1), the Secretary may waive compliance with the requirements of section 1902 of the Act for any State that is operating an experimental, pilot or demonstration project. Under section 1115(a)(2), the Secretary may also make payments notwithstanding restrictions under section 1903. In accordance with these provisions, a State operating under a section 1115(a) demonstration project waiver may have the requirements of section 1902(a)(54) of the Act, concerning compliance with applicable requirements of section 1927, waived. In addition to the extent that section 1927 requirements act as conditions under section 1903 for Federal matching funds to such a State, these conditions may be excused.

We note that section 1115(a) does not provide authority to waive or excuse requirements applicable to States other than the waiver State. Thus, there is no authority to waive inclusion of manufacturer sales within a waiver State from the calculation of best price or average manufacturer price applicable to other States.

Section 1927(j) of the Act specifies that the provisions of the drug rebate program do not apply to covered outpatient drugs dispensed by (1) health maintenance organizations (HMOs), including those organizations that contract to provide services to Medicaid recipients under section 1903(m) of the Act; and (2) hospitals that dispense covered outpatient drugs using drug formulary systems and bill the Medicaid program no more than the hospitals' purchasing costs for these drugs as determined under the State plan. Even though HMOs and certain hospitals are exempt from the requirements of the rebate program, section 1927(j) specifically states that its provisions should not be construed as providing that the amounts paid by these organizations should be excluded from the best price calculations. (Section

V.B.2.a. of this preamble contains a discussion on best price.)

On February 15, 1991, we made available to drug manufacturers a national rebate agreement developed in response to section 1927 of the Act. Prior to that date, we held extensive discussions with representatives from States and drug manufacturers. These parties reviewed and commented on the proposed language of the national rebate agreement. We also provided information to the public regarding the national drug rebate agreement through a notice with comment period in the Federal Register on February 21, 1991 (56 FR 7049). The February 1991 notice reprinted the text of the national drug rebate agreement. We received a number of timely public comments in response to this notice.

A detailed discussion of the public comments and the Department's responses appear under section X. of this preamble. We have given these public comments full consideration and have incorporated certain provisions in this proposed rule based on that consideration. We are not amending the national rebate agreement at this time. We will amend the national rebate agreement in the future, as necessary, to conform the agreement with the regulations and to take into consideration public comments received on the February 21, 1991, notice that are not addressed in this rule and public comments that we receive on this proposed rule.

This proposed rule would interpret in regulations the amendments made by section 4401 of the Omnibus Budget Reconciliation Act of 1990 (OBRA '90), Public Law 101-508, enacted on November 5, 1990; section 601(b)(1) of the Veterans Health Care Act of 1992 (VHCA), Public Law 102-585, enacted on November 4, 1992; and section 13602 of the Omnibus Budget Reconciliation Act of 1993 (OBRA '93), Public Law 103-66, enacted on August 10, 1993, as discussed below.

#### *B. Changes Made by the Omnibus Budget Reconciliation Act of 1990*

Under the Medicaid program, States may provide coverage of prescription drugs as an optional service under section 1905(a)(12) of the Act. Section 1903(a) of the Act provides for FFP in State expenditures for these drugs.

Section 4401 of OBRA '90 added a Medicaid State plan requirement under section 1902(a)(54) of the Act to provide that: (1) if a State elects to cover outpatient prescription drugs, the State plan must provide that any formulary or similar restriction, except as provided in section 1927(d) of the Act, shall permit

coverage of covered outpatient drugs of any manufacturer that enters into and complies with a rebate agreement under section 1927 of the Act, if the drugs are prescribed for a medically accepted indication; and (2) the State must comply with certain reporting and other coverage requirements specified in section 1927 of the Act.

Section 4401 of OBRA '90 also redesignated the existing section 1927 of the Act as section 1928 and added a new section 1927. New section 1927 provides that for payment to be made under section 1903 of the Act for covered outpatient drugs, the manufacturer must enter into and have in effect a rebate agreement with the Secretary of the Department of Health and Human Services (HHS) on behalf of the States (except that the Secretary may authorize a State to enter directly into agreements with manufacturers). (Section I.D. of this preamble contains a description of changes to sections 1902(a)(54) and 1927 made by section 13602 of the OBRA '93.)

Section 1927 of the Act specifies the requirements for the rebate agreements with manufacturers of covered outpatient drugs, the terms and length of the agreement, the requirements for States to provide State Medicaid drug utilization information to HCFA and the manufacturers, the requirements for manufacturers to provide pricing information to HCFA, the formulas to be used to determine the amount of the drug rebate, and the limitations on coverage of drugs. Section 1927 of the Act also contains provisions on termination procedures for agreements, and the imposition of civil money penalties on manufacturers that fail to comply with the requirements concerning pricing data submissions.

Section 4401 of OBRA '90 also amended section 1903(i) of the Act by adding a new paragraph (10) to provide for the denial of FFP in expenditures for covered outpatient drugs of a manufacturer dispensed in any State if, except as specified in section 1927(a) of the Act (whereby the Secretary may authorize a State to enter directly into agreements with a manufacturer), the manufacturer does not comply with the rebate requirements specified in section 1927; and, effective January 1, 1993, if the State does not provide for drug use review in accordance with section 1927(g) of the Act. (Section I.D. of this preamble contains a description of changes to section 1903(i)(10) made by section 13602 of OBRA '93.)

### *C. Changes Made by the Veterans Health Care Act of 1992*

The VHCA amended section 1927 of the Social Security Act in several areas. This proposed regulation reflects the self-implementing amendments required under VHCA.

One major change required by VHCA affects the conditions that manufacturers must meet so that payment can be made under Medicaid for a manufacturer's covered outpatient drugs. Section 601(b)(1) of VHCA amended section 1927(a)(1) of the Act to provide that a manufacturer must meet the requirements of section 1927(a)(5) (with respect to drugs purchased by a covered entity on or after December 1, 1992) and section 1927(a)(6) of the Act (with respect to drugs purchased by the Department of Veterans Affairs (DVA) and certain other Federal agencies).

A manufacturer meets the requirements of section 1927(a)(5)(A) of the Act if it has entered into an agreement with the Secretary that meets the requirements of section 340B of the Public Health Service (PHS) Act with respect to covered outpatient drugs purchased by a covered entity on or after December 1, 1992. The term "covered entity" means an entity described in section 340B(a) of the PHS Act. In general, VHCA amended section 1927 of the Act to require that drug manufacturers enter into pharmaceutical pricing agreements with the PHS and offer discounts on covered outpatient drugs to PHS covered entities that are at least as great as the rebates (both basic and additional rebates) received by State Medicaid agencies.

A manufacturer meets the requirements of section 1927(a)(6) of the Act if it complies with the provisions of section 8126 of title 38 of the United States Code, including the requirement of entering into a master agreement with the Secretary of the DVA under such section. In general, effective January 1, 1993, a manufacturer must enter into a pharmaceutical pricing agreement (master agreement) with the DVA for all single source drugs, innovator multiple source drugs, biologicals, and insulin. Generally, beginning January 1, 1993, the prices that manufacturers charge Federal agencies listed in the master agreement may not exceed the annual Federal ceiling prices specified for such drugs.

In accordance with these amendments to section 1927(a) of the Act, a manufacturer must enter into a pharmaceutical pricing agreement with the PHS and, if necessary, the DVA in order for a manufacturer's drugs to be paid for under Medicaid. Manufacturers

that do not enter into and comply with these agreements are subject to termination of the Medicaid national rebate agreement.

Section 1927(b)(4)(B)(ii) of the Act specifies that a manufacturer may terminate its rebate agreement for any reason. Section 601(b)(4) of VHCA amended section 1927(b)(4)(B) of the Act to provide that any such termination not be effective until the rebate period beginning at least 60 days after the date the manufacturer provided notice to the Secretary. Section 601(b)(4) of VHCA also added section 1927(b)(4)(B)(iv) of the Act, which provided that, in the case of a termination of a manufacturer, the Secretary will provide notice of the termination to the State not less than 30 days before the effective date of the termination.

### *D. Changes made by the Omnibus Budget Reconciliation Act of 1993*

Section 13602 of OBRA '93 modified the Medicaid drug rebate program by amending sections 1902(a)(54), 1903(i)(10), and 1927 of the Act.

This section of the preamble contains a discussion of the amendments to the sections of the Act and how they differ from the original language under OBRA '90. Where applicable, effective dates are noted in the discussion.

Sections 13602(d)(1) and (2) of OBRA '93 specify two different effective dates of the OBRA '93 amendments. Section 13602(d)(1) provides that, except for changes made to sections 1902(a)(54) and 1927(d) of the Act, the OBRA '93 amendments are effective as if included in the enactment of OBRA '90. Under section 13602(d)(2) of OBRA '93, amendments to sections 1902(a)(54) and 1927(d) of the Act are effective with rebate periods (calendar quarters) beginning on or after October 1, 1993, without regard to whether or not regulations to carry out these amendments have been published by that date.

#### **1. Payment for Covered Outpatient Drugs**

Section 13602(b) of OBRA '93 amended section 1903(i)(10) of the Act to provide that FFP for covered outpatient drugs will be denied (1) unless there is a rebate agreement in effect under section 1927 for covered outpatient drugs or unless the drug is rated 1-A by the Food and Drug Administration, and (2) with respect to any amount expended for innovator multiple source drugs dispensed on or after July 1, 1991, if, under applicable State law, a less expensive multiple source drug could have been dispensed,

but only to the extent that such amount exceeds the upper payment limit for such multiple source drug.

OBRA '93 amended section 1903(i)(10) of the Act to remove from this section the requirement for States to provide for drug use review as a condition to receive FFP. (A drug use review is still required under section 1927(g).) Former section 1927(e) of the Act, with respect to multiple source drugs, has also been added to section 1903(i)(10) and modified. This section now requires only that any amount above the upper payment limit be disallowed for an innovator multiple source drug if, under applicable State law, a less expensive multiple source drug could have been dispensed. As is the case with our current policy, this provision only applies to drugs subject to the Federal upper limits payment.

#### **2. Formulary Provisions and Permissible Restrictions**

Section 13602(c) of OBRA '93 amended section 1902(a)(54) of the Act to delete the reference that prohibits a State from maintaining a restrictive formulary. Section 1927(d)(1)(B)(iv) provides that a State may exclude a covered outpatient drug if the State has excluded coverage from its formulary in accordance with section 1927(d)(4). Section 13602(a)(1) of OBRA '93 added section 1927(d)(4) which provides that States may establish a formulary if the formulary meets the requirements specified in that section, as discussed below. States may continue to exclude or restrict drugs or classes of drugs specified in section 1927(d)(2). Previously, any State formulary or similar restriction must have permitted coverage, for all medically accepted indications, of a participating manufacturer's drugs except for those drugs or classes of drugs specified in the list of permissible restrictions in section 1927(d)(2).

*a. Formulary Requirements.* Section 13602(a)(1) of OBRA '93 added section 1927(d)(4) which provides that States may establish a formulary if it meets certain requirements, effective October 1, 1993. The formulary must:

(i) Be developed by an appropriate Governor-appointed committee consisting of physicians, pharmacists, and other appropriate individuals, or, at State option, the State drug use review board;

(ii) Except as specified in item (iii), include covered outpatient drugs, other than those drugs excluded from coverage or restricted under section 1927(d)(2), of manufacturers which have entered into and comply with the Medicaid drug rebate agreement;

(iii) Exclude only those drugs (with respect to the treatment of a specific disease or condition for an identified population) where the drug's labeling or its medically acceptable indication (based on appropriate compendia) does not have a significant, clinically meaningful therapeutic advantage, in terms of safety, effectiveness, or clinical outcome, over other drugs included in the formulary;

(iv) Have available to the public, a written explanation of the reasons for excluding drugs under item (iii); and

(v) Permit coverage of drugs that are excluded under item (iii) from the State's drug formulary (other than those drugs excluded from coverage in accordance with section 1927(d)(2)) and subject them to prior authorization consistent with the requirements in section 1927(d)(5).

This proposed rule does not address any further requirements that a formulary must meet. If we determine later that additional requirements should be imposed on States with regard to formularies, we will address them in a separate notice of proposed rulemaking.

*b. List of Drugs Subject to Restriction.* Section 1927(d)(1)(B) of the Act permits States to exclude or restrict drugs contained in the list of permissible restrictions in section 1927(d)(2) of the Act. Prior to OBRA '93, section 1927(d)(2) contained a paragraph (I) which meant that States could exclude or restrict drugs described in section 107(c)(3) of the Drug Amendments of 1962 ("DESI" drugs) and those identical, similar, or related drugs (IRS drugs). OBRA '93 amended section 1927(d)(2) to eliminate paragraph (I). However, the removal of coverage restrictions from section 1927(d)(1)(B) does not mean that coverage is necessarily required in light of existing funding restrictions under section 1903(i)(5) and restrictions in the definition of a covered outpatient drug.

Thus, effective with rebate periods beginning on or after October 1, 1993, States cannot exclude or restrict these DESI/IRS drugs. This includes DESI/IRS drugs approved prior to 1962 that have not yet been approved under or subject to the DESI review process. If these drugs otherwise meet the criteria of a covered outpatient drug and are not subject to funding restrictions under section 1903(i)(5) of the Act, States must provide coverage of these drugs and manufacturers must pay rebates on these drugs if they are dispensed and paid for by the State.

### 3. Terms of the Rebate Agreement

*a. Periodic Rebates.* Section 13602(a)(2)(A) of OBRA '93 amended sections 1927(b)(1)(A) and (b)(2)(A) of the Act and made technical changes to the original language under OBRA '90 as follows:

- The period of time used to calculate rebates was previously referenced as "calendar quarter." OBRA '93 changed this term of reference to "rebate period." However, this change does not alter the quarterly rebate period as previously established.

- OBRA '93 clarified the language in section 1927(b)(1)(A). This clarification supports the policy in the national rebate agreement that manufacturers will be responsible for rebates calculated for drugs dispensed after December 31, 1990 for which payment was made under the State Medicaid plan during a rebate period. Since the beginning of the Medicaid rebate program, Medicaid utilization data and rebates have been based on the date the State paid for the drug and not the date it was dispensed.

*b. State Provision of Information.* Section 13602(a)(2)(A)(ii) of OBRA '93 amended section 1927(b)(2)(A) of the Act to specify that States must report information to each manufacturer on the total number of units of each dosage form and strength and package size of each covered outpatient drug dispensed and paid for by the State. This change clarifies the language in section 1927(b)(2)(A), and supports the standard reporting format established by the Secretary and approved by the Office of Management and Budget that States must report drug utilization data to manufacturers using an 11-digit National Drug Code (NDC) number for each drug. Previously, section 1927(b)(2)(A) of the Act did not specify that States must report information on the package size, which represents the last two digits of the 11-digit NDC code.

### 4. Amount of Rebate

*a. Revisions to Definition of Best Price.* Section 13602(a)(1) of OBRA '93 amended section 1927(c)(1)(C) of the Act to ratify our interpretation that the definition of "best price" includes those prices available to providers and health maintenance organizations (HMOs). This interpretation of the definition of best price has been in effect since OBRA '90. Manufacturers must include in their best price calculation, for a single source or innovator multiple source drug, the lowest price available from the manufacturers during the rebate period to any wholesaler, retailer, provider, health maintenance organization,

nonprofit entity, or governmental entity within the United States except for those entities specifically excluded by statute.

Section 13602(a)(1) of OBRA '93 also amended section 1927 of the Act to clarify the term "free good" to specify which free goods must be included in the best price calculation. Section 1927(c)(1)(C)(ii)(I) of the Act specifies that best price must include free goods that are contingent on any purchase requirement. Thus, only those free goods that are not contingent on any purchase requirements may be excluded from best price.

### 5. Additional Rebate for Single Source and Innovator Multiple Source Drugs

Section 13602(a)(1) of OBRA '93 amended section 1927(c)(2) of the Act regarding how additional rebates for single source and innovator multiple source drugs are calculated if the increase in the average manufacturer price (AMP) of the drug exceeds the increase in the Consumer Price Index-Urban (CPI-U). OBRA '93 deleted the requirement that effective January 1, 1994, additional rebates would be calculated using a weighted average manufacturer price (WAMP). Amended section 1927(c)(2) provides that additional rebates for single source and innovator multiple source drugs will continue to be calculated on a drug-by-drug basis, that is, the method in effect since January 1, 1991.

The additional rebate calculation utilizes the drug's "base date AMP" (the AMP of the drug when it was first marketed) and the "base CPI-U" (the CPI-U in effect when the drug was first marketed). Section 1927(c)(2) of the Act further clarifies "base date AMP" and "base CPI-U" for the calculation of the additional rebates as follows:

*a. For Drugs Approved on or Before October 1, 1990.* Base Date AMP—For drugs approved by the FDA on or before October 1, 1990, the base date AMP means the AMP for the calendar quarter beginning July 1, 1990. This base date AMP remains the same as the definition in the national rebate agreement. Consequently, the base date AMP remains the AMP reported for the July - September 1990 calendar quarter. OBRA '93 clarified our interpretations of section 1927(c)(2)(A)(ii) of the Act previously contained in language in the rebate agreement and in operating instructions provided to manufacturers, and, thus, there is no change in methodology. Therefore, the base date AMP is the AMP for the calendar quarter beginning July 1, 1990, without regard to whether or not the drug has been sold or transferred to an entity,

including a division or subsidiary of the manufacturer, after the first day of such calendar quarter.

Base CPI-U—The base CPI-U used for calculating the additional rebate amounts for drugs approved by the FDA before October 1, 1990 is also unchanged, that is, the base CPI-U in effect for September 1990.

*b. For Drugs Approved After October 1, 1990.* Base Date AMP—OBRA '93 changed the criteria for determining base date AMP for drugs approved by the FDA after October 1, 1990. However, as discussed in section VI.C. of this preamble, for rebate periods beginning on or after January 1, 1991 through September 30, 1993, the original policy in effect under OBRA '90 and explained in paragraph 5.a. of this section will continue to be used. That is, the base date AMP will continue to be the AMP for the first day of the first full month in which the drug was first marketed.

In accordance with the amended language of section 1927(c)(2)(B) of the Act, effective for rebate periods beginning on or after October 1, 1993 (as discussed in section VI.C. of this preamble), the AMP in effect for the first full rebate period after the day on which the drug was first marketed is the base date AMP and will be used to calculate the additional rebate.

Thus, for drugs approved by the FDA after October 1, 1990, but before October 1, 1993, there is the potential for the same drug to have different base date AMPs, that is, one AMP for the January 1, 1991 through September 30, 1993 period and one AMP for the period beginning October 1, 1993.

OBRA '93 amended section 1927(c)(2)(A)(ii) of the Act to clarify that the base date AMP in effect for both of these periods is to be determined without regard to whether or not the drugs have been sold or transferred to an entity, including a division or subsidiary of the manufacturer, after the first day of such rebate period. Thus, a manufacturer's base date AMP (whether for drugs approved by FDA prior to or after October 1, 1990) is drug-specific and should follow the drug regardless of which manufacturer has current legal title.

Base CIP-U—OBRA '93 also amended the criteria for determining the base CIP-U for drugs approved by the FDA after October 1, 1990. In accordance with the amended language of section 1927(c)(2)(A)(ii), effective for rebate periods beginning on or after October 1, 1993, the CIP-U for the month prior to the month of the first full rebate period on which the drug was first marketed is used to calculate the additional rebate as the base CIP-U.

In accordance with section 1927(c)(2)(A)(ii)(II) of the Act, the base CIP-U is the CPI in effect for the month prior to the month of the first full rebate period after the day on which the drug was first marketed. This change will be effective for rebate periods beginning on or after October 1, 1993.

For rebate periods beginning January 1, 1991 through September 30, 1993, the original policy in effect under OBRA '90 will be used. That is, the base CIP-U continues to be the CIP-U for the month before the month in which the drug was first marketed.

#### 6. Requirements of the Prior Authorization Program

Except with respect to new drugs, OBRA '93 did not modify existing requirements on a State's ability to establish and maintain a program to subject drugs to prior authorization. The statute clarified in section 1927(d)(4) of the Act that a prior authorization program established by a State under section 1927(d)(5) is not a formulary subject to the requirements of section 1927(d)(4) (A) through (E).

#### 7. Treatment of New Drugs

OBRA '93 eliminated all special coverage requirements for new drugs by deleting the former section 1927(d)(6) and deleting a reference to new drugs in sections 1902(a)(54), 1927(d)(1)(A) and 1927(d)(3) of the Act. Former section 1927(d)(6) provided that States could not exclude from coverage, subject to prior authorization, or otherwise restrict any new biological or drug approved by the FDA for 6 months after FDA approval.

Effective for rebate periods on or after October 1, 1993, States may exclude or restrict from coverage or prior authorize any new drugs approved by the FDA. New drugs approved by the FDA prior to October 1, 1993 will only receive the unrestricted coverage specified in former section 1927(d)(6) of the Act through September 30, 1993. Beginning October 1, 1993 the unrestricted coverage no longer applies to these new drugs.

#### 8. Treatment of Pharmacy Reimbursement

*a. Treatment of Pharmacy Reimbursement Limits.* Section 13602(a)(1) of OBRA '93 redesignated section 1927(f) of the Act as section 1927(e), "Treatment of Pharmacy Reimbursement Limits". This section continues to specify that for the moratorium period of January 1, 1991 through December 31, 1994, a State cannot reduce its reimbursement limits or dispensing fees for certain covered

outpatient drugs below the limits in effect as of January 1, 1991. For this provision to apply, States must have been in compliance with Federal regulations at 42 CFR 447.331 through 447.334.

OBRA '93 amended section 1927(e)(2) of the Act to clarify that if a State is not in compliance with the regulations at 42 CFR 447.331 through 447.334, the moratorium provisions do not apply to the State until it is in compliance with these regulations.

*b. Effect on State Maximum Allowable Cost Limitations.* Section 13602(a)(1) of OBRA '93 also added section 1927(e)(3) to clarify that the moratorium provisions do not affect State Maximum Allowable Cost (MAC) limitations in effect prior to or after the moratorium period. That is, as allowed under OBRA '90, States may continue to operate their MAC programs in effect prior to January 1, 1991, in accordance with the terms of that program, for example, adjusting limits and adding drugs within the requirements of the MAC.

#### 9. Average Manufacturer Price

Section 13602(a)(2)(B)(i)(II) of OBRA '93 amended section 1927(k)(1) of the Act to clarify that the AMP for a rebate period is the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade after deducting customary prompt pay discounts. The policy that AMP will be calculated after deducting customary prompt pay discounts is reflected in the national rebate agreement.

#### 10. Limiting Definition of Covered Outpatient Drug

Section 13602(a)(2)(B)(ii) of OBRA '93 amended section 1927(k)(3) to clarify the limiting definition of what is not included in the definition of a covered outpatient drug. In addition to the criteria originally defined in section 1927(k)(3), a covered outpatient drug does not include the following two items:

- Any drug or product for which a NDC number is not required by the FDA. This category includes whole blood and blood components separated by physical or mechanical means.
- Any drug, biological, or insulin provided as part of, or as incident to and in the same setting as, services in an intermediate care facility for the mentally retarded (ICF/MR) (and for which payment is made as part of the service and not as direct reimbursement for the drug.)

## 11. Medically Accepted Indication

Section 13602(a)(2)(B)(iii) of OBRA '93 amended section 1927(k)(6) to further define the term "medically accepted indication." OBRA '93 deleted the reference to the use of peer-reviewed medical literature and specified that the medical indication must be on the label or be supported by one or more citations included or approved for inclusion in any of the compendia described in section 1927(g)(1)(B)(i).

OBRA '93 amended section 1927(k)(6) to specify that the term "medically accepted indication" means any use for a covered outpatient drug which is approved under the Federal Food, Drug and Cosmetic Act or the use which is supported by one or more citations or approved for inclusion in any of the specified compendia. Those compendia have not changed and are the American Hospital Formulary Service-Drug Information, the American Medical Association Drug Evaluations, and the United States Pharmacopeia-Drug Information.

### *E. Organization of Remainder of Preamble*

The following sections of the preamble explain the actual provisions of the regulations being issued at this time without a description of the history of the statute. In the remainder of the preamble, unless otherwise indicated, references to the statute should be read as the provisions as amended by both the VHCA and OBRA '93. The preamble is structured into six main sections which discuss all related drug covered rebate issues and policies: rebate agreements, drugs covered under the rebate agreement, limitations on drug coverage, reporting requirements, computation of drug rebates, and payment limitations for covered drugs. The balance of the preamble deals with other required regulatory sections, such as responses to comments and an impact analysis. The accompanying regulation text follows section XV. of the preamble.

## II. Rebate Agreements

In general, section 1927(a)(1) of the Act provides that, in order for payment to be available under section 1903(a) of the Act for covered outpatient drugs of a manufacturer, the manufacturer must (1) have entered into and have in effect a national rebate agreement with the Secretary on behalf of the States; and (2) also enter into a pharmaceutical pricing agreement with PHS and, if necessary, with DVA (as discussed in Section I.B. of this preamble) for payment to be made under Medicaid for a

manufacturer's covered outpatient drugs. The requirements for the rebate agreements are specified in section 1927(b) of the Act.

Section 1927(a)(1) also provides that the Secretary may authorize States to enter directly into separate agreements with manufacturers. For purposes of this rule, we are referring to separate agreements as either "existing," that is, agreements that were entered into on or before the date of enactment of OBRA '90 (November 5, 1990); or "new," that is, agreements that were entered into after the date of enactment of OBRA '90.

The Secretary's authority to approve separate State agreements is consistent with the statute and HCFA's understanding of Congressional intent to decrease program costs and maximize Medicaid savings. Section 1927(a)(1) of the Act gives the Secretary broad authority to authorize separate State agreements. There are no provisions in section 1927 that circumscribe the Secretary's authority to establish criteria for approving separate State agreements.

Thus, in accordance with the authority under section 1927(a)(1) of the Act, we would not approve a new agreement unless the manufacturer has entered into the national rebate agreement and the new agreement provides rebates at least as large as those required by the national agreement. (42 CFR 447.510) We believe these requirements are necessary to effectuate section 1927 of the Act and to uphold Congressional intent.

We would require that a manufacturer enter into the national rebate agreement as a condition of entering into a new State agreement, in order to ensure that Medicaid recipients in all 50 States and the District of Columbia have access to that manufacturer's drugs. In passing various provisions of section 1927, the Congress made it clear that Medicaid recipients be assured access to all medically necessary covered outpatient drugs. (H.R. Rept. No. 881, 101st Cong., 2d Sess. 96-98 (1990)). Without requiring that manufacturers enter into the national agreement, recipients could be denied access if a manufacturer only entered into separate agreements with several large States with a lucrative market for that manufacturer's drugs. Thus, access could be denied in other States.

We would require that a new State agreement provide rebates at least as large as those required by the national agreement because there would be little or no benefit to the Secretary in terms of savings to approve a new State agreement that provides less savings. Approving a new agreement that provides less savings would be contrary

to the general understanding of Congressional intent to decrease program costs and maximize Medicaid savings.

The conditions that all existing agreements and new agreements between a State Medicaid agency and a manufacturer must meet in order to comply with the requirements in section 1927 of the Act are described below. The statute defines the entities considered manufacturers to which section 1927 applies. Section 1927(k)(5) of the Act defines the term "manufacturer" to mean any entity that is engaged in—

- 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
- The packaging, repackaging, labeling, relabeling, or distribution of prescription drug products.

Under the statutory definition, the term "manufacturer" does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law. For the reasons set forth below, we would clarify and interpret this statutory definition to require that the entity must possess legal title to the National Drug Code (NDC) number for a covered outpatient drug, insulin, or biological product. The NDC is a national, readily available numbering system maintained by the Food and Drug Administration (FDA) that identifies each drug by manufacturer, product, and package size. We believe this clarification is necessary to permit a practical means of identifying the manufacturer of the drug to determine which manufacturer is responsible for paying the rebate due under the statute to the State. This approach prevents duplicative manufacturer responsibilities for the drug.

In addition, we would further clarify and interpret the term to specify that if a corporation meets the statutory definition of manufacturer and possesses legal title to the NDC number, we would consider the term to include—

- Any corporation that owns at least 80 percent of the total combined voting power of all classes of stock or 80 percent of the total value of shares in all classes of stock in such entity (that is, a parent corporation);
- Any other corporation in which a parent corporation of the entity owns at least 80 percent of the total combined voting power of all classes of stock or 80 percent of the total value of shares

of all classes of stock in the other corporation (that is, a brother-sister corporation); and

- Any other corporation in which the entity owns at least 80 percent of the total combined voting power of all classes of stock or 80 percent of the total value of shares of all classes of stock in the other corporation (that is, a subsidiary corporation).

We would establish this definition of "manufacturer" because we believe that the statutory definition requires clarification to implement the provisions of OBRA '90 consistent with Congressional intent. As noted previously, section 1927(k)(5) of the Act defines a manufacturer, in part, as "any entity" engaged in the production, packaging or distribution of prescription drug products. We believe that when defining a manufacturer, the term "entity" should be interpreted to include any parent, brother-sister, or subsidiary corporation. Such an interpretation, in our opinion, comports with the Congress' desire to maximize recipient access to medically necessary drugs, while at the same time providing a more favorable drug purchasing arrangement for State Medicaid programs. (H. R. Conf. Rept. No. 964, 101st Cong., 2d Sess. 822, 832 (1990); H. R. Rept. No. 881, 101st Cong., 2d Sess. 996 (1990).)

The Congress, in passing the drug rebate provisions, made it clear that States that elect to cover prescription drugs must, except for certain restriction/exclusions allowed under the statute, for the most part, cover the drugs of a manufacturer that enters into and complies with a drug rebate agreement. In return for such coverage, a manufacturer would be responsible for providing a rebate to the State that would give the Medicaid program the benefit of those discounts that other large public and private purchasers receive. (*Id.*) We believe that it would be directly contrary to such intent for us to define manufacturer in a fashion that would permit a manufacturer (by forming a subsidiary corporation) to exclude some of its drugs from the drug rebate program.

#### A. Existing Agreements

Section 1927(a)(4) of the Act sets forth the conditions that an existing agreement must meet to be in compliance with the provisions of section 1927. Under section 1927(a)(4), existing agreements that were in effect between a manufacturer and a State Medicaid agency on November 5, 1990, will be considered to be in compliance with section 1927 of the Act until the end of the initial period specified in the

agreement if (1) the State agrees to report any rebates paid under the agreement to HCFA; and (2) the agreement provides for a minimum aggregate 10-percent rebate of the State's total expenditures under the State plan for all of that manufacturer's drugs paid for by Medicaid in the rebate period. During the initial agreement period, manufacturers may calculate rebates in accordance with that existing agreement as long as these two requirements are met. (Because no manufacturer had existing agreements in all 50 States and the District of Columbia, and in light of the requirements of sections 1927(a) and 1903(i)(10) of the Act, we required all drug manufacturers with approvable existing agreements with State Medicaid agencies as of November 5, 1990, to enter into and comply with the national agreement to cover those States where manufacturers did not have existing agreements.)

As stated above, section 1927(a)(4) of the Act requires that existing individual State agreements provide for a minimum aggregate rebate of 10 percent of the State's total expenditures under the State plan for coverage of the manufacturer's drugs. However, given other provisions of the statute and the legislative history of OBRA '90, we do not believe that the Congress intended that the minimum aggregate rebate be calculated using State expenditures. Other provisions in section 1927 of the Act calculate rebates using manufacturer prices, and there is no evidence in the legislative history that the Congress intended existing rebates to be calculated using a different formula. In fact, the Conference Report specifies that manufacturer sales, not State expenditures, be used to calculate the minimum aggregate rebate. (H. R. Conf. Rept. No. 964, 101st Cong., 2d Sess. 822 (AMP), 832 (manufacturer sales) (1990).)

The House Conference Report, in discussing the House bill, specifically states that existing rebate agreements must be considered in compliance with the statute if the State can establish that "the agreement can reasonably be expected to provide rebates at least as large as the rebates under this bill [which uses manufacturer prices]." (H. R. Conf. Rept. 964, 101st Cong., 2d Sess. 822 (1990); *Id.* at 822 (Senate Amendment).) Similarly, the Conference agreement establishes a similar standard and specifies an aggregate rebate test using manufacturer pricing data. The Conference agreement provides that existing agreements should be considered in compliance with the statute if "the amount of the rebate under the [existing] contract totals at

least 10 percent of the manufacturer's sales to Medicaid in the State." (*Id.* at 832.) Therefore, to read the statute in its proper context, and to give effect to our understanding of Congressional intent, we have decided to use manufacturer prices to calculate the minimum aggregate rebate.

Furthermore, as noted previously, using State total expenditures conflicts with other rebate provisions that use manufacturer prices (referred to as average manufacturer prices (AMPs) and best prices) to calculate rebates. (Section V.B.2.a. of this preamble contains the definition of AMP.) A State's total expenditures include, among other items, wholesaler and retailer markup and dispensing fees. These additional charges are not included in the rebate calculations that base rebates on the AMP. Thus, using other than AMP as a percentage of a rebate test would result in an inequitable treatment of manufacturers participating in the rebate program. In light of the legislative history, we believe that the Congress intended that a similar formula based on manufacturer pricing data be used to calculate minimum aggregate rebates under section 1927(a)(4) of the Act.

Therefore, we have concluded that the 10-percent rebate test applies to the manufacturer's AMP (which represents the manufacturer's sale of the drug) and not other State components of drug expenditures. Accordingly, we would specify in our regulations at § 447.510(b)(1)(i) that, to calculate a State's total quarterly expenditures for a manufacturer's drugs for purposes of determining whether the minimum aggregate 10-percent rebate requirement for existing rebate agreements is met, the State must receive a minimum rebate of 10 percent of the AMP for the manufacturer's drugs. Actual rebates on specific drugs may be less than 10 percent as long as the aggregate rebate from that manufacturer for all of its covered outpatient drugs in that separate agreement meets the minimum 10-percent rebate.

An existing agreement must have provided for the minimum aggregate rebate as of November 5, 1990. If this minimum rebate condition was met, we believe it would be consistent with section 1927(a)(4) of the Act to permit States to modify an existing agreement to provide for a greater rebate. Therefore, under these regulations, States would be permitted to modify existing agreements if the State and the manufacturer are in agreement with all modifications and the terms of the agreement allow such modifications. Existing agreements would also be amended to add other drugs of the

manufacturer if the agreement continues to meet a minimum aggregate rebate of 10 percent of AMP. However, we do not believe it would be consistent with the statute or our understanding of Congressional intent to permit modifications to increase the length of the initial term since section 1927(a)(4) of the Act specifically references the initial agreement period.

In cases where an existing agreement did not have a stated percentage of rebate, we have required the State to submit to the HCFA regional office (RO) a written assurance from the manufacturer that the minimum 10-percent rebate, as calculated above, was met as of November 5, 1990. We would require in § 447.510(b)(2) that the rebates under an existing agreement also continue to meet the 10-percent threshold in order for payment to be made available under section 1903(a) of the Act for the manufacturer's covered outpatient drugs throughout the initial period specified in the agreement. We would monitor the savings figures, and, if this threshold is not met, we would consider the existing agreement as no longer in compliance with section 1927(a) of the Act. In this case, HCFA would notify the State that the manufacturer's drugs are subject to the rebate terms of the national drug rebate agreement.

The requirements for renewal of existing rebate agreements between States and manufacturers at the end of the initial period specified in the agreement are generally specified in section 1927(a)(4) of the Act. Under this section, a State/manufacturer agreement is renewable after the initial period specified in the agreement if the State establishes to HCFA's satisfaction that the agreement provides for rebates that are at least as large as the rebates required under the national rebate agreement, and the State agrees to report to HCFA any rebates received under the agreement. We would not approve the renewal of an existing agreement unless the manufacturer has entered into the national rebate agreement. As is the case for existing agreements in the initial period, the State is responsible for submitting to the HCFA RO, along with the agreement, a written assurance from the manufacturer that the agreement submitted for renewal meets the minimum rebate requirements described above.

If the actual rebates fail to be at least as large as those rebates required under the national agreement for the renewal period, the renewed agreement would not be considered to be in compliance with section 1927(a) of the Act. In this case, HCFA would notify the State that

the manufacturer's drugs are subject to the rebate terms of the national agreement.

#### *B. New Agreements*

New rebate agreements are those individual rebate agreements between a manufacturer and a State that are entered into on or after November 6, 1990, and specifically authorized by HCFA. Section 1927(a)(1) of the Act provides that the manufacturer may enter into a rebate agreement with the Secretary on behalf of a State, or the Secretary may authorize a State to enter directly into a rebate agreement with a manufacturer, thus providing an alternative to the national rebate agreement.

In accordance with section 1927 of the Act, HCFA would authorize State Medicaid agencies to enter directly into new agreements with drug manufacturers. However, we would apply the requirements in section 1927(a)(4) to these new State manufacturer agreements, that is, the agreements must provide rebates at least as large as those required under the national rebate agreement, and the State must agree to report any rebates under the agreement to HCFA. Therefore, we would require in § 447.510(c)(4) that the State include with its agreement authorization request to HCFA a written assurance from the manufacturer that the agreement provides rebates that equal or exceed the rebate amounts specified in the national agreement.

We believe this additional verification of the rebate amounts specified in the new agreement would be necessary since these contracts can differ in form and content in each State. A written assurance from the manufacturer would be evidence that both parties certify that the rebate amounts under the new agreement meet or exceed the rebate amounts in the national agreement.

We would not authorize individual State agreements that provide for rebates less than those required under the national agreement. In our opinion, such agreements are contrary to our understanding of Congressional intent to maximize program savings while expanding access to covered outpatient drugs. Thus, since there is little or no additional benefit for either the States or HCFA to authorize these types of individual agreements, which would increase Medicaid drug costs without offsetting national rebate savings, we would not approve such agreements.

#### *C. Length of Agreements*

We would specify in § 447.512(a) that the initial period of an existing State/manufacturer agreement and a new

State/manufacturer agreement is the period specified in the agreement, and that the national rebate agreement is effective for an initial period of at least 1 year. While we would not require a 1-year timeframe for the initial period in a new State/manufacturer agreement, we recommend its use to avoid administrative delays from HCFA reviewing new agreements with shorter timeframes. More frequent reviews add to unnecessary administrative costs and burdens for all parties involved.

Under this section we also would specify that the national agreement will be automatically renewed for successive periods of at least 1 year unless (1) HCFA terminates the agreement under the conditions specified in section 1927(b)(4)(B)(i) of the Act; or (2) the manufacturer terminates the agreement for any reason as permitted under section 1927(b)(4)(B)(ii) of the Act.

#### *D. Termination of Agreements*

##### *1. Termination by HCFA*

In accordance with section 1927(b)(4)(B)(i) of the Act, a rebate agreement may be terminated by the Secretary if the manufacturer violates the requirements of the agreement or for "other good cause shown." HCFA has been delegated the Secretary's authority under section 1927(b)(4)(B) to provide for termination of a rebate agreement. We would interpret "other good cause shown" to be any violations of the provisions of the national rebate agreement, section 1927 or the related regulations, or the persistent failure to provide timely information on pricing and other required information or to pay timely rebates. HCFA would send a written notice of the decision to terminate the agreement to the manufacturer. HCFA would also notify State agencies of the termination. The termination would not be effective earlier than 60 days after the date a notice of the termination is sent to the manufacturer (§ 447.514(b)). If a manufacturer is dissatisfied with a termination decision made by HCFA, the manufacturer may request a hearing (as specified in section II.D.5. of this preamble). However, a request for a hearing would not delay the effective date of the termination.

##### *2. Termination by the Manufacturer*

In accordance with section 1927(b)(4)(B)(ii) of the Act, the manufacturer may terminate its rebate agreement for any reason. Section 601(b)(4) of VHCA amended section 1927(b)(4)(B) of the Act to provide that any such termination not be effective until the rebate period beginning at least

60 days after the date the manufacturer provides notice to the Secretary. A termination notice from a manufacturer is considered a request to end its participation in the national rebate agreement with the understanding that there is a delay before reinstatement (as discussed in section II.D.4. of this preamble).

We would provide in § 447.514(c)(1) that a manufacturer that wishes to terminate an agreement must provide to HCFA a written notice of intent to terminate at least 60 days before the beginning of the rebate period in which the termination will occur. We would specify that the effective date of a requested termination will be the first day of the first rebate period beginning at least 60 days after the manufacturer gives written notice requesting termination, or a later date if specified by the manufacturer. We would specify in § 447.514(c)(3) that the date of notice will be considered to be the postmark date of the U.S. Postal Service or common mail carrier.

If the manufacturer fails to terminate the agreement at least 60 days before the renewal date, the automatic renewal provisions of section 1927(b)(4)(A) would be effective and the agreement would not terminate until the rebate period following the renewal. For example, if a manufacturer intended to terminate the rebate agreement effective January 1, 1994, HCFA must have received the written notice on or before November 1, 1993. Otherwise, if HCFA received the notice on November 15, 1993, the termination date would be April 1, 1994 (the first day of the first rebate period beginning at least 60 days after receipt of the notice).

Any termination would not affect rebates due under the agreement before the effective date of the termination.

### 3. Nonrenewal of Rebate Agreement

To effectuate sections 1927(b)(4)(A) and (b)(4)(B)(ii) of the Act, we would require in § 447.514(c)(2)(i) that a manufacturer give written notice of its decision not to renew the rebate agreement (nonrenewal notice) at least 60 days before the end of the current agreement period. (We would consider the date a manufacturer gives written notice of its decision not to renew to be the date of the postmark of the U.S. Postal Service or common mail carrier (§ 447.514(c)(3)).) If HCFA receives a manufacturer's nonrenewal notice at least 60 days before the end of the agreement period, the nonrenewal would be effective on the ending date of the agreement period. This 60-day period would give HCFA the time needed to notify States that the

manufacturer's drugs are no longer eligible for FFP under Medicaid.

If the manufacturer fails to meet this 60-day advance notice requirement, the agreement would be automatically renewed for another 1-year term. In this case, HCFA would deem the nonrenewal notice a termination notice because the manufacturer missed the nonrenewal deadline. Therefore, in accordance with the regulations at § 447.514(c)(2)(ii)(B), HCFA would terminate the rebate agreement effective the second calendar quarter of the renewed agreement period.

### 4. Reinstatements

Section 1927(b)(4)(C) of the Act provides that, if a rebate agreement is terminated, another agreement with the manufacturer (or a successor manufacturer) may not be entered into until a period of 1 calendar quarter has elapsed from the date of the termination, unless the Secretary finds good cause for an earlier reinstatement of the agreement. We would incorporate this provision in § 447.514(d) of our regulations. For example, if HCFA received a written notice on October 1, 1993, to terminate an agreement, the rebate agreement would be terminated on January 1, 1994, and a manufacturer could not enter into another agreement until April 1, 1994, unless HCFA finds good cause to do otherwise. An example of good cause might be if a manufacturer's drug is medically necessary to a significant number of Medicaid recipients and there is no therapeutic substitute available.

### 5. Opportunity for Appeal

Section 1927(b)(4)(B) of the Act provides that the Secretary must provide a manufacturer with a hearing concerning a termination of a rebate agreement if the manufacturer requests one. In accordance with this section of the Act, we would provide in § 447.514(b)(4) that, if a manufacturer is dissatisfied with a termination of a rebate agreement by HCFA, the manufacturer may appeal the termination under the administrative procedures specified in the contract provision in the rebate agreement. We believe the appeal procedures specified in the national rebate agreement afford manufacturers the due process rights to which they are entitled under section 1927 of the Act, since the process provides a written notification process, the right to appeal the termination and, if applicable, a hearing before a HCFA official or other party.

Section 1927(b)(4)(B)(i) of the Act also requires that the hearing not delay the effective date of the termination.

Accordingly, we would provide in § 447.514(b)(4) that, while manufacturers have the right to an administrative hearing, such a hearing would not delay the effective date of the termination.

### 6. Notice to States

Section 601(b)(4) of VHCA added section 1927(b)(4)(B)(iv) of the Act, which provides that in the case of a termination of a manufacturer, the Secretary will provide notice of the termination to the States not less than 30 days before the effective date of the termination. In accordance with this section of the Act, we would provide in § 447.514(f) that HCFA will notify States of any termination from the drug rebate program at least 30 days prior to the effective date of the termination.

## III. Drugs Covered Under the Rebate Agreement

### A. *Rebated and Non-Rebated Drugs*

Sections 1927(k)(2) and (k)(4) of the Act specify the covered outpatient drugs that are subject to rebate agreements. Covered outpatient drugs are defined as (1) those drugs that may be covered as prescribed drugs under Medicaid under section 1905(a)(12) of the Act, are dispensed only upon prescription (except over-the-counter drugs), and that meet certain requirements specified in sections 1927(k)(2)(A)(i) through (iii) of the Act; (2) a biological product other than a vaccine that may be dispensed only upon prescription, is licensed under section 351 of the Public Health Service Act, and is produced at an establishment licensed under section 351 to produce such products; (3) insulin certified under section 506 of the Federal Food, Drug, and Cosmetic Act; and (4) "over-the-counter" drugs that are prescribed by a physician or other person authorized to prescribe under State law, if the State provides for coverage of these drugs as prescribed drugs under its approved State plan. We would add this definition to § 447.516(a) of our regulations.

We would require in § 447.516(b) that a manufacturer submit as part of its rebate agreement a listing of all of its drugs that fall within the definition of covered outpatient drugs in sections 1927(k)(2) through (k)(4) of the Act. We also would require use of National Drug Code (NDC) numbers to identify the drugs.

We would interpret "covered outpatient drug," as defined in section 1927(k)(2) of the Act, to include all covered outpatient drugs for which that manufacturer holds legal title to the NDC number. The statutory definition

encompasses all FDA-approved prescription drugs and biologicals except for vaccines or drugs that fall within the limiting definition in section 1927(k)(3) of the Act (§§ 447.504 and 447.516(b)(2)). Manufacturers that have entered into the national rebate agreement have agreed to submit a listing of all covered outpatient drugs, not a partial listing. Therefore, in accordance with the statute and the provisions of the national rebate agreement, manufacturers that enter into a rebate agreement could not exclude any covered outpatient drug specified in section 1927(k) of the Act from its listing of covered outpatient drugs.

Even though States may choose to exclude or restrict certain drugs under section 1927(d) of the Act (as discussed in section IV.B of this preamble), the drugs may be covered in other States or covered by that State at a later date. Therefore, a manufacturer would be required to list by NDC number all of its covered outpatient drugs, regardless of whether its drugs are dispensed or covered by Medicaid programs in all States. In addition, HCFA would not allow a manufacturer to withhold its covered outpatient drugs from being subject to the rebate provisions, regardless of whether the drugs are sold by the manufacturer's subsidiaries or parent company, as discussed in section I.A. of this preamble.

In § 447.522(a), we would provide for an exclusion from the definition of covered outpatient drugs consistent with section 1927(k)(3) of the Act. Section 1927(k)(3) of the Act, as amended by section 13602(a)(2)(B)(ii) of OBRA '93, provides certain exclusions from the definition of covered outpatient drugs. This section specifies that covered outpatient drugs do not include "any drug, biological product, or insulin provided as part of, or as incident to and in the same setting as, any of the following (and for which payment may be made under [Medicaid] as part of payment for the following and not as direct reimbursement for the drug): Inpatient hospital services; hospice services; dental services (except that drugs for which the State plan authorizes direct reimbursement to the dispensing dentist are covered outpatient drugs); physicians' services; outpatient hospital services; nursing facility services and services provided by an intermediate care facility for the mentally retarded; other laboratory and x-ray services; and renal dialysis" (§ 447.522(a)).

The term "covered outpatient drug" also would not include any such drug, biological product, or insulin for which an NDC number is not required by the

FDA that is used for an indication that is not "medically accepted" (§ 447.522(b)). A medically accepted indication is defined under section 1927(k)(6) of the Act, as amended by section 13602(a)(2)(B)(iii) of OBRA '93, as any use for a covered outpatient drug that is approved under the Federal Food, Drug and Cosmetic Act, or the use of which is supported by one or more citations included or approved for inclusion in any of the following compendia: The American Hospital Formulary Service-Drug Information, the American Medical Association Drug Evaluations, and the United States Pharmacopeia-Drug Information. We would incorporate this definition in § 447.504 of our regulations.

There are additional drugs and biologicals that do not fall within the definition of covered outpatient drugs set forth in section 1927(k) of the Act. These drugs are not subject to rebates, although Medicaid coverage may be provided under section 1905(a)(12) of the Act at State option, and FFP is available. Generally, these additional drugs and biologicals that do not fall within the section 1927(k) definition are discussed below and would be specified in § 447.522(c) through (g) of the regulations. We do not consider this a definitive list due to the vast nature of drugs and biologicals regulated by the FDA and the unique situations that exist for particular products. Drugs that fall outside of the scope of section 1927 of the Act would not be considered covered outpatient drugs and, therefore, would not be subject to rebate.

- Any drug, biological product, or insulin for which an NDC number is not required by the FDA would not meet the definition of a covered outpatient drug in section 1927(k) and, therefore, would not be subject to a rebate as a condition of FFP. This would include whole blood (collected from a single human donor) and blood components (which are the result of physical or mechanical separation either as part of the collection process or subsequent to the collection of whole blood).

- Medical items and supplies, such as syringes (except insulin-filled syringes), urine and blood glucose testing strips and devices, lancets, and inhalers (except pre-filled inhalers) do not meet the definition of covered outpatient drugs in sections 1927(k)(2) through (k)(4) of the Act and, therefore, would not be subject to a rebate as a condition of FFP.

- Certain nutritional products that are regulated as drugs would be covered under the rebate program. Parenteral products that are administered intravenously are approved as drugs by

the FDA under section 505 of the Federal Food, Drug, and Cosmetic Act. These parenteral products that are approved as drugs, are administered intravenously, and meet the definition of a covered outpatient drug in accordance with section 1927(k) of the Act would be subject to a rebate as a condition of FFP. Parenteral products that are not administered intravenously are regulated as "foods" by the FDA and would not meet the definition of a covered outpatient drug.

- Enteral nutrition products that are not approved by FDA as a drug under sections 505, 506, or 507 of the Federal Food, Drug, and Cosmetic Act would not be considered covered outpatient drugs under section 1927(k)(2)(4) of the Act, and would not be subject to rebate.

HCFA has permitted States the option to cover enteral nutrition products that are not approved as a drug by the FDA, under Medicaid benefit categories other than prescription drugs. These categories include outpatient hospital services, home health services, clinic services, and rural health clinic services. The nutrient products may be covered in these settings as a medical supply. These supplies would not be considered covered outpatient drugs and, therefore, would not be subject to rebate.

- States have the option to cover under their Medicaid program investigational new drugs (IND) (for example, Treatment IND drugs, Parallel Track, and Group C cancer drugs). (State Medicaid programs often use the term "experimental" when referring to these types of drugs.) Since section 1927 of the Act made no changes to a State's previous ability to cover these drugs, FFP continues to be available for these drugs. However, because they do not meet the definition of covered outpatient drugs in sections 1927(k)(2) through (4) of the Act, they would not be covered under the drug rebate program or subject to a rebate.

#### *B. Definitions of Drug Categories*

As defined in section 1927(k)(7)(A)(iv) of the Act, "single source drug" means a covered outpatient drug that is produced or distributed under an original new drug application (NDA) approved by the FDA, including a drug product marketed by any cross-licensed producers or distributors operating under the NDA. (Section III.C.3. of this preamble contains the definition of original new drug application.) Section 1927(k)(7)(A)(i) of the Act defines "multiple source drug" as a covered outpatient drug for which there are two or more drug products that are—

- Rated as therapeutically equivalent by the FDA under its most recent publication of *Approved Drug Products with Therapeutic Equivalence Evaluations*;

- Are pharmaceutically equivalent and bioequivalent as determined by the FDA; and

- Are sold or marketed in the State during a calendar quarter.

Drugs are pharmaceutically equivalent if the products contain identical amounts of the same active drug ingredient in the same dosage form and meet compendial or other applicable standards of strength, quality, purity, and identity.

Drugs are bioequivalent if they do not present a known or potential bioequivalence problem, or if they do present such a problem, they are shown to meet an appropriate standard of bioequivalence. (This condition does not apply if FDA changes by regulation the requirement that in order for drug products to be rated as therapeutically equivalent, they must be pharmaceutically equivalent and bioequivalent.)

Sections 1927(k)(7)(A)(ii) and (iii) of the Act define "innovator multiple source drug" as a multiple source drug that was originally marketed under an original NDA approved by the FDA and "noninnovator multiple source drug" as a multiple source drug that is not an innovator multiple source drug. To clarify the statutory definition, we would further define multiple source drugs to distinguish the differences between an innovator multiple source drug and a noninnovator multiple source drug.

In accordance with our understanding of Congressional intent, we would define an "innovator multiple source drug" as a multiple source drug from 1938 to present that was originally marketed under an original NDA approved by the FDA. We would define a "noninnovator multiple source drug" as a multiple source drug that was marketed under an abbreviated NDA or any marketed, unapproved pre-1938 drug product for which the FDA has not made a final determination about its legal status. This would include (1) all products approved under an abbreviated NDA (authorized under the Drug Price Competition and Patent Term Restoration Act of 1984, Public Law 98-417), paper NDA under the FDA's former "Paper NDA" policy (54 FR 28873), or an application under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act; and (2) any marketed, unapproved pre-1938 drug product that has not been evaluated under the new

drug provisions of the Federal Food, Drug and Cosmetic Act. (§ 447.504)

### C. Treatment of New Drugs

#### 1. Elimination of New Drug Coverage Under OBRA '93

OBRA '93 eliminated all special requirements for new drugs by deleting the former section 1927(d)(6) of the Act. That section provided that a State may not exclude, subject to prior authorization, or otherwise restrict from coverage under the rebate program any new drug or biological approved by the FDA after the date of enactment of OBRA '90 (November 5, 1990) for a period of 6 months after the date of FDA approval. OBRA '93 also deleted the references to new drugs in section 1927(d)(1)(A) and (d)(3) of the Act.

Section 13602(d)(2) of OBRA '93 provided that amendments to section 1927(d) of the Act are effective with rebate periods beginning on or after October 1, 1993. That is, effective October 1, 1993, States may exclude or restrict from coverage or prior authorize any new drugs approved by the FDA. In accordance with section 13602(d)(2), new drugs approved by the FDA prior to October 1, 1993 may only receive the unrestricted coverage specified in former section 1927(d)(6) of the Act through the rebate period ending September 30, 1993. Beginning October 1, 1993 the unrestricted coverage no longer applies to these new drugs.

#### 2. New Drug Coverage Provision in Effect for January 1, 1991–September 30, 1993

(Note: The discussions of sections 1927(d)(1), (3), and (7) throughout this section III.C.2. of the preamble pertain to any amendments made by OBRA '93.)

Prior to OBRA '93, section 1927(d)(6) of the Act provided that a State may not exclude, subject to prior authorization, or otherwise restrict from coverage under the rebate program any new drug or biological approved by the FDA after the date of enactment of OBRA '90 (November 5, 1990) for a period of 6 months after the date of FDA approval. Except as authorized in section 1927(d)(1) and (2) of the Act for the period of January 1, 1991–September 30, 1993, States must have covered these drugs with no restrictions for 6 months from the date of FDA approval, regardless of when the manufacturer began to market the drugs. We would incorporate these provisions in § 447.520(a) of our regulations. For purposes of these provisions, we did not consider a delay in the marketing of a new drug following FDA approval a cause for extending the 6-month period.

The mandatory coverage provisions of section 1927(d)(6) of the Act did not encompass those drugs that a State may exclude under sections 1927(d)(1) and (d)(2) of the Act. Sections 1927(d)(1) and (d)(2) provide that a State may exclude or otherwise restrict coverage of a covered outpatient drug if the drug is used to treat, for example, anorexia, weight gain, hair loss, or cough or cold symptoms. Section 1927(d)(2), when read in conjunction with sections 1927(d)(1) and 1927(k)(2) of the Act, circumscribes those covered outpatient drugs that must be covered by States under their State plan. In other words, the mandatory coverage provisions of section 1927(d)(6) did not affect those drugs that a State may exclude or otherwise restrict under sections 1927(d)(1) or (d)(2).

In addition, we would provide under § 447.520(c) of the regulations that coverage of new drugs between January 1, 1991 and September 30, 1993 for the first 6 months after approval by the FDA would not be available for manufacturers that did not have agreements in existence with HCFA for this 6-month time period, since section 1927(a) of the Act provides FFP only for covered outpatient drugs of manufacturers with rebate agreements. However, if the new drug is rated as 1–A, section 1927(a)(3) of the Act authorizes payment, at State option, for certain 1–A drugs not covered under a rebate agreement. (Section III.D.1 of this preamble contains a discussion of 1–A drugs.)

Before the enactment of OBRA '93, sections 1927(d)(1) and (d)(6) of the Act provided that a State may not subject a new drug to prior authorization during the 6-month period after FDA approval. If the State chose to cover a new drug or class of drugs that was listed in section 1927(d)(2) of the Act, it could not prior authorize a new drug within that category during the 6-month period. After the 6-month period, a drug that was considered a new drug could be subject to the prior authorization provisions of section 1927(d)(1) at State option. We would incorporate these provisions in § 447.520(b) of our regulations.

Before the enactment of OBRA '93, section 1927(d)(3) of the Act prohibited new drugs from being added to the list of drugs subject to restriction in section 1927(d)(2) during the 6-month period specified in section 1927(d)(6). After the 6-month period, new drugs could be added to the list, as discussed in section IV.B.2. of this preamble.

Before the enactment of OBRA '93, section 1927(d)(7) of the Act permitted a State to impose limitations on all

drugs in a therapeutic class, on the minimum or maximum quantities per prescription, or on the number of refills, provided such limitations are necessary to discourage waste. We believe that to effectuate Congressional intent, sections 1927(d)(6) and 1927(d)(7) of the Act must have been read in concert to discourage waste in the use of new drugs during the 6-month period after FDA approval. Section 1927(d)(7), in our opinion, permitted States to impose limitations on all drugs, including new drugs, in a therapeutic class, on the minimum or maximum quantities per prescription, or on the number of refills, provided such limitations were necessary to discourage waste.

We believe such an interpretation would be consistent with the statutory provisions in both section 1927(d)(6) and section 1927(d)(7). We believe the Congress mandated that States could not exclude from coverage, subject to prior authorization, or otherwise restrict a new drug for 6 months from FDA approval to ensure that medically necessary new drugs were made available to the general population. The limitations for waste in section 1927(d)(7) of the Act did nothing to discourage the proper prescribing, dispensing, and use of a new drug. They simply ensure that, for Medicaid recipients, the minimum supply of the drug is sufficient to be medically effective and economical and that the maximum supply of the drug discourages waste in the event the drug cannot be used (for example, because of allergic reactions, side effects, drug interaction, or other reasons of medical necessity). The foregoing would give effect to the provisions in both section 1927(d)(6) and section 1927(d)(7) and, thus, would uphold the intent of the Congress as set forth in the statute. (See section IV.C. of the preamble for a discussion of a State's attorney authority to impose limitations as amended by OBRA '93.)

### 3. Definition of Original New Drug Application (NDA)

Sections 1927(k)(7)(A)(ii) and (iv) of the Act reference the term "original NDA" in the definitions of "innovator multiple source drug" and "single source drug." Under the national rebate agreement, a drug marketed under an original NDA, in addition to other criteria, may be classified as either a single source or an innovator multiple source drug. Neither the statute nor the rebate agreement, however, define the term "original NDA." This term is also not defined in the Federal Food, Drug, and Cosmetic Act.

Because the statute does not provide specific guidance on this term, we would interpret it to comport with our understanding of the intent of the Congress. We would define in regulations at § 447.504 the term "original NDA" as an FDA-approved drug or biological application that received one or more forms of patent protection, patent extension under title II of Public Law 98-417, the Drug Price Competition and Patent Term Restoration Act, or marketing exclusivity rights granted by the FDA. This definition would include an NDA, an amended NDA, an antibiotic drug application (ADA), an amended ADA, a product license application (PLA), and an amended PLA.

Based on the statute, which requires larger rebates for single source and innovator multiple source drugs, we believe the term "original NDA" was included in sections 1927(k)(7)(A)(ii) and (iv) of the Act for the purposes of extracting larger rebates from those products that received some form of patent or marketing protection for a specific period of time. This form of protection could have been achieved through either some type of patent on the drug or some type of marketing exclusivity rights granted by the FDA.

Patent protection is generally granted for 17 years. Exclusivity rights generally run for a period of 3 to 7 years and are granted by the FDA for such innovations as new medical indications, new dosage strengths, new dosage forms, new regimens, or new routes of administration. Exclusivity rights can extend beyond the life of the patent and protect the manufacturer from competition in one or more specific market areas. Thus, the innovators of drug products with market protection often benefitted from a lack of competition and increased profits for a specific period of time. Therefore, innovators with market protection are required to pay larger rebates than noninnovators that produce generic drugs with no market protection. We believe the term "original NDA," as proposed above, produces this effect.

The rebate classification system has raised questions among manufacturers regarding how to classify certain products. We believe some drugs that appear to meet the rebate agreement's definition of innovator multiple source drug are actually noninnovator multiple source drugs. The FDA may consider a previously approved drug product to be a new drug and require an NDA before marketing. However, in accordance with our understanding of these provisions, this drug may actually be a noninnovator. For example, under 21

CFR 310.509, the FDA does not generally recognize any parenteral drug product packaged in a plastic immediate container as safe and effective. Therefore, this type of drug product is considered a new drug within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act and requires an approved NDA as a condition for marketing. In this case, if no patent protection or marketing exclusivity rights were granted by the FDA for the covered outpatient drug of that manufacturer, we would consider it to be a noninnovator multiple source drug.

### D. Covered Drugs of Manufacturers Without Rebate Agreements

#### 1. Coverage of 1-A Rated Drugs

Prior to 1992, the FDA maintained a rating system under which drugs were rated based on various factors. Under that system, the FDA rating "1-A" signified the chemical type (1) and the therapeutic potential (A). The FDA, in its 1991 publication *Offices of Drug Evaluation Statistical Report*, defined the rating 1-A as follows:

- The chemical type "1" identifies the drug as a new molecular entity, that is, a drug for which the active moiety has not been previously marketed in the United States for use in a drug product, either as a single ingredient or as part of a combination product, or as part of a mixture of stereoisomers. The term "new molecular entity" is equivalent to "new chemical entity".

- The therapeutic potential type "A" is defined as a drug with important therapeutic gain. The drug may provide effective therapy or diagnosis for a disease not adequately treated or diagnosed by any marketed drug, or provide improved treatment of a disease through improved effectiveness or safety (including decreased abuse potential).

A 1-A drug may also be labeled "1-A/AA". The 1-A/AA designation means it is a 1-A drug that is generally being developed for AIDS and AIDS-related opportunistic infections and that the FDA has placed the drug on a fast track and will monitor it through the drug review process.

Section 1927(a)(3)(A) of the Act authorizes FFP for single source or innovator multiple source drugs rated by the FDA as 1-A that are furnished by manufacturers without rebate agreements if certain conditions are met. Under this section, Medicaid payments may be made if: (1) The State has determined that the availability of the drug is essential to the health of recipients under the approved State plan; and (2) the physician has obtained

approval for use of the drug before it is dispensed in accordance with a prior authorization program, or the Secretary has approved the State's determination regarding drug necessity to obviate the need for prior authorization (§ 447.518(b)). Necessity would be judged based on alternative therapies available and the probable outcome if a specific drug is not dispensed.

Even though section 1927(a)(3) of the Act authorizes HCFA to provide FFP for 1-A rated drugs under certain circumstances, States retain the option under sections 1902(a) and 1905 of the Act to choose which 1-A drugs they will cover under their approved State Medicaid plans.

The FDA recently changed its therapeutic classification system in which drugs were rated as either A, B, or C. As indicated in the FDA's *Staff Manual Guide*, Center for Drug Evaluation and Research, this three-tiered system has been replaced by a mutually exclusive two-tiered system in which the potential therapeutic classification of a drug product is either a Type P (Priority review, therapeutic gain) or a Type S (Standard review, substantially equivalent drug product). Type P is assigned to drugs that appear to represent a therapeutic gain over already marketed or approved drugs (formerly rated A or B). Type S is assigned to drug products that appear to have therapeutic qualities similar to drugs already approved or marketed (formerly rated C).

The Type P and S therapeutic classification system is effective for all NDAs approved on or after January 1, 1992. The classifications for NDAs approved prior to January 1, 1992, will remain unchanged, that is, these drugs will retain their A, B, or C therapeutic classification and 1-A drugs would continue to be covered by States as specified in this regulation. For purposes of section 1927(a)(3)(A) of the Act, we are inviting public comments on possible methods to identify 1-P-rated drugs that we could include as 1-A-drugs under this provision using the FDA's former classification system.

## 2. Coverage of Drugs During the First Rebate Period of 1991

Section 1927(a)(3)(B) of the Act provides for Medicaid payment for drugs not covered under rebate agreements if the Secretary determined that in the first rebate period of 1991 there were extenuating circumstances. On March 8, 1991, HCFA notified all State Medicaid Directors of its determination that extenuating circumstances did exist and that, for the first rebate period of 1991, outpatient

prescribed drugs of manufacturers without rebate agreements were covered under Medicaid if they were included in the approved State Medicaid plan. States were not formally notified until March 15, 1991, of manufacturers participating in the rebate program. There was no practical way States could retroactively discontinue drug coverage on January 1, 1991, for drugs of nonparticipating manufacturers. However, as of April 1, 1991, FFP is available only for those covered outpatient drugs of manufacturers with rebate agreements.

Section 1927(a)(1) of the Act required that manufacturers enter into a rebate agreement by March 1, 1991, for payment to be available for their drugs under Medicaid for the January-March 1991 rebate period. As discussed earlier, HCFA also extended through April 30, 1991, the deadline for manufacturers to enter into rebate agreements that are retroactive to January 1, 1991.

## IV. Limitations on Coverage of Drugs

Section 1927(d) of the Act, as amended by OBRA '93, permits States to place certain limitations on drugs that are covered under a rebate agreement. States may limit the coverage of drugs by: (1) Implementing a prior authorization program that complies with the requirements in section 1927(d) (5); (2) restricting or excluding from coverage drugs listed in section 1927(d) (2); (3) restricting the quantities of outpatient drugs per prescription and the number of refills under section 1927(d) (6); and (4) excluding coverage of the drug from its formulary in accordance with section 1927(d)(4). These limitations, that are proposed in the regulations at §§ 447.524 and 447.526, are explained below.

### A. Prior Authorization

Section 1902(a)(54) of the Act provides that in the case of a State plan that provides medical assistance for covered outpatient drugs (as defined in section 1927(k) of the Act), the State must comply with the applicable requirements of section 1927 of the Act. Section 1927(d)(1)(A) provides that a State may subject any covered outpatient drug to prior authorization; that is, require approval of the drug before its dispensing for any medically accepted indication. The prior authorization system must meet two conditions specified under section 1927(d)(5) of the Act.

For drugs dispensed on or after July 1, 1991 section 1927(d)(5) of the Act permits a State to maintain a prior authorization program if the State responds by telephone or other

telecommunication device to requests within 24 hours of a request for prior authorization. A State must, except for those drugs listed in section 1927(d)(2) of the Act, further provide for the dispensing of at least a 72-hour supply of the drug in emergency situations.

The provisions in section 1927 of the Act make no other changes to the State's ability to maintain or establish prior authorization programs. Thus, as specified in section 1927(d)(1) of the Act, States may subject to prior authorization any covered outpatient drug.

In passing these provisions, the Congress made it clear that Medicaid recipients should be assured access to all medically necessary covered outpatient drugs. (H. R. Rep. No. 881, 101st Cong., 2d Sess. 96-98 (1990).) Even though OBRA '93 added section 1927(d)(4) of the Act to allow States to establish formularies which meet specific requirements, section 1927(d)(4)(D) provides that the State plan must permit coverage of a drug excluded from the formulary (other than any drug excluded or restricted under section 1927(d)(2)) pursuant to a prior authorization program. In accordance with our understanding of Congressional intent, we believe that it is necessary to prevent States from using a prior authorization program as a proxy for a closed formulary beyond what the statute allows under the formulary provisions of section 1927(d)(4). In addition, we believe it is necessary to ensure that States respond to prior authorization requests within the timeframes specified in the statute. We believe these requirements are necessary to effectuate section 1927 of the Act and to uphold Congressional intent.

Prior authorizing drugs as a proxy for a closed formulary, beyond what the statute allows under the formulary provisions of section 1927(d)(4) without regard for medical necessity could result in recipients being treated with alternate therapies that may not be in their best interest. This could result in increased program costs if other medical services, such as inpatient hospital services, are necessary because a drug therapy is made less accessible under the State Medicaid program. Thus, a recipient's access to medically needed drugs could be unduly hampered if medical necessity is not used in a prior authorization program.

Therefore, we are proposing requirements to ensure that States utilize individuals with the appropriate level of medical expertise when determining which drugs are prior authorized and when deciding if the drug can be dispensed. Accordingly, we

believe it most appropriate that the level of expertise be reflected by the ability to prescribe/dispense drugs. We believe individuals with this knowledge would more likely be aware of negative consequences that could result if a specific drug is prior authorized or not approved for dispensing. Thus, the State Medicaid program and recipients would benefit from such a prior authorization system that considers medical necessity as its primary concern.

We note that this same level of expertise need not be present in those individuals responding to the prior authorization requests, as these persons would be acting in accordance with guidelines developed by those persons who place the drugs on prior authorization. However, as there may be requests for prior authorized drugs that do not fit into present guidelines, access to those persons responsible for putting drugs into a prior authorization program is needed.

Therefore, in accordance with section 1902(a)(54) of the Act, we would specify in these regulations at § 447.526(d) and (e) that:

- State staff who place drugs in a prior authorization system must be licensed to prescribe or dispense drugs in the State, for example, physicians or pharmacists, since these persons would have the medical knowledge necessary to determine criteria for prior authorization.

- State staff who respond to prior authorization requests are not limited to persons licensed to prescribe or dispense drugs as long as all decisions involving drugs subject to prior authorization are made—

- + In consultation with these licensed professionals; or

- + Under guidelines promulgated by such individuals as long as States provide access to licensed professionals in difficult or unusual cases.

- The State must establish a process to ensure recipients access to medically necessary covered outpatient drugs. We would not permit a State to use a prior authorization program as a means to deny covered outpatient drugs when medical necessity is shown.

- The State must provide annual written assurances to HCFA that the State's prior authorization program does not prevent recipients from gaining access to medically needed drugs.

Generally, we would allow States flexibility in implementing the statutory provisions relating to a 24-hour turnaround time for prior authorization requests and at least a 72-hour supply for emergency situations. For example, States may continue to prescribe the format for sending the request (for

example, mail, telephone, or telefax). States may also continue to staff this function only during normal business hours, provided the requirement concerning a response to prior authorization requests within 24 hours of a request can be met.

However, to ensure access to medically necessary drugs, we would require States to structure their system so that, in emergency situations, a State's response is given to the dispenser or physician requesting the authorization before the emergency supply is exhausted. In these emergency situations, we would require the State to provide a mechanism so that a dispenser or physician can make a prior authorization request 24 hours before the supply is exhausted and a response returned by the State within that 24-hour period. We would require the State to allow a dispenser to provide a sufficient emergency supply (of at least 72 hours) until the prior authorization response can be returned to the dispenser. For example, the supply of a drug dispensed on Friday evening should not be exhausted before the prior authorization is requested on Monday morning and a response returned to the requester by the State on Tuesday morning (within 24 hours of a request).

We would allow States to develop a reasonable definition of emergency situations, as long as the definition does not prevent recipients from acquiring medically necessary covered outpatient drugs within the parameters set forth below. We would require in § 447.526(c)(2)(i) that States specify in their State plans the process that will be used to determine what constitutes an emergency situation. Emergency situations may involve immediate and severe adverse consequences or continuation of an immediate and severe adverse consequence if a covered outpatient drug is not dispensed when a prescription is submitted. We would not consider an emergency situation to exist if (1) the lack of a drug supply does not pose an immediate threat to the recipient, or (2) a drug must be prior authorized before it can be dispensed if there is no immediate threat to the recipient.

#### *B. Exclusion or Restriction of Drugs*

##### *1. Drugs Subject to Restriction*

Section 1905(a)(12) of the Act and regulations at 42 CFR 440.120 define prescribed drugs that may be covered by a State under its Medicaid program. Existing regulations under § 441.25 contain prohibitions on FFP for certain prescribed drugs. Except for covered outpatient drugs defined in section 1927

of the Act, these rules are not affected by the requirements for rebate agreements as a condition of FFP. This proposed rule would implement, in part, the provisions of section 1927(d)(2) of the Act, which specify the specific drugs or classes of drugs that States may exclude or restrict from coverage.

As noted previously in this preamble, section 1927(d)(1)(B) of the Act as amended by OBRA '93 specifies conditions under which a State may exclude or restrict coverage of an outpatient drug under a drug rebate agreement. A State may exclude or restrict a drug if—

- The prescribed use of the drug is not for a medically accepted indication;
- The drug is contained in the list of drugs subject to restriction under section 1927(d)(2) of the Act;
- The drug is subject to restrictions in a separate or existing agreement between a manufacturer and a State agency that has been authorized by HCFA under sections 1927(a)(1) of the Act or in effect in accordance with section 1927(a)(4) of the Act (§ 447.524(b)); or

- The State has excluded coverage of the drug from its formulary established in accordance with the requirements for formularies specified in section 1927(d)(4).

Section 1927(d)(2) limits a State's option to exclude or restrict drugs from coverage under the rebate program to the following drugs, classes of drugs, or their medical uses:

- Agents when used for anorexia, weight loss or weight gain.
- Agents when used to promote fertility.
- Agents when used for cosmetic purposes or hair growth.
- Agents when used for the symptomatic relief of cough or colds.
- Agents when used to promote smoking cessation.
- Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparation.
- Nonprescription drugs.
- Covered outpatient drugs that the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee.

- Barbiturates.
- Benzodiazepines.

We would allow States flexibility in specifying the drugs and medical uses that fall within these descriptions. We do not intend to further identify or define these drugs at this time. We would allow States to exclude or restrict drugs that fall within these descriptions. However, when a drug that is primarily

formulated to treat a medically accepted indication not included on the list set forth in section 1927(d)(2) of the Act is also prescribed for a medical use included in section 1927(d)(2), that use of the drug for the medically accepted indication outside of section 1927(d)(2) would not be excludable. For example, a drug that is primarily formulated to treat asthma or some condition other than coughs and colds should not be excluded for the treatment of asthma. However, a State could prior authorize the drug and exclude or restrict it if the drug is prescribed for a cough or cold in an individual case.

We would require in § 447.524(g) that a State amend its State Medicaid plan to include a list of those drugs or classes of drugs or medical uses under section 1927(d)(2) of the Act that the State is excluding or restricting from coverage. We would also require a State to describe in its plan limitations or conditions of coverage for these drugs. However, we would not require the State to list those drugs for which it requires prior authorization. We would require States to amend their State plans in this manner to ensure that both HCFA and the public are adequately informed of those drugs covered by various State plans.

## 2. Updating the List of Drugs Subject to Restriction

*a. Adding Drugs to the List.* In accordance with section 1927(d)(3) of the Act as amended by OBRA '93, the Secretary must periodically update, by regulation, the list of drugs, classes of drugs, or their medical uses subject to restriction under the rebate program if there is evidence of clinical abuse or inappropriate use. Section 1927(d)(3) provides that the Secretary must update the list on the basis of data collected by the State Medicaid agencies' surveillance and utilization review (SUR) programs. We would incorporate this provision in our regulations at § 447.524(d). As necessary, we will announce a proposed updated list in the Federal Register and allow public comment before the list is issued in final.

We request public comments with suggestions on how we should administer a process to determine when a drug, class of drug, or its medical use should be added to the list in section 1927(d)(2) of the Act when the item is subject to clinical abuse or inappropriate use. At a minimum, any suggestions made for the process must take into consideration that we must use SUR data to substantiate any proposal to add an item to the list. In accordance with section 1927(d)(3) of the Act, a

SUR report submitted as supporting documentation would need to provide HCFA with the data necessary to make an objective analysis regarding clinical abuse or inappropriate use of an item.

While we currently have reporting requirements for SUR data, we would need to modify them to accommodate the additional information needed to update the list of drugs subject to restriction. These reporting requirements would be addressed in a separate document.

*b. Deleting Drugs From the List.* Section 1927(d)(3) of the Act provides that the Secretary must "update" the list of drugs subject to exclusion or restriction. In this proposed rule, we would interpret this provision to mean that drugs subject to clinical abuse or inappropriate use may be added to the list. However, we do not believe that section 1927(d)(3) allows the Secretary to delete drugs from the list. That list, set forth in section 1927(d)(2) of the Act, represents drugs that, as noted in the Senate Report, are "commonly subject to exclusion or restriction by State Medicaid programs." (136 *Cong. Rec.*, S15658, daily ed. October 18, 1990) The tenor of that report, as with the statute, is that drugs may be added to the list, but that the categories already on the list will remain subject to State restriction.

An example to reinforce this point can be made with paragraph (H) under section 1927(d)(2) of the Act. Paragraph (H) refers to "covered outpatient drugs that the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee." If we were to conclude that we have the authority to remove any drug from the list if it were not subject to clinical abuse or inappropriate use (as noted in section 1927(d)(3) of the Act), and data were available demonstrating that a product was not subject to clinical abuse or inappropriate use, we would have to remove the drug from the list (regardless of any exclusive arrangement) and require all State Medicaid programs to cover the drug. This result would clearly conflict with the statute and with the legislative history. Accordingly, the drugs on the list would be statutorily mandated and could only be deleted from the list by amendments to the statute.

## 3. DESI and IRS Drugs

*a. The DESI Program.* Before enactment of the Federal Food, Drug, and Cosmetic Act of 1938, drugs could be marketed in the United States as long as a drug's label did not present false information regarding the drug's strength and purity. The Federal Food,

and Cosmetic Act first established the requirement that a manufacturer has to prove the safety of a drug before the manufacturer could market it in the United States. In accordance with that statute, drugs marketed before the passage of the Federal Food, Drug, and Cosmetic Act were "grandfathered" so that manufacturers, if they do not change the representations on the drugs' labels, were allowed to continue to market them unless evidence was developed to indicate that they were not safe (referred to as pre-38 drugs). However, once a manufacturer changed the representation on a pre-38 drug's label, that drug was considered by the FDA to be a "new drug" and the manufacturer was required to prove that the drug was safe for its intended use.

In 1962, the Federal Food, Drug, and Cosmetic Act was amended to require that drugs sold in the United States be regulated more closely. Under the provisions of the Drugs Amendments of 1962 (Public Law 87-781), all new drugs must be shown by adequate studies to be both safe and effective before they can be marketed. This legislation also applied retroactively to all drugs approved as safe from 1938 to 1962 (referred to as pre-62 drugs). These pre-62 drugs were permitted to remain on the market while evidence of their effectiveness was reviewed. The program established under which the FDA would review the effectiveness of drugs approved between 1938 and 1962 was named the Drug Efficacy Study Implementation (DESI) program.

If the DESI review indicates a lack of substantial evidence of a drug's effectiveness for all of its labeled indications, the FDA will publish a Notice of Opportunity for a Hearing (NOOH) in the Federal Register concerning its proposal to withdraw approval of the drug for marketing. At that time, a manufacturer of that drug or identical, related, or similar (IRS) drugs has the opportunity to request a hearing and provide FDA with documentation of the effectiveness of the drug product before a final determination is made. Drugs for which a NOOH has been published are referred to as less than effective (LTE) DESI drugs. The IRS drug counterpart of a LTE DESI drug is also considered less than effective. (We note that the terms "DESI drug" and "LTE DESI drug" are not synonymous.)

If all the labeled indications of the product are found to lack substantial evidence of effectiveness, a withdrawal notice is published in the Federal Register withdrawing approval of the NDA for the product. At that time, shipping this product and any IRS drug product in interstate commerce after the

effective date of the withdrawal notice is unlawful.

If only some of the labeled indications of the product are found to lack substantial evidence of effectiveness, the manufacturer must delete those LTE indications from the drug's label. If a manufacturer does not comply with this requirement, the manufacturer's NDA can be withdrawn by the FDA. All manufacturers of IRS drug products must also revise their labeling and submit an application to the FDA to obtain approval for their product to be allowed to continue marketing their drug.

In accordance with section 1903(i)(5) of the Act, FFP is not available for LTE DESI/IRS drugs for which a NOOH is issued for all labeled indications. Under the drug rebate program, a drug is not considered a covered outpatient drug if a NOOH is issued for some or all labeled indications.

At present, drugs subject to the DESI review process are in various stages of review. The mandatory and optional State coverage requirements and FFP restrictions on these drugs are discussed in section IV.B.3.b. of this preamble. The term "DESI/IRS drugs" is used when discussing coverage of a DESI drug and its IRS counterparts.

*b. Coverage of DESI/IRS Drugs Under the Medicaid Program.* This section describes the general coverage, FFP requirements, and rebate requirements for DESI/IRS drugs. Detailed instructions on how to identify DESI drugs and the roles that HCFA, States, manufacturers, and the FDA play in this process have been sent to the manufacturers and States.

- Non-DESI/IRS Drugs or DESI/IRS Drugs Determined Safe and Effective. Non-DESI/IRS drugs (pre-38 drugs and post-62 drugs) and pre-62 DESI/IRS drugs that have undergone the DESI review process and have been determined by the FDA to be safe and effective for their labeled uses under sections 505 and 507 of the Federal Food, Drug, and Cosmetic Act meet the definition of a covered outpatient drug. Therefore, these drugs of a participating manufacturer must be covered under the drug rebate program and are, therefore, subject to a rebate and FFP.

- DESI/IRS Drugs under Review (No NOOH Issued). DESI/IRS (pre-62 drugs) of participating manufacturers which meet the definition of a covered outpatient drug that are undergoing the DESI review process but for which a NOOH has not been issued must be covered under the rebate program. These drugs include:

- + Drugs described in section 107(c)(3) of the Drug Amendments of 1962 and

for which the Secretary has determined there is a compelling justification for its medical need, or is identical, similar, or related to such a drug; and

- + Drugs for which the Secretary has not issued a NOOH under section 505(e) of the Federal Food, Drug, and Cosmetic Act to withdraw approval of an application for such drug under such section because the Secretary has determined that the drug is less than effective for some or all conditions of use prescribed, recommended, or suggested in its labeling.

In other words, a State must cover DESI/IRS drugs of a participating manufacturer for which a NOOH has not been issued for some or all of the drug's labeled indications. FFP is available and the drugs are subject to a rebate. DESI/IRS drugs under this category do not include drugs that have been found to be safe and effective under the DESI review program.

- Less Than Effective (LTE) DESI/IRS Drugs for Some Indications. Section 1903(i)(5) of the Act does not prohibit FFP if a DESI drug is effective for at least one indication. A drug would meet this criterion if a NOOH has been issued for some, but not all, indications. These DESI/IRS drugs may be covered at State option and FFP is available.

For purposes of the rebate program, the definition of a covered outpatient drug in section 1927(k)(2)(A)(iii) of the Act specifically excludes those DESI/IRS drugs for which a NOOH has been issued because the FDA has determined that the drugs are less than effective for some or all of their prescribed recommended uses. However, when these drugs have an FDA-approved, labeled indication for which a NOOH has not been issued, the drug is considered a covered outpatient drug for that indication (and other medically accepted indications). Therefore, these drugs of participating manufacturers must be included in the drug rebate program for their approved indications (and other medically accepted indications) and are subject to a rebate and FFP.

- Less Than Effective (LTE) DESI/IRS Drugs for All Indications. Under section 1903(i)(5) of the Act, FFP is prohibited for DESI drugs for which a NOOH has been issued for all conditions of use prescribed, recommended, or suggested in its labeling. Therefore, if a State chooses to cover these LTE DESI/IRS drugs, FFP is not available. This prohibition was not changed by OBRA '90 and applies regardless of whether the manufacturer is appealing the NOOH for some or all of the drug's indications.

- Less Than Effective DESI/IRS Drugs Withdrawn from the Market. The FDA has determined this group of DESI/IRS drugs to be less than effective and published a NOOH and subsequent withdrawal notice in the Federal Register. Based on these findings, the manufacturer is required to discontinue the distribution of these drug products. However, because the FDA does not institute recalls of these drug products to the retail level, these products may still be available in pharmacies. In any event, under section 1903(i)(5), FFP is not available for these DESI/IRS drugs.

*c. Reporting DESI/IRS Drugs.* The rebate agreement requires that the manufacturer's list of covered outpatient drugs include the NDC numbers for all drugs currently marketed by the manufacturer. Manufacturers are also required to list the NDC number for a drug that it no longer markets because the manufacturer will be responsible for providing a rebate on the drug until the entire supply of the drug under an NDC has expired, the drug has been taken off the market, or for other reasons, the potential no longer exists that the covered outpatient drug may be dispensed under the manufacturer's NDC number. To comply with these requirements, manufacturers must include on their lists of covered outpatient drugs all DESI/IRS drugs.

Even though some drugs are not subject to the rebate program, manufacturers must report to HCFA the required information for all LTE DESI/IRS drugs. A change from one DESI category to another DESI category, as described in section IV.B.3.b. of this preamble, could change a drug's coverage under Medicaid. For example, LTE DESI/IRS drugs could be potentially covered at some point under the rebate program if the FDA reverses its decision on a NOOH. HCFA must have the baseline pricing data (for single source and innovator multiple source drugs) from October 1, 1990, and for all drugs, the DESI drug indicator, as well as other data, in the event they are covered at a later date.

A manufacturer is responsible for knowing the status of DESI/IRS drugs by reviewing DESI notices published in the Federal Register by the FDA. (See 52 FR 1663 and 1668, January 15, 1987.) Manufacturers must identify in their list of covered outpatient drugs which they submit to HCFA those DESI/IRS drugs that they produce that are the subject of a NOOH.

In accordance with section 1927(b)(3)(C)(ii) of the Act, any manufacturer with an agreement under section 1927 that knowingly provides false information is subject to a civil

money penalty in an amount not to exceed \$100,000 for each item of false information. This provision also applies to any manufacturer that knowingly reports false information to HCFA regarding the status of a DESI/IRS drug for coverage purposes. In addition to civil money penalties, the manufacturer may also be subject to termination because it is not in compliance with section 1927 of the Act, the national rebate agreement, and regulations under § 447.534 that specify manufacturer reporting requirements.

*C. Amount, Duration, and Scope of Services.* Prior to the enactment of OBRA '90, States could establish amount, duration, and scope restrictions on Medicaid services, including prescription drugs. These restrictions could be based on such criteria as medical necessity and utilization control, or could be based on other factors so long as the amount of the services provided was sufficient to "reasonably achieve its purpose" (See section 1902(a)(10) of the Act and § 440.230 (Sufficiency of amount, duration, and scope)). States could impose prior authorization restrictions and also limit the number of prescription drugs that they covered through a formulary.

Section 1927 of the Act curtails a State's authority to exclude drugs from coverage and limited its authority to impose prior authorization requirements under section 1927(d)(5). However, the statute did not alter the State's authority to establish amount, duration, and scope restrictions, and, in fact, specifically recognized States' authority to impose additional restrictions on the quantities per prescription and the number of refills. Specifically, section 1927(d)(6) of the Act allows a State to impose restrictions on minimum and maximum quantities of outpatient drugs per prescription and on the number of refills within a therapeutic class to discourage waste. Section 1927(d)(6) also allows a State to impose these limitations and address instances of fraud or abuse by individuals in any manner authorized under the Act.

The legislative history of OBRA '90 indicates that this statutory provision was designed to enhance, not limit or replace, a State's authority to impose reasonable amount, duration, and scope restrictions. The House Report, adopted by the Conference Committee, states that "States are not prevented from restricting the amount, duration, and scope of coverage of covered outpatient drugs consistent with the need to safeguard against unnecessary utilization." (H. R. Conf. Rept. No. 964, 101st Cong., 2nd Sess., 825, 832 (1990))

This statement supports the conclusion that the Congress did not intend to circumscribe a State's authority to impose amount, duration, and scope restrictions. Therefore, in regulations at § 447.524(e), we would specify that a State may continue to impose limitations on the minimum and maximum quantities of drugs per outpatient prescription and the number of prescriptions or dispensing fees allowed per month as it did before the enactment of OBRA '90.

A State, in accordance with section 1927(d)(6) of the Act, may impose coverage restrictions on package sizes of a drug when required to prevent waste. We do not believe that, given the general goals of the drug rebate provisions, Congress intended for States to pay for more expensive package sizes when less costly alternatives exist. Thus, we would permit States to impose coverage restrictions based on the relative economy, or the high cost, of a specific package size. For example, a State may exclude from coverage the unit dose packaging of a particular drug based on its cost; however, such restrictions may be imposed, given the formulary requirements of section 1927(d), only if the manufacturer packages the drug in other sizes which the State covers.

#### V. Reporting Requirements

Under section 1927(b)(2) of the Act as amended by OBRA '93, States are responsible for providing to the manufacturer Medicaid utilization data for a rebate period regarding the quantity of drugs that they have dispensed after December 31, 1990 for which payment was made under their State plan during a rebate period. Section 1927(b)(3) of the Act requires a manufacturer to supply to HCFA, for each rebate period, information concerning AMP and, as required, best price for its covered outpatient drugs. Rebates are calculated for each rebate period on the basis of this information, as explained in section VI. of this preamble.

##### A. State Reporting Requirements

Under section 1927(b)(2)(A) of the Act, the State Medicaid agency must provide to manufacturers with drug rebate agreements State drug utilization data regarding the total number of "units" of each dosage form, strength, and package size of the manufacturer's drug that were dispensed after December 31, 1990 and paid for under the State plan during a rebate period. In the regulations at § 447.530(a)(2), we would define "unit" as the lowest commonly identifiable amount of a drug

for example, tablet or capsule for solid dosage form, milliliter for liquid forms, and gram for ointments or creams, as supplied to HCFA in accordance with instructions in the rebate agreement. The use of units with regard to State reporting requirements and rebate calculations is discussed throughout sections V. and VI. of the preamble.

To comply with the provisions of section 1927(b)(2)(A), we would specify in our regulations at § 447.530(b) that States provide Medicaid drug utilization data based on claims paid by the State Medicaid agency during a rebate period.

##### 1. Pharmacy Coding, Oversight, and Audit

To comply with the provisions of section 1927(b)(2)(A) of the Act, and to facilitate uniform reporting, we would require in § 447.530(a)(1) that States report their utilization data by the 11-digit NDC number. We note that FDA's regulations at 21 CFR 207.35 refer to the NDC number as a 10-character code. This code can show leading zeros in any segment of the NDC number. However, for standardization purposes in the drug rebate program, we are using a consistent 11-digit code that reflects leading zeros and the maximum number of digits that can appear in each segment of the NDC code.

We are recommending that, in order to implement these provisions in the most efficient and cost-effective manner, State Medicaid agencies identify for pharmacies certain information, as discussed below, that will enable them to determine those drugs that are covered under a State plan. The State should make available to pharmacies information concerning the labeler codes of manufacturers with rebate agreements; drugs under section 1927(d) of the Act that are excluded or restricted from coverage and the limitations or conditions of coverage; and drugs that are subject to prior authorization.

For purposes of this regulation, the term "pharmacy" applies to any entity authorized by the State to dispense covered outpatient drugs in that State. Thus, these requirements will be binding on all dispensers of covered outpatient drugs to Medicaid recipients.

The State agency may establish its own policies to ensure accurate pharmacy coding. However, we would require the agency to establish and implement an oversight and auditing process to ensure proper pharmacy coding and reporting practices. We would also require States to establish and implement procedures for investigating allegations of erroneous utilization data at the pharmacy level by participating manufacturers or other

interested parties (§ 447.530(e) (2) and (3)). We would require State agencies to establish procedures to comply with section 1927(b)(2)(B) of the Act, which gives manufacturers the authority to audit State data. The agency would also be responsible for taking the actions necessary to ensure accurate coding (§ 447.530(e)(4)).

We believe these requirements regarding accurate pharmacy coding are necessary to effectuate OBRA '90 drug rebate provisions. Accurate pharmacy coding is a fundamental and critical component of the Medicaid drug rebate program under section 1927 of the Act. Without these requirements, pharmacies may use incorrect NDC numbers when billing the Medicaid State agencies, which could result in numerous problems.

Use of incorrect NDC numbers could have a detrimental effect that would carry through the entire drug rebate process. First, pharmacies could bill States for a brand name drug although a generic drug was dispensed, resulting in overpayments to pharmacies, increased drug costs, and erroneous utilization data. If pharmacies substitute the NDC numbers of one manufacturer for another, even if the drugs cost the same amount, the Medicaid utilization data would be flawed. Secondly, flawed data would cause the States to invoice manufacturers for erroneous rebates, resulting in over and under billing for rebates. Thirdly, erroneous data may increase the likelihood that manufacturers would dispute the data and withhold rebate payments to States. Thus, inaccurate pharmacy coding would increase a State's dispute resolution workload, delay rebate payments, and cause interest to accrue on unpaid amounts. The dispute resolution process is an expensive, lengthy, and resource-intensive process for all parties involved.

In addition to disputing the data, manufacturers may, in accordance with section 1927(b)(2)(B) of the Act, audit the drug utilization data provided (or required to be provided) by the State. A manufacturer could also request a State to audit a pharmacy, which is also expensive and resource intensive. Because of the magnitude of the problems and costs inaccurate pharmacy coding can cause, we believe the requirements discussed above are necessary to properly and efficiently effectuate the drug rebate program requirements in OBRA '90.

Therefore, we would require in § 447.530(e)(1) that the State must inform pharmacies that they are required to use accurate NDC numbers for the drugs dispensed in submitting

their Medicaid claims and that payment can be denied for a drug that has been inaccurately coded by a pharmacy. States may consider inaccurate coding to be good cause for terminating provider agreements subject to applicable Federal and State laws. Also, under anti-fraud provisions, pharmacy claims with incorrect NDC numbers may subject these pharmacies to criminal or civil money penalties, as well as exclusion from the Medicare and Medicaid programs.

States must implement the requirements of § 447.530(e) within 60 days after publication of the final rule. We believe this timeframe is adequate for establishing procedures to ensure accurate pharmacy coding since we informed States of these requirements in mid-1991. We are aware that many States have since established procedures to ensure accurate pharmacy coding. States that do not ensure accurate pharmacy coding may be considered to be out of compliance with section 1927 of the Act and, therefore, subject to compliance proceedings. In addition to effectuating OBRA '90 drug rebate provisions, we believe these pharmacy coding requirements are essential to comply with section 1902(a)(30) of the Act. Section 1902(a)(30) generally provides that methods and procedures relating to the utilization and payment of services under the State plan safeguard against unnecessary utilization and to ensure that payments are consistent with efficiency, economy and quality of care.

In accordance with section 1927(b)(2)(B) of the Act, a manufacturer may audit the drug utilization data provided (or required to be provided) by the State. If the information indicates that utilization was greater or less than the amount previously specified, adjustments to the rebates must be made on the next quarterly report submitted by the State. All corrections must be applied to the quarter for which utilization data are adjusted. If the adjustments result in a manufacturer owing an additional rebate amount, the manufacturer must include that amount, plus interest, in the rebate payment for next rebate period.

Since the statute permits manufacturers to audit drug utilization data but does not authorize manufacturers to directly audit pharmacies, we would require States to have procedures to investigate manufacturers' allegations of erroneous utilization data produced at the pharmacy level. If the State agrees to such a request, it may apply a process that uses a sampling methodology to audit pharmacies in a targeted area

where erroneous data are believed to be occurring, or by other means that will address the alleged problem. Given the large volume of Medicaid drug claims, we believe a targeted sampling of pharmacies and their claims is a reliable method to discover inaccurate coding and billing practices, especially when targeted for specific drugs. Doing otherwise could prove costly for States without providing a significant amount of additional information. If erroneous data are discovered, a State could expand the audit to determine the severity of inaccurate billing practices.

An audit may be performed at any time throughout the dispute resolution process. However, both parties must agree to the audit and develop mutually agreeable audit procedures. (Section V.F. of this preamble contains a discussion of dispute resolution.)

## 2. Format and Contents of Report

Section 1927(b)(2)(A) of the Act requires that the Secretary establish a standard reporting format that States must use to report drug utilization data to manufacturers and to HCFA. Using this standard reporting format, States must identify drugs by manufacturer to ensure that the proper rebates are paid. As indicated earlier, we selected the NDC number that identifies each drug by manufacturer, product, and package size as part of the standard reporting format to be used throughout the rebate program.

We have issued, through the rebate agreement and a notice published in the Federal Register on May 1, 1991 (56 FR 20006), the standard reporting format for States to use in reporting for the rebate period to HCFA and manufacturers. We have also issued subsequent letters to State Medicaid Directors containing instructions to provide additional guidance in using the reporting format. This standard reporting format includes the following information:

- State identification;
- Rebate period and year for which data apply;
- NDC number to identify labeler code, product code, and package size code;
- Total number of units paid for during the rebate period for each NDC;
- FDA registration name to provide a cross-check for the product code;
- Total amount of rebate that a State claims for each NDC;
- Number of prescriptions reimbursed by NDC;
- Rebate amount per unit and total reimbursement amount to verify manufacturer's payment; and

- A correction record flag to alert HCFA of a change or correction from a previous report.

These data elements will be updated through separate instructions as needed to further program objectives in this area. We would incorporate in the regulations at § 447.530(a) through (d) the basic reporting requirements and timeframes. HCFA instructions will provide guidelines for States to use when reporting utilization data.

### 3. Timeframe for State Reporting of Utilization Data

In accordance with section 1927(b)(2)(A) of the Act, we would require in § 447.530(c) that each State Medicaid agency report drug utilization data to HCFA and the manufacturer no later than 60 days after the end of each rebate period. The data for the first rebate period (January-March 1991) were originally due to HCFA and the manufacturer on May 30, 1991. However, since the Secretary had not developed a standard reporting format, we extended the May 30, 1991, deadline to July 30, 1991, for States to submit data to HCFA and the manufacturer. This delay resulted, in part, from a lack of either baseline and/or first rebate period data from many of the manufacturers, including the majority that joined the rebate program during the extension period to April 30, 1991. We believe the extension alleviated the need for States to send to HCFA and manufacturers multiple updates of corrected data, prevented disputes on partial data, and allowed for smoother implementation of the drug rebate program.

States should mail the utilization data to manufacturers in a form that will provide evidence of the date the data were received by the manufacturers. Manufacturers must pay rebates for each rebate period or provide a written notice of disputed utilization data by the 30th day after receipt of State utilization data. Evidence of the date received is important so that States can accurately determine when rebate payments are due, when interest begins accruing on any unpaid balances, and when the interest period begins for purposes of the dispute resolution process. (Section V.F.4. of this preamble contains a discussion of the interest provision.)

### 4. Effect of Timeliness of State Utilization Data on Payment of Rebates

Section 1927(b)(2)(A) of the Act provides that a State Medicaid agency shall report rebate period information on the drugs dispensed and paid for to each manufacturer not later than 60 days after the end of each rebate period

and in a form consistent with a standard reporting format established by the Secretary. As noted previously in section V.A. of this preamble, we would specify in regulations that States provide Medicaid drug utilization data based on claims paid by the State during a rebate period. However, we believe circumstances could arise that prevent States from being able to generate Medicaid utilization information in the standard reporting format to meet this 60-day deadline. While the statute requires States to meet this 60-day requirement, we do not believe the statute relieves manufacturers from the obligation of paying rebates if States cannot meet the requirement. States do not have an incentive to submit late rebate claims to manufacturers since they are losing revenue by doing so. While processing late rebate claims may be an inconvenient administrative task for manufacturers, manufacturers have the advantage, in this case, by having access to these rebate funds which should have been paid to the State had the State submitted the data within the specified timeframe.

Thus, we realize that we must establish a maximum timeframe during which the manufacturer is bound to pay rebates on all drugs sold to Medicaid recipients. We would, therefore, establish a maximum time limit of 1 year from the end of a rebate period for States to bill a manufacturer for a rebate. However, if a State submits claims later than the required 60-day period, the State can only bill the manufacturer for the rebate amount that would have been due during the rebate period in which the State paid the drug claim. Consequently, we would specify in regulations at § 447.530(c) that the manufacturer is not required to pay a rebate on its drugs when a State does not submit its rebate period utilization data to the manufacturer within 1 year after the rebate period ended.

We believe this 1-year timeframe meets the needs of both States and manufacturers and is equitable because it parallels the maximum 1-year timeframe for providers' and States' responsibilities. Other Medicaid provisions allow a maximum timeframe of 1 year for pharmacies to submit claims and up to 1 year for States to pay claims (42 CFR 447.45(d)). A State would not lose rebates on those drugs for which it cannot compile the data within 60 days, and a manufacturer would not be held liable for rebates for an extensive period of time due to a State's failure to report utilization data within 60 days. As a general matter, HCFA will not find a State to be out of compliance if its utilization data are

submitted to the manufacturer within this 1-year timeframe.

We consider any time period longer than 1 year after the rebate period ended to be extensive since this period could ultimately translate into a manufacturer being responsible for rebates for more than 3 years after the drug is dispensed. In accordance with § 447.45, pharmacies have up to 1 year to bill the State agency for drugs dispensed to Medicaid recipients, and States could take as long as 1 year to pay a drug claim. Thus, these two processing timeframes and the 1-year cutoff total 3 years. This 3-year time period also comports with general business principles. The Internal Revenue Service generally requires that records be maintained for 3 years unless they are involved in some type of action requiring their use. Manufacturers may not be able to substantiate rebate claims for more than 3 years after a drug is dispensed since they are not required to maintain records for more than 3 years. Adding more disputes to the resolution process for data where no records may exist is not, in our opinion, a cost effective or efficient manner of operating the drug rebate program. Thus, we believe this 1-year threshold for States to submit utilization data to manufacturers is reasonable and consistent with the drug rebate provisions of section 1927 of the Act and necessary to effectuate the OBRA '90 drug rebate provisions.

States that lose rebates required under section 1927 of the Act for failure to submit rebate period utilization data to manufacturers within 1 year after the rebate period ended may be considered out of compliance with section 1927. Therefore, HCFA could initiate a compliance action against a State if it fails to collect rebates to reduce the amount expended under their State plan for medical assistance (§ 447.530(c)).

### 5. Data Edits on State Utilization Data

As discussed in section V.A.2. of this preamble, States are required, under section 1927(b)(2)(A) of the Act, to submit drug utilization data to manufacturers in a format established by HCFA. Since the accuracy of the invoiced rebates is dependent upon the reliability of the State utilization data, we would require States to establish a system of edits to its Medicaid utilization information. These edits must be performed before the State submits its utilization data to the manufacturer. The data reports generated from these edits will not be disclosed to the manufacturer but will be used to verify the accuracy of the information disclosed. We believe this requirement is necessary to effectuate

the OBRA '90 drug rebate provisions and to prevent unnecessary disputes between States and manufacturers that delay the timely payment of rebates.

The types of edits described in this section are intended to verify the accuracy of the Medicaid utilization information by examining whether:

- The unit types claimed are appropriate for NDC number claimed;
- The units claimed match the amount paid by the State; and
- The amount paid by the State is an amount allowable for the NDC (for example, a brand name payment amount was not made for a generic drug or the opposite).

We believe that, by verifying the accuracy of such items described in this section before submitting the information to the manufacturer, the State will identify inconsistencies, correct them, and reduce the number of subsequent disputes. The State must submit the utilization data to the manufacturer within the timeframes contained in § 447.530(c), as described in sections V.A.3. and V.A.4. of this preamble, and only after the State has performed the types of edits described in § 447.530(f) and believes the data are accurate.

The requirement in § 447.530(f) for State edits on Medicaid utilization information would be effective 60 days following publication of the final rule. That is, State data submitted to manufacturers for that rebate period must have been verified through the use of system edits.

#### 6. Use of Rounding Indicator

We also would establish the requirement in § 447.530(g) that States must identify by NDC number those drugs for which the number of units has been rounded by showing a rounding indicator for the number of units dispensed. States must include this information in their rebate period Medicaid utilization information submitted to the manufacturers. We have determined that this requirement is necessary since some pharmacies lack the ability to report decimal quantities in the Medicaid utilization information and, thus, in accordance with accepted industry standards, round up decimal quantities to the nearest whole unit. This practice can result in manufacturers being sent inflated utilization data or lead to disputes over the number of units billed.

We believe this requirement is necessary to effectuate the OBRA '90 drug rebate provisions and to prevent unnecessary disputes between States and manufacturers which delay the timely payment of rebates. We would,

therefore, require States to indicate in the appropriate data field whether or not the number of units reported in the Medicaid utilization information has been rounded. This indicator will alert the manufacturer that a rounding adjustment factor has been applied to appropriately deflate the State's utilization data.

The requirement in § 447.530(g) for States to use the rounding indicator would be effective 60 days following publication of the final rule. That is, State data submitted to manufacturers for that rebate period must include the rounding indicator field and the number of units billed. We will provide separate instructions to the States and manufacturers regarding the use of the rounding indicator.

#### 7. Rebate Tolerance Limits for Invoicing

Many States have informed us that the costs of preparing an invoice for drug rebates can often exceed the amount of a minimal rebate. For instance, some States have spent \$50 preparing an invoice for a \$5 rebate. We believe that if administrative costs are more than the rebates, the State should not expend its resources to collect a rebate that reduces State savings. Thus, to effectuate the OBRA '90 drug rebate provisions in the most efficient manner, we would establish a rebate tolerance limit for States to use in determining whether it should bill a manufacturer for a rebate when the administrative expense exceeds the rebate savings.

Generally, if the rebate amount due per labeler code is less than the administrative costs associated with preparing the invoice and collecting the rebate, the State should not invoice the labeler for that rebate amount. We have determined that a maximum tolerance of \$50 per rebate period would be acceptable if State-supplied information establishes this as the reasonable cost of preparing a labeler's utilization data. In situations where the tolerance is applied, the State need not invoice the manufacturer, although it is free to establish its own tolerance below \$50 and continue to submit utilization data above that tolerance. (We note that, in either event, the unit rebate amount must have been supplied by HCFA for all of that manufacturer's drugs in that rebate period and the State applied that unit rebate amount to its utilization data. If the manufacturer fails to supply pricing information for a drug, the unit rebate amount would be zero or missing from the HCFA pricing file. In this case, the tolerance would not apply.) Further, the State would not be at risk of loss of FFP on that portion of the uncollected rebates within the tolerance limits.

The State should maintain supporting documentation that identifies the instances when the tolerance levels were applied. We believe our policy promotes efficiency by allowing States the authority to pursue only those rebate amounts that exceed the States' administrative costs associated with those rebate amounts. Our policy also alleviates States' concern that they may be liable for the Federal share of those rebates that are within the tolerance limits.

#### B. Reporting Requirements for Manufacturers

Section 1927(b)(3)(A) of the Act requires manufacturers to supply drug pricing information to HCFA. In addition to pricing data, we would require manufacturers to complete and submit to States Form HCFA-304, the Medicaid Remittance Advice Report (RAR), within 30 days of receiving State Medicaid utilization information. The RAR has been approved by OMB prior to publication of this proposed regulation (OMB approval No. 0983-0676). The basis and timeframes for meeting this requirement, as well as what information is required on the RAR, are discussed below.

##### 1. Timeframes for Reporting

Under the terms of the statute and the national rebate agreement, manufacturers must supply HCFA with a list of all covered outpatient drugs, the applicable baseline AMP, and, for single source and innovator multiple source drugs, best price within 30 calendar days of entering into the national rebate agreement. Manufacturers must update the list for each rebate period under the agreement to include AMP and, as appropriate, best price of drugs (both terms are discussed more fully below) and must report the update to HCFA no later than 30 days after the last day of each rebate period. We would incorporate these requirements in the regulations under § 447.534 (a) and (b).

In accordance with the dispute resolution process described in section V.F. of this preamble, and as set forth in regulations under § 447.536(b), we would require manufacturers to complete and submit to States the RAR within 30 days of receiving a State's Medicaid utilization information. We believe this requirement is necessary to effectuate the drug rebate provisions in OBRA '90, and to aid in the timely resolution of disputes and the timely payment of rebates.

##### 2. Content of Reporting

a. Manufacturer Reporting Requirements to HCFA. Section

1927(b)(3)(A)(i) of the Act requires that the manufacturer's list of covered outpatient drugs submitted under the rebate agreement must be updated by the manufacturer on a rebate period basis to include the AMP and, for single source drugs and innovator multiple source drugs, the manufacturer's best price.

(1) **Definition of Average Manufacturer Price (AMP).** As stated earlier, under section 1927(k)(1) of the Act, AMP means, with respect to a rebate period, the average unit price paid to the manufacturer for the drug in the States by wholesalers for drugs distributed to the retail pharmacy class of trade after deducting customary prompt pay discounts. We would incorporate the definition of AMP in § 447.534(c). Under this definition, sales that a manufacturer makes to other than the retail class of trade must be excluded. Thus, sales where the buyer relabels or repackages the drug with another NDC number and sales through wholesalers where the manufacturer pays a chargeback for sales to an excluded buyer, such as a hospital, would not be considered sales to the retail class of trade.

We would also exclude from this definition direct sales to hospitals, health maintenance organizations and to distributors where the drug is relabeled under that distributor's NDC number because these entities are not considered the retail pharmacy class of trade. We would also exclude Federal Supply Schedule (FSS) prices from the calculations of AMP since the statute does not include FSS and FSS does not represent a retail level of trade.

We have interpreted AMP to include cash discounts and all other price reductions and customary prompt pay discounts (other than rebates under section 1927 of the Act) that reduce the actual price paid. This definition comports with the statute and HCFA's understanding of Congressional intent as set forth in the legislative history. (H.R. Conf. Rept. No. 964, 101st Cong., 2nd Sess. 825 (1990).)

The manufacturer must calculate AMP as a weighted average price for all of its package sizes for each covered outpatient drug sold during that rebate period but only report a single AMP for the weighted average. AMP must be calculated as net sales divided by number of units sold, excluding goods or any other items given away that are not contingent on any purchase requirements. For bundled sales, the allocation of the discount is made proportionately to the dollar value of the units of each drug sold under the bundled arrangement. In this context,

bundled sale refers to the packaging of drugs of different product codes where the condition of rebate or discount is that more than one drug is purchased, or where the resulting discount or rebate is greater than that which would have been received had the drug products been purchased separately. Because we are defining the AMP to include cash discounts allowed and all other price reductions, we would require in § 447.534(c)(5) that the manufacturer adjust the AMP for a rebate period if cumulative discounts or other arrangements subsequently adjust the prices actually realized.

(2) **Definition of Best Price.** We have interpreted "best price," as defined in section 1927(c)(1)(C) of the Act, to mean, with respect to single source and innovator multiple source drugs, the lowest price at which the manufacturer sells the covered outpatient drug to any purchaser (as discussed later in this section of the preamble) in the United States (excluding the Territories). We would further interpret best price at § 447.534(d) to mean the lowest price in any pricing structure (including capitated payments) in the same rebate period for which the AMP is computed.

The best price must include cash discounts, free goods that are contingent on any purchase requirements, volume discounts, and rebates other than rebates under section 1927 of the Act. Best price must be determined on a unit basis without regard to special packaging, labeling, or identifiers on the dosage form or product or package, and will not take into account prices that are nominal in amount (that is, less than 10 percent of AMP). Unlike AMP, the best price is the single lowest price of the drug at the product code level during the rebate period and is not a weighted average.

For bundled sales, the allocation of the discounts is made proportionately to the dollar value of the units of each drug sold under the bundled arrangement. We would require the manufacturer to adjust the best price for a rebate period if cumulative discounts, rebates, or other arrangements subsequently adjust the prices actually realized. We believe this is consistent with our understanding of the statute and the Congress' desire that the Medicaid program benefit from the same discounts available to other bulk purchasers.

OBRA '93 amended section 1927(c)(1)(C) of the Act by adding to the definition of "best price" providers and health maintenance organizations (HMOs) as entities included in the best price calculation. This reflects our existing policy in this area as the result

of OBRA '90. The best price reflects any price of a manufacturer except those prices specifically exempted by the law. For purposes of best price we interpret "provider" to mean a physician, hospital and other health maintenance organizations or entities that treat individuals for illnesses and injuries or provide services or items in the provision of health care.

OBRA '93 amended section 1927(k)(3) to specify that any drug, biological, or insulin excluded from the definition of covered outpatient drug as a result of section 1927(k)(3) must be treated as a covered outpatient drug for the purpose of determining the drug's best price.

That is, any prices offered to the entities listed in section 1927(k)(3) of the Act must be included in a manufacturer's best price calculation even though drugs provided as part of these settings are not considered covered outpatient drugs.

Because of legislative changes, best price varies over time regarding the prices that are included and excluded from its definition. To identify these variances, we have separated them into the specific time periods.

(a) *Best Price Definition Effective January 1, 1991–October 27, 1991 and July 1, 1992–September 30, 1992.* For these periods, best price includes prices to wholesalers, retailers, providers, HMOs, nonprofit entities or governmental entities within the States (excluding depot prices and single-award contract prices of any agency of the Federal Government). "Depot prices" mean prices available to any depot of the Federal Government for purchase of drugs from a manufacturer through the depot system of procurement, irrespective of whether the drug products physically flow through the depot. "Depot" means any Federal warehousing facility and distribution arrangement whether: (1) Government owned and operated; (2) government owned and privately operated; or (3) privately owned and operated. The Department of Defense's (DOD's) Electronic Commerce Initiative (ECI), which is an electronic ordering system that ships drugs directly to Federal Government medical facilities that were previously shipped through the depot system, is included in this definition. "Single-award contract prices" mean prices under a contract between the Federal Government and a manufacturer resulting in a single supplier for a covered outpatient drug within a class of drugs.

Given the definition of best price provided in section 1927(c)(1)(C) of the Act, it is our opinion that the FSS prices must be included in the best price calculation for these periods, since FSS

prices are neither depot nor single award prices, which are the only statutory exclusions relative to best price. Since prices for drugs and biologicals that are either paid by the DVA or in contracts administered by the DVA are listed in the FSS, these prices must also be included in the best price calculation for these periods.

(b) *Best Price Definition Effective October 28, 1991–June 30, 1992.* For this period, best price includes prices to wholesalers, retailers, providers, HMOs, nonprofit entities, governmental entities within the States (excluding depot prices and single-award contract prices of any agency of the Federal Government). The Department of Veterans Affairs Appropriations Act (Public Law 102–139), enacted on October 28, 1991, provides that effective October 28, 1991, through either June 30, 1992, or the date of enactment of other DVA drug price legislation, whichever is earlier, prices for drugs and biologicals paid by the DVA, and drugs and biologicals sold under contracts administered by that Department that are listed in the FSS, shall not be considered in the Medicaid drug rebate calculation. Therefore, for the period October 28, 1991, through June 30, 1992, the definition of best price excludes FSS prices for drugs and biologicals paid by the DVA and drugs and biologicals sold under contracts administered by that Department that are listed in the FSS. (Note: In accordance with this legislation, manufacturers must reflect any sales of drugs or biologicals to the DVA or of drugs and biologicals sold under contracts with that Department that are listed in the FSS during the period of October 1, 1991, through October 27, 1991, in their best price for the fourth quarter of 1991 and again beginning in the rebate period starting July 1, 1992.)

(c) *Best Price Definition Effective October 1, 1992.* Beginning October 1, 1992, best price includes prices to wholesalers, retailers, providers, HMOs, nonprofit entities or governmental entities within the States (excluding depot prices and single award contract prices of any agency of the Federal Government). The Veterans Health Care Act broadened the exclusions from best price effective October 1, 1992. Section 601(a) of VHCA amends section 1927(c)(1)(C) of the Act to exclude from best price any prices charged on or after October 1, 1992, to the Indian Health Service, the DVA, a State home receiving funds under section 1741 of title 38 of the United States Code, the Department of Defense, the Public Health Services, or a covered entity described in section 1927(a)(5)(B) of the

Act; any prices charged under the FSS of the General Services Administration; or any prices used under a State pharmaceutical assistance program. Best price excludes depot prices and single-award contract prices of any agency of the Federal Government.

(3) Requirements for the List of Covered Outpatient Drugs. We would require that the manufacturer's list of covered outpatient drugs include the NDC numbers for all drugs currently marketed by the manufacturer and continue to list the NDC numbers for drugs that are no longer marketed until such time as it is no longer possible for a State Medicaid agency to properly make payment for the drug and report this payment to the manufacturer. We would require that a manufacturer continue to list an NDC number for a drug that it no longer markets because the manufacturer will be responsible for providing a rebate on the drug until the entire supply of the drug under an NDC has expired, the drug has been taken off the market, or, for other reasons, there no longer exists the potential that the drug may be dispensed under the manufacturer's NDC number (for example, the FDA recalls the drug or reverses its approval on an approved NDA). In addition, since the manufacturer must pay the rebate on State utilization data for up to 1 year after the rebate period in which the data are submitted (as discussed in section V.A.4. of this preamble), the manufacturer must continue to report the data during this period. A rebate would be calculated on drugs that are no longer marketed using the AMP and best price from the last rebate period reported for those drugs (§ 447.534(b)).

In accordance with the provisions of the rebate agreement and the May 1, 1991, Federal Register notice (56 FR 20006), and to implement the drug rebate provisions of OBRA '90, we would require the manufacturer to supply the following information:

- NDC number with labeler code, product code, and package size code;
- Period covered for rebates (rebate period and year);
- Product FDA registration name;
- Drug category of single source, innovator multiple source, or noninnovator multiple source;
- DESI drug indicator;
- FDA therapeutic equivalence explanation code;
- Unit type;
- Units per package size;
- Average manufacturer price (AMP);
- Base date AMP;
- Best price;
- FDA approval date;
- Date drug entered market;

- Drug termination date;
- Drug type (Rx/OTC indicator);
- Rounding adjustment factor; and
- Correction record flag.

The above information is needed to meet the requirements set out in section 1927 of the Act. To calculate the rebate amounts required for each manufacturer under section 1927(c) of the Act, we need specific information to identify the manufacturers, drugs, prices, number of units sold, and the time period covered. The drug category is used to determine which rebate calculation to apply. The FDA approval date and the date the drug entered the market are necessary to determine baseline AMP for drugs approved by the FDA after October 1, 1990. The drug termination date is necessary to avoid making payment for a drug that is no longer on the market. The FDA registration name, DESI drug indicator, FDA therapeutic equivalence code, and the drug type indicate whether the drug meets the definition of a covered outpatient drug in sections 1927(k)(2) and (4) of the Act, and allow States to properly exclude drugs under section 1927(d)(2) of the Act. The rounding adjustment factor is supplied for drugs sold in decimal quantities and is used by a State when the quantity of a drug has been rounded up. The correction flag signals that the record contains corrected information from a previous submission.

(4) Rounding Adjustment Factor. We would establish a requirement that manufacturers include a rounding adjustment factor for those drugs sold in decimal quantity sizes, for example, a 1.4 gram of ointment. We have determined that this requirement is necessary to effectuate the OBRA '90 drug rebate provisions because, as described in section V.A.6. of this preamble, some pharmacies lack the capability to report decimal quantities of drugs to the State agencies. In this situation, the pharmacy rounds the utilization data upward so that a 1.4-gram tube is reported as a 2-gram tube. Rounding up is the pharmacy industry standard and is a common practice in all States that round decimal quantities of drug utilization data. Since, in this case, the rebate amount is calculated on a unit basis of grams, the manufacturer may be invoiced for an excessive rebate amount. Thus, the use of a rounding adjustment factor can reduce the amount of disputes for decimal quantity packages. Therefore, we would require manufacturers to provide a rounding adjustment factor for each of their rebate period pricing data submitted to HCFA for those drugs sold in decimal quantities.

As described in section V.A.6. of this preamble, we would also require States to identify for manufacturers those utilization data by NDC number that have been rounded. Therefore, HCFA will submit the rounding adjustment factors to the States with the rebate period unit rebate amount information. This will enable States that round decimal quantity packages to apply the rounding factor to its data before submitting utilization data to the manufacturer. Such data will help ensure that rebates are an accurate reflection of the units paid during a rebate period.

We will issue specific program instructions to States and manufacturers regarding the use of the rounding adjustment factor.

The requirements for reporting the rounding adjustment factor for manufacturers and the requirements for States to identify rounded utilization data with the rounding indicator, as described in section V.A.6. of this preamble, would be effective 60 days following publication of the final rule. That is, the rebate period pricing data submitted to HCFA by manufacturers for that rebate period must include the rounding adjustment factor for those applicable NDCs. We believe this allows sufficient time for manufacturers and States to implement the rounding requirements.

As stated earlier, section 1927(b)(3)(A)(i) of the Act requires that the manufacturer's list of covered outpatient drugs submitted under the rebate agreement be updated by the manufacturer on a rebate period basis to include the AMP and, for single source drugs and innovator multiple source drugs, the manufacturer's best price. We will issue program instructions to manufacturers to update the data elements, as needed, to further program objectives in this area.

**b. Manufacturer Reporting Requirements to States.** We would require manufacturers to complete and submit to States Form HCFA-304, the Medicaid Remittance Advice Report (RAR). The RAR has been approved by OMB prior to publication of this proposed regulation (OMB approval No. 0938-0676). The RAR is a mandatory form that provides a uniform format for manufacturers to report the remittance of rebate payments to States, adjustments to previous rebate period payments, and disputed rebate amounts. The RAR is available in two formats, electronic and paper, depending on the preference of the manufacturer. Each participating manufacturer would be required to complete and submit the RAR to States within 30 days of

receiving State Medicaid drug utilization information. In addition to reporting regular rebate period rebates and disputed amounts, manufacturers would use the RAR on an unscheduled basis when the States need the RAR to process adjustments to prior periods. The regulations pertaining to the RAR are found in §§ 447.534(f) and 447.536(b).

HCFA developed the RAR in response to a need for improved data exchange between manufacturers and States. In order to develop the RAR to meet the needs of both manufacturers and States, HCFA convened several dispute resolution conferences beginning in February 1992. These conferences were attended by groups representing manufacturers, pharmacists, States and HCFA. HCFA received suggestions from these groups to help develop a uniform reconciliation report to improve data exchange between manufacturers and States, to enable States to verify rebate payments, and to provide a vehicle for manufacturers to identify specific disputed amounts. HCFA considered these suggestions in preparing the final version of the RAR.

The RAR will function as a reconciliation report with the intent of reducing disputes by standardizing data exchange and improving communication between manufacturers and States regarding Medicaid utilization data, rebates, adjustments, and disputes. For these reasons, we have determined that the requirement for the completion and submission of the RAR is necessary to effectuate the OBRA '90 drug rebate provisions and to provide for the efficient administration and function of the Medicaid drug rebate program as required under section 1927 of the Act.

The RAR includes the following information:

- Manufacturer name;
- Labeler code;
- Manufacturer address;
- Name of manufacturer contact person;
- Telephone number of contact person;
- Facsimile (FAX) number of contact person;
- State;
- Rebate period and year for which the information applies;
- Invoice number, if State provided one;
- NDC number;
- Product name;
- Rebate amount per unit;
- Units invoiced;
- Rebate amount invoiced;
- Rebate amount paid;
- Adjusted rebate per unit, if applicable;

- Adjustment code, if applicable;
- Credit/debit indicator, if applicable;
- Adjusted invoice amount, if applicable;
- Units disputed, if applicable;
- Dispute code, if applicable;
- Withheld invoice amount, if applicable;
- Total rebate amount invoiced;
- Total rebate amount paid;
- Total adjusted invoice amount, if applicable; and
- Total withheld invoice amount, if applicable.

These data elements will be updated, as needed, through separate instructions to further program objectives in this area. We would incorporate the basic reporting requirements and timeframes in our regulations at § 447.534(f).

We believe the above information is needed for the State to identify and verify rebates per NDC and reconcile any disputed amounts as a result of the requirements set forth in section 1927 of the Act and these regulations. We further believe the information is necessary for HCFA to more accurately monitor the operation of the drug rebate program. To verify the rebate amounts paid as calculated under section 1927(c) of the Act, or to reconcile any disputed amounts, it is essential that the information contained in the RAR identify the manufacturers, drugs by NDCs, rebate amounts per units, units invoiced, rebate amounts invoiced, and rebate amounts paid, as well as any adjusted rebate amounts, reasons for any adjustments, units disputed, reasons for any disputed amounts, and any withheld invoice amounts, if applicable. We would also require that manufacturers separately report supporting documentation if a State requests it to verify the information contained on the RAR.

**c. Prior Period Adjustments.** A prior period adjustment is a change in the unit rebate amount based on a manufacturer's revised AMP or best price data for a prior rebate period after that rebate period's pricing data has been submitted to HCFA. HCFA uses the manufacturer's pricing data to generate the unit rebate amount for each 9-digit NDC which States use to calculate rebate amounts due from manufacturers. Any changes to a manufacturer's AMP or best price result in changes to the unit rebate amount and rebates due from the manufacturer. Thus, prior period adjustments are necessary to correct rebate amounts that are owed by manufacturers or credits due to manufacturers.

We would establish a time limitation of 3 years during which prior period adjustments will be generated based on

revised AMP or best price data from manufacturers. Therefore, we would require manufacturers to report changes to AMP or best price for 3 years after the rebate period to which the data pertains (§ 447.534(h)). No prior period adjustments will be generated for a quarter more than 12 quarters prior to the current quarter. For example:

(1) No prior period adjustment pertaining to the rebate period ending December 31, 1991, may be generated after December 31, 1994.

(2) All prior period adjustments pertaining to the rebate period ending June 30, 1992, must be generated prior to July 1, 1995.

We believe this 3-year timeframe is reasonable since it is consistent with the record retention requirements we would establish under § 447.534(g)(1). That is, we would require manufacturers to retain records (written or electronic) for 3 years after the date the manufacturer reports its rebate period AMP or best price. This 3-year time-frame also comports with the requirements for the maintenance of records on State Medicaid expenditures imposed on States. (See section V.C. of the preamble for a discussion of the record retention requirements.)

The 3-year timeframe during which manufacturers must report changes to AMP or best price parallels the record retention period and the possible corrective actions from audits during this 3-year period. During this timeframe, a manufacturer's records on the drug rebate program could be audited with findings that result in an adjustment of pricing information and rebate payments. Thus, any changes to AMP or best price should also be required during this 3-year timeframe.

After States receive prior period adjustments from HCFA on the quarterly pricing file, States should calculate the difference between the original and revised unit rebate amounts and adjust the rebate amounts due from or credited to manufacturers.

We note that changes to the unit rebate amount from prior period adjustments cannot be disputed by manufacturers nor handled through the normal dispute resolution mechanism because this information is reported by manufacturers to HCFA. Any discrepancies in the unit rebate amounts should be reported to HCFA for clarification and resolution. HCFA will review all pricing information changes that result in a revised unit rebate amount.

### C. Recordkeeping Requirements

#### 1. AMP and Best Price Calculations

Section 1927(b)(3)(B) of the Act gives the Secretary the authority to survey a manufacturer's records and data to verify the pricing information reported under section 1927(b)(3)(A) of the Act. To facilitate such surveys, we would require under § 447.534(g) that a manufacturer must retain for 3 years from the date the manufacturer reports that rebate period's data, all records (written or electronic) of the data and any other materials from which the calculations of the AMP and best price were derived. A manufacturer must retain records beyond the 3-year period if audit findings related to the AMP and best price have not been resolved. In addition, if the manufacturer makes reasonable assumptions in its calculations of AMP and best price, the manufacturer must also maintain a written or electronic record outlining these assumptions. We will consider reasonable assumptions to include: that the AMP can never be zero or a negative number; that the methodology used to determine base date AMP, as well as AMP and best price, is used consistently for all rebate period calculations; and that accounting methods are in accordance with generally acceptable accounting principles and conform to the manufacturer's tax reporting accounting policies.

We would require manufacturers to maintain records for 3 years since this time period is necessary to verify the accuracy of information received. Also, the 3-year time period comports with the requirements for the maintenance of records on State Medicaid expenditures imposed on States. Regulations at § 433.32 require that States retain records for 3 years from the date of submission of a final expenditure report for FFP. Therefore, we believe that manufacturers should also maintain records for this same timeframe, in the event that manufacturers' records on the drug rebate program are audited and the audit results in an adjustment of pricing information and rebate payments.

#### 2. Dispute Resolution Process and RAR

The dispute resolution process described in section V.F. of this preamble and § 447.536 would require that both States and manufacturers maintain supporting documentation at various stages of the dispute resolution process. For example, manufacturers and States must maintain supporting documentation for certain types of disputes indicated on the RAR, data inconsistencies, and agreements reached between both the manufacturer and

State in settling a dispute. States must also maintain documentation if States choose to cease the dispute resolution process based on the cost effectiveness thresholds. Thus, in § 447.534(g)(2) we would require both States and manufacturers to keep all supporting documentation required under the dispute resolution process and in conjunction with the RAR for a 3-year period from the date the dispute is resolved between the manufacturer and the State.

As discussed in section V.C.1. of this preamble, States are required to maintain records on State Medicaid expenditures for 3 years from the date of submission of a final expenditure report for FFP. The final expenditure report for FFP must contain any rebate payment adjustments as a result of the final dispute settlement (§ 447.534(g)(2)).

We would require manufacturers to maintain supporting documentation for this 3-year period under our general rulemaking authority since this requirement comports with the State maintenance of record requirements and is necessary to effectuate the provisions of OBRA '90 and the dispute resolution process.

### D. Confidentiality of Reported Information

In accordance with section 1927(b)(3)(D) of the Act (as amended by VHCA), we would specify in § 447.540(a) that manufacturer-specific pricing information disclosed by the manufacturer in connection with the rebate agreement is confidential and, notwithstanding other provisions of law (including the Freedom of Information Act (FOIA), 5 U.S.C. 552), must not be disclosed by the Secretary of HHS, the Secretary of Veterans Affairs, the State Medicaid agency or its contractors in a form that reveals the manufacturer or wholesaler, or prices charged by the manufacturer or wholesaler, except as necessary for:

- The Secretary to carry out the provisions of section 1927 of the Act;
- The Comptroller General to review the information provided; and
- The Director of the Congressional Budget Office to review the information provided.

Based on this explicit confidentiality language, HCFA is prohibited from disclosing specific manufacturer data that identify the base date AMP, AMP, best price, unit rebate amount, or the total rebate amount claimed. We believe that it is reasonable to expect that disclosure of any of these data would lead to the identity of a manufacturer and its prices. We do not believe,

however, that this prohibits us from releasing data in a non-manufacturer specific or aggregate form, such as that required in section 1927(i) of the Act, which describes the information to be included in the Secretary's annual report regarding the operation of the drug rebate program. Under this section, the Secretary must include in the annual report such information as the total value of rebates received and the number of manufacturers providing such rebates, and the effect of inflation on the value of rebates required under the drug rebate program.

While we are not precluded from releasing AMP and best price to the States (inasmuch as the confidentiality provisions of section 1927(b)(3)(D) of the Act contemplate such release), we have determined that supplying the specific unit rebate amount to the States, as opposed to other pricing data, will give States sufficient information to invoice and verify rebate payments.

States are prohibited from releasing any manufacturer-specific pricing data supplied by HCFA in relation to the drug rebate program. States are also prohibited from releasing these data to individual pharmacists or pharmacy groups. However, release of a State's utilization data, excluding manufacturer-specific pricing data, is permitted to the extent it is allowed under Federal or State confidentiality laws.

These confidentiality provisions will remain in full force and effect on the States and HCFA, regardless of the nonrenewal or termination of the rebate agreement. The statute does not specify that the confidentiality provisions are limited to the period when an agreement is in effect.

#### *E. Penalty for Failure to Report Information or for Reporting False Information*

Section 1927(b)(3)(B) of the Act provides that the Secretary may survey wholesalers and manufacturers that directly distribute their covered outpatient drugs, when necessary, to verify manufacturer prices reported to HCFA. The Secretary may impose a civil monetary penalty in an amount not to exceed \$100,000 on a wholesaler, manufacturer, or direct seller of a covered outpatient drug if the wholesaler, manufacturer, or direct seller refuses a request for information about charges or prices by the Secretary in connection with a survey or knowingly provides false information. The provisions of section 1128A of the Act regarding civil monetary penalties (except for subsections (a) (with respect to amounts of penalties or additional

assessments) and (b)) apply to the imposition of these penalties in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

If a manufacturer fails to provide the required information on AMP and best price or the list of covered outpatient drugs, the amount of the civil money penalty is \$10,000 for each day beyond the due date that the information is not provided. We have included the list of covered outpatient drugs as a required item because we believe it is a necessary component of the pricing information required by the statute. The corresponding drug identifiers provided by the list of covered outpatient drugs, such as NDC numbers, names, and package sizes, are needed to accurately verify the pricing information of the vast number of drugs on the market. If all of the required information is not reported within 90 days of the required timeframe, HCFA is authorized to suspend the drug rebate agreement after the end of that 90-day period and continue the suspension until the information is provided. The suspension period must not be for less than 30 days. A manufacturer will continue to be responsible for rebates on drugs covered during the period the agreement was not suspended.

Any manufacturer with an agreement, that knowingly provides false information, will be subject to a civil money penalty in an amount not to exceed \$100,000 for each item of false information. These penalties are in addition to other penalties prescribed by law. The provisions of section 1128A (other than subsections (a) and (b)) apply to a civil money penalty under this paragraph in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a). We would incorporate these provisions under § 447.542.

#### *F. Dispute Resolution for Medicaid Utilization Information*

##### 1. Background

As required under section 1927(b)(1) of the Act, a manufacturer must provide to each State a rebate for covered outpatient drugs within 30 days after receipt of the State utilization information. For purposes of the Medicaid drug rebate program, and, as set forth in section II.(b) of the national rebate agreement, the manufacturer is responsible for timely payment of the rebate amounts within 30 days of receiving, at a minimum, information, by NDC number, on the number of units reported by the State. Additionally, section V.(b) of the national rebate

agreement sets forth broad guidelines for a dispute resolution process for States and manufacturers to follow in cases where the manufacturer believes the State utilization data are erroneous. We would clarify these guidelines and timeframes for dispute resolution in these regulations.

The resolution of disputes has been a source of concern for manufacturers and States alike. The type of process needed to resolve disputes over utilization data is unique to the drug rebate program under Medicaid. Because these disputes often do not involve legal issues but can be resolved by exchange of information and refinement of data collection methods through discussions between the principals, the process must provide a full opportunity for such resolution before any proceeding before a hearing officer (the method commonly used to resolve other types of disputes). There are no existing regulations, under either the Medicaid or Medicare program, that can be applied to this dispute process. Likewise, there are no regulations that could be used as a model for developing the dispute resolution requirements.

Recognizing the need for improvements in this area, HCFA convened a meeting in February 1992 on dispute resolution with members of organizations representing manufacturers, pharmacists, and States. At that meeting, we discussed the concerns of the participants relating to dispute resolution. A workgroup was formed from the conferees to explore ways in which HCFA could develop a uniform set of guidelines for States and manufacturers to follow in the resolution of disputes.

In May 1992, the conferees reconvened and recommendations of the workgroup were discussed. As a result of the meetings and suggestions received from participants, HCFA decided to provide more detailed requirements in the area of dispute resolution. In part, we have established a two-phase process for settling disputes. Phase I involves the manufacturer and State working jointly to resolve the dispute. Phase II involves using the State hearing process or an arbitrator or mediator to help resolve the dispute. We would identify specific steps and timeframes within each phase for the resolution of disputes and have incorporated them into our regulations at § 447.536. We believe these requirements are necessary to effectuate the drug rebate provisions of OBRA '90, and to ensure that rebates are paid in a timely manner.

Under phase I of the process, there is a 240-day timeframe after the State receives the manufacturer's RAR for the

States and manufacturers to seek resolution of the dispute through exchange of information and informal negotiation. If both parties cannot reach a resolution within this timeframe, they must take one of several actions described in Step 4 of phase I or proceed to phase II of the dispute resolution process.

Under phase II of the process, the State must schedule a hearing to settle the dispute. Proceeding to phase II to settle disputes is generally done after all steps in phase I have been completed. However, either a State or a manufacturer may proceed to phase II if either party has not fulfilled its obligations under any step in the first phase of the process. For example, the manufacturer may request that the State schedule a hearing at any stage of the dispute resolution process if the State fails to perform required phase I actions within the specified timeframes. Conversely, the State may schedule a hearing at any stage of the process if the manufacturer fails to perform required phase I actions within the specified timeframes, and/or request HCFA, through the HCFA Regional Office (RO), to terminate the manufacturer's national rebate agreement.

We believe the timeframes established for each of the steps in the first and second phases of the dispute resolution process are reasonable for both States and manufacturers based on our experience to date with the drug rebate program, and based on feedback from States and manufacturers in compiling such data and working with the original dispute resolution process under the national rebate agreement. The timeframes established in these proposed regulations were extensively discussed with the workgroup participants for the dispute resolution process. We believe that delaying the payments of rebates due to a more time-consuming dispute resolution process would harm both States and manufacturers. Rebates are needed on a predictable basis to reduce State expenditures for drugs and to allow States to estimate future budgeting for drug spending based on expected rebates. Longer timeframes could result in the manufacturer being liable for substantial amounts of interest accruing on disputed data.

Therefore, to effectuate the OBRA '90 drug rebate provisions and to ensure that rebates are paid in a timely manner, we would require manufacturers and States to comply with the process and timeframes outlined in this section of the preamble beginning with disputes associated with data for the rebate period occurring 60 days following

publication of the final rule. We believe this timeframe is sufficient since both manufacturers and States have had extensive experience in handling a variety of disputes since 1991. Disputes in existence prior to this rebate period would not be subject to the dispute resolution requirements of the final rule, as in some cases the applicable timeframes will already have passed. However, we expect such disputes to be resolved as quickly as possible or the State hearing process, as specified in the initial rebate agreement, to be made available to the manufacturer by the State.

While current State law may not include manufacturers as "providers" under State Medicaid programs, for purposes of these proposed regulations, we would require States to provide a hearing which we anticipate will involve the same procedure as provider hearings. There are no specific Federal requirements that govern this hearing process. In these regulations, we would not establish any new requirements or criteria for this process, except for the overall timeframe for the conduct of the hearing.

## 2. Identifying and Resolving Data Inconsistencies Prior to Phase I of the Dispute Resolution Process

In general, within prescribed timeframes after a State submits to a manufacturer the Medicaid utilization information, the manufacturer must review the data and pay a rebate on the undisputed portion. The disputed portion of the data must be resolved through the dispute resolution process. However, to prevent both phase I and phase II of the process from being used to handle disputes involving data inconsistencies, we would require both States and manufacturers to take certain actions, as discussed below, to resolve data inconsistencies before they initiate phase I of the dispute resolution process. We would consider data inconsistencies to be data errors unrelated to actual utilization, such as incorrect NDC numbers, unit types, or decimal positions (§ 447.536(a)).

The dispute resolution process is a costly and time-consuming activity for all parties, delays the payment of rebates for disputed data, and causes interest to accrue on disputed amounts. Therefore, to effectuate the drug rebate provisions of OBRA '90 and to ensure the timely payment of rebates, we would require in § 447.536(a) that manufacturers attempt to identify and resolve State Medicaid utilization data inconsistencies with the State no later than 30 days after receipt of the data. We believe that requiring States and

manufacturers to resolve data inconsistencies during the 30-day period before a manufacturer must pay a rebate on the undisputed data will result in timely rebates being paid for a larger percentage of State utilization data and reduce the volume of data involved in disputes. Thus, administrative costs incurred from the dispute resolution process would be reduced for both States and manufacturers.

Examples of data inconsistencies that manufacturers must screen for are items such as:

- Incorrect unit types;
- Reported NDC numbers failing to match manufacturer's NDC numbers; and
- Incorrect decimal position in units reported.

If, in any rebate period, a manufacturer discovers discrepancies in a State's utilization data, the manufacturer must distinguish between disputes that will require further resolution and data inconsistencies before initiating phase I of the dispute resolution process. If data inconsistencies are detected, a manufacturer must contact the State, identify the inconsistencies, and propose possible corrective actions. Examples of an attempt by the manufacturer and State to resolve these data inconsistencies could involve:

- Verifying that unit types are appropriate for the product;
- Examining the data to verify that the total number of units is appropriate for the amount paid; and
- Matching State-reported NDCs to the manufacturer's NDCs.

If an agreement is reached and the data inconsistencies are resolved, both the State and manufacturer must maintain written documentation of the resolution. The manufacturer must record the resolution of data inconsistencies on the RAR. If these preliminary attempts to resolve the data inconsistencies fail, the manufacturer and State must initiate phase I of the dispute resolution process as described below.

## 3. Steps in the Dispute Resolution Process

*a. Steps in Phase I of the Dispute Resolution Process.* Phase I of the dispute resolution process is divided into four steps. These steps describe the actions that manufacturers and States must take and specify the timeframes within which the actions must be completed. The HCFA RO will monitor the dispute resolution process, and problems that occur in the process

should be referred to the appropriate RO.

Step 1: Manufacturer Submits RAR to State (To be completed within 30 days after the manufacturer receives State utilization information)

In the event a manufacturer discovers a discrepancy in the Medicaid utilization information that the manufacturer and the State are unable to resolve within the 30-day timeframe, as discussed in section V.F.2. of this preamble, the manufacturer must complete the following actions:

- Pay the rebate on undisputed data and provide written notice of any discrepancies by submitting the RAR to the State Medicaid agency. The manufacturer may, at this time, pay rebates on the disputed portion of the data;
- Ensure that the RAR is postmarked by the United States Postal Service or common mail carrier no later than 30 days after receipt of State data; and
- Identify on the RAR, among the other requirements of that form, the reason(s) why the data are disputed, by NDC number, and, if the entire amount of the rebate is not paid, why the disputed portion of the rebate is withheld.

We would require the manufacturer to submit supporting documentation with the RAR for certain types of disputes, as indicated on the RAR. The manufacturer must submit supporting documentation for other types of disputes if a State requests it to verify information contained on the RAR. This support will allow the State to verify the dispute and submit relevant information in the next step to move towards a resolution.

Interest begins to accrue on the withheld portion of rebates for disputed data on the 31st day after the manufacturer receives State data. Interest ceases to accrue only when payment is made for both rebates and accumulated interest, or an excess payment is refunded, consistent with the resolution of the dispute.

Step 2: State Responds to Manufacturer Regarding Disputes Identified on RAR (To be completed within 90 days after the State receives the manufacturer's RAR).

Within 90 days after the State receives the manufacturer's RAR, the State must complete two actions. First, the State must contact the manufacturer to discuss, by NDC number, the items disputed and the reasons why the manufacturer is disputing the items. Second, the State must present its preliminary response on the items identified on the RAR as being in dispute. Both the State and manufacturer must maintain

documentation of the items disputed and the State's preliminary response to the manufacturer.

Step 3: Exchange of Data and Negotiations Between Manufacturer and State (To be completed within 150 days after the State receives the manufacturer's RAR).

Within 150 days after the State receives the manufacturer's RAR, the State must take definitive steps, as discussed below, to resolve the disputed items. If State confidentiality laws allow, we would require that the State provide the manufacturer with zip code or pharmacy-level data, a sampling of pharmacy claims, or historical trends data on such items as the manufacturer may have found in dispute. We would require the State to provide the manufacturer with the same type of data that the manufacturer used to dispute the rebate payment. That is, if the manufacturer based its dispute on pharmacy-level data, the State must provide pharmacy-level data to enable the manufacturer to analyze and compare the two sources in an effort to resolve the discrepancies. We would define zip code-level data or pharmacy-level data as a report by NDC number for a particular covered outpatient drug dispensed by pharmacies within a particular zip code or dispensed by a particular pharmacy respective to Medicaid recipients.

We believe these requirements for data exchange between States and manufacturers are necessary to effectuate the OBRA '90 drug rebate provisions and to resolve disputes in a timely manner. Without additional like data to substantiate or refute disputes, neither party may be able to resolve the discrepancies and, thus, further delay the payment of rebates and increase the amount of interest accruing on disputed rebates. Further, if the State disagrees with the manufacturer on the disputed items, the State must provide the manufacturer with this further breakdown of data or other reasons to support its position. Otherwise, the process may reach an impasse if the State and the manufacturer have no basis to resolve the underlying dispute.

Both the State and the manufacturer must ensure that any exchange of data protects the confidentiality requirements of section 1927(b)(3)(D) of the Act. Specifically, the statute prohibits disclosure by the State of any information that would disclose the identity of the manufacturer or the prices of the manufacturer's drugs.

Furthermore, if State confidentiality laws prohibit the release of certain data, such as pharmacy specific data, the State may require the manufacturer to

supply to the State the data on which it based its dispute. If the manufacturer supplies the State with like data in this situation, we will consider the manufacturer to have satisfied this data exchange requirement and to be in compliance with the requirements under this step of phase I of the dispute resolution process.

Step 4: Post-Negotiations Decision (To be completed within 240 days after the State receives the manufacturer's RAR) Within 240 days after the State receives the manufacturer's RAR, the negotiations between the State and the manufacturer must be completed and one of the following options must be chosen and acted upon:

- The State may decide to cease the dispute resolution process based on its cost-effectiveness determination as described in section V.F.6 of this preamble. However, the State maintains the discretion to continue the dispute resolution process for disputed amounts that fall below the thresholds. Further, the State must maintain adequate documentation to support its determination to discontinue the dispute based on cost-effectiveness or maintain adequate documentation that clearly describes any settlement reached with a manufacturer.

- The State and the manufacturer may agree to a settlement based on the State's Medicaid utilization information.

- The State and the manufacturer may agree to a settlement based on valid documentation that other data were more representative of the actual Medicaid utilization.

- If none of the above settlements are reached, the State and manufacturer must proceed to phase II of the process to settle the dispute.

*b. Phase II of the Dispute Resolution Process.* Phase II of the dispute resolution process is initiated when the dispute is not resolved in step 4 of phase I, or when either party does not comply with the requirements under any of the phase I steps and either the manufacturer or State wants to proceed to phase II. In either case, under phase II the State must schedule a hearing within 30 days from the end of the phase I process, or within 30 days from the date the manufacturer or the State chooses to proceed to phase II due to noncompliance. We would require that the hearing be conducted no later than one year from the 240th day after the State receives the manufacturer's RAR (§ 447.536(d)). The State and the manufacturer could continue to attempt to settle the dispute between themselves before the hearing is conducted. However, we would require that the hearing be scheduled and conducted, if

still necessary, within the one-year timeframe.

In lieu of a State hearing, the State and the manufacturer may agree to arbitration or mediation to settle the dispute. In this case, we would require the State to maintain documentation that clearly describes the agreement with the manufacturer to settle the dispute through arbitration or mediation rather than a State hearing (§ 447.536(e)).

After the dispute is resolved, the disputed amount plus the rate of interest, as set forth in section 1903(d)(5) of the Act, must be paid or credited on the entire balance by the manufacturer or the State no later than the due date of the next rebate period payment. As noted in section V.F.4 of this preamble, interest would begin to accrue 38 calendar days from the date the State mails its Medicaid utilization information to the manufacturer. Interest would continue to accrue until the date payment is made or excess payment is refunded for the part of the disputed Medicaid utilization information that the State and manufacturer agree is appropriate, as resolved through the dispute resolution procedures set forth in this section.

4. Interest Rate under Section 1903(d)(5) of the Act

The interest rate under section 1903(d)(5) of the Act is the average of the yield of the weekly 90-day Treasury bill auction rates during the period for which interest will be charged. For purposes of section 1903(d)(5) of the Act, the investment yield is considered the bond equivalent rate or the true discount rate. HCFA will supply the manufacturers and States with the rates to assure that both parties are using the same interest rates in the calculation.

Interest would be applied to disputed or unpaid amounts and late rebate payments but not to prior period adjustments of unit rebate amounts or State utilization adjustments.

Interest would begin accruing 38 calendar days from the date the State mails the State utilization data, as evidenced by the postmark by the United States Postal Service or other common mail carrier on the envelope (not a postage meter stamp). We would allow 7 additional days (from the 31st day after utilization data are sent from a State) to begin the interest clock which will allow time for receipt of the mailing by the manufacturer. For documentation purposes, we would require States to maintain a record of the date of mailing and manufacturers must maintain the envelope bearing the postmark from the State.

Interest accrues on the disputed portion of the rebate amount or on the total amount of the late rebate payment for all rebate periods beginning January 1, 1991 and only stops accruing on the date the check is disbursed. We would consider the date of disbursement to be the date the check is mailed by the manufacturer. Interest must be collected and may not be disregarded as part of the dispute resolution process by the State or manufacturer.

Interest calculation is based on a 365-day year with simple interest applied to the average of the yield of the weekly 90-day Treasury bill auction rates during the period for which interest will be charged. (For purposes of this calculation, include the rate for the entire week if the beginning and/or ending date fall within that week.)

The following formula and example illustrate how interest should be calculated:

Obtain yield rates (bond equivalent rates) for period involved:

Auction dates	Yield rates (Percent)
March 1, 1993 .....	3.035
March 8, 1993 .....	3.043
March 15, 1993 .....	3.064
March 22, 1993 .....	3.003
March 29, 1993 .....	3.022

(a) Total the yield rates of each weekly auction of 90-day Treasury Bill. Total = 15.167%

(b) Divide the total from (a) by the number of rates to determine the average interest rate.

15.167% divided by 5 = 3.0334% = Average Interest Rate.

(c) Multiply average interest rate by amount of unpaid rebate.

\$1,000 × 3.0334% = \$30.33 Amount of Interest Due.

(d) Divide the amount of the interest due by 365 days to obtain the amount of interest due per day.

\$30.33 divided by 365 days = \$.08309 = Amount of Interest Due Per Day.

(e) Multiply daily amount of interest due per day by the number of days the unpaid rebate amount is outstanding.

\$.08309 × 29 days (March 4, 1993–April 1, 1993) = \$2.41 Total Interest Due.

5. Manufacturer's Right To Audit Data

The manufacturer retains the right provided under section 1927(b)(2)(B) of the Act to audit the Medicaid utilization information reported (or required to be reported) by the State. While not mandated by the statute or this regulation, but as specified in the national rebate agreement, we encourage the manufacturer and the State to

develop mutually beneficial audit procedures that promote a cooperative relationship that saves time and money for both parties.

Adjustments to rebate payments will be made if information indicates either that Medicaid utilization were greater or less than the amount previously specified, or that other information is inaccurate (for example, a drug is not properly classified as a single source, innovator multiple source, or noninnovator multiple source drug that affects the amount of rebates).

6. Cost-Effectiveness of Dispute Resolution

In some cases, a State may consider that engaging in continued attempts to resolve a dispute with a manufacturer is not cost-effective in that the State resources required to settle the dispute exceed the amount in dispute, or that the accuracy of the utilization data can be established only to a certain degree. Many States have expressed concern that guidelines are needed to determine cost-effectiveness tolerance limits for the dispute resolution process. Thus, to effectuate the OBRA '90 drug rebate provisions in the most efficient manner, we would establish the following cost-effectiveness tolerance limits for States.

For any rebate period, a State need not proceed into further dispute resolution process steps beyond final negotiations (Step 4 of phase I) with a manufacturer if the disputed amount is (1) under \$10,000 per manufacturer's labeler code, and (2) under \$1,000 per product code. States must maintain supporting documentation of the determination that may be subject to review by the Department. Further, when a State decides to cease the dispute resolution process based on these cost-effectiveness criteria and adequately documents that the process is not cost-effective, as discussed above, FFP will generally be available for the drugs dispensed and the Federal portion of the rebate will generally not be required from the State.

States maintain the discretion to proceed with the dispute resolution process in cases that fall below the thresholds described in this section. We believe this policy provides States with the flexibility to determine the merits of pursuing disputed rebates in terms of cost-effectiveness.

VI. Formulas for Computation of Amount of Drug Rebates

Section 1927(c) of the Act specifies that each manufacturer must remit a basic rebate and an additional rebate to the State Medicaid agency for single source drugs and innovator multiple

source drugs, and a rebate for covered outpatient drugs other than single source and innovator multiple source drugs. We would require in regulations at § 447.546(a) and (b) that the manufacturer must make timely payment of the rebate, that is, within 30 days of receiving State Medicaid utilization information that includes, at a minimum, the number of units paid by NDC number during the rebate period under the approved State plan. We would also require in § 447.546(a)(3) that the manufacturer continue to make rebate payments for all of its covered outpatient drugs for as long as an agreement is in force and utilization information reports are made. Also, a rebate payment would be required for all drugs until the entire supply of the drug under an NDC number has expired; the drug has been taken off the market; or, for other reasons, there no longer exists the potential that the drug may be dispensed under the manufacturer's NDC number or paid for and a rebate requested by the State Medicaid agency.

Section 1927(c) of the Act specifies the formulas to be used to compute the rebates as follows:

*A. Rebate for Noninnovator Multiple Source Drugs*

The rebate for noninnovator multiple source drugs is—

For October 1, 1992—December 31, 1993: 10 percent of the AMP.

For January 1, 1994, and thereafter: 11 percent of the AMP.

*B. Basic Rebate for Single Source Drugs and Innovator Multiple Source Drugs*

In general, section 1927(c)(1)(B) of the Act, as established under OBRA '90, provided for the following basic rebate for single source drugs and innovator multiple source drugs:

For January 1, 1991—December 31, 1991:

The greater of 12.5 percent of the AMP or the AMP minus best price. (The rebate is capped at 25 percent of AMP.)

For January 1, 1992—December 31, 1992:

The greater of 12.5 percent of the AMP or the AMP minus best price. (The rebate is capped at 50 percent of AMP.)

For January 1, 1993 and thereafter: The greater of 15 percent of the AMP or the AMP minus best price. (The rebate is not capped.)

Section 601(c) of VHCA amended section 1927(c)(1)(B) of the Act to account for a budget neutrality adjustment to the basic rebate for single source drugs and innovator multiple source drugs. This budget neutrality adjustment was established to offset a

reduction in rebates resulting from the additional exclusion of prices from the best price calculation required under section 601(a) of VHCA. On April 12, 1993, the Veterans Health Care Act of 1992—Technical Corrections (Public Law 103–18) was enacted. Section 2(a) of Public Law 103–18 amended section 1927(c)(1)(B)(ii)(II), as amended by section 601(c) of VHCA, to restore the 50 percent rebate cap for the rebate period October 1, 1992, through December 31, 1992. This amendment is effective as if it were included in the enactment of section 601(c) of VHCA. Thus, section 1927(c)(1)(B)(ii)(II) of the Act has been amended to provide that for the rebate period beginning after September 30, 1992, and before January 1, 1993, the amount of the rebate may not exceed 50 percent of the AMP.

In general, for period beginning with October 1, 1992, the following basic rebate for single source or innovator multiple source drugs are as follows:

For October 1, 1992—December 31, 1993:

The greater of 15.7 percent of the AMP or the AMP minus best price. (The rebate is capped at 50 percent of AMP for the rebate period October 1, 1992—December 31, 1992.)

For January 1, 1994—December 31, 1994:

The greater of 15.4 percent of the AMP or the AMP minus best price.

For January 1, 1995—December 31, 1995:

The greater of 15.2 percent of the AMP or the AMP minus best price.

For January 1, 1996, and thereafter: The greater of 15.1 percent of the AMP or the AMP minus best price.

*C. Additional Rebate for Single Source and Innovator Multiple Source Drugs*

Section 1927(c)(2) of the Act requires that manufacturers pay an additional rebate amount for single source and innovator multiple source drugs if, for rebate periods beginning January 1, 1991, the AMP exceeds the "base date" AMP by a greater percentage than the percentage increase in the CPI-U for the rebate period from the "base CPI-U." Section 13602(a)(1) of OBRA '93 made clarifying changes to section 1927(c)(2), deleted requirements that would have replaced the calculation with one based on a weighted average manufacturer price (WAMP), and changed the calculation method for drugs approved by the FDA after October 1, 1990. Under section 13602(d)(2) of OBRA '93, these amendments are effective without regard to whether or not regulations to carry out these amendments have been promulgated by that date. HCFA adopted an October 1, 1993 effective date with respect to the OBRA '93 amendments to section 1927(c). Using a retroactive effective date for these

provisions would require HCFA, manufacturers, and States to recalculate additional rebates for 11 quarters. This would generate an enormous amount of prior period adjustments and changes to rebate amounts in the dispute resolution process. Such a volume of changes would place an undue administrative burden on States, manufacturers, and HCFA without a level of additional rebates to warrant the administrative costs involved in such a task. We believe our adoption of an October 1, 1993 effective date comports with HCFA's understanding of Congressional intent, as demonstrated in the legislative history. Since the amendments clarified but did not substantively change methods for calculating the additional rebate for drugs approved by the FDA before October 1, 1990, a single calculation method can be used for those drugs. Since OBRA '93 substantively changed the method for calculating the additional rebate for drugs approved by the FDA after October 1, 1990, different calculation methods must be used for the periods January 1, 1991 through September 30, 1993 and October 1, 1993 and thereafter. We discuss all of these methods in more detail below.

*1. For Drugs Approved on or Before October 1, 1990*

Section 1927(c)(2)(A) of the Act requires that manufacturers pay an additional rebate amount for single source and innovator multiple source drugs if, for rebate periods beginning January 1, 1991, the AMP exceeds the base date AMP by a greater percentage than the percentage increase in the CPI-U for the rebate period from the base CPI-U. The statute provides that the CPI-U used for calculating the additional rebate amounts be based on the CPI-U in effect for the month preceding the rebate period (or other period) involved. Therefore, to be consistent with the statute and the national rebate agreement, we have defined the following terms to be used in the formulas for calculating additional rebates:

**Base Date AMP**—The base date AMP means the AMP for the calendar quarter beginning July 1, 1990, i.e., that originally reported for the July–September 1990 rebate period. Section 1927(c)(2)(A)(ii)(II) of the Act, as amended by OBRA '93, provides that the base date AMP is the base date in effect at the time of the rebate period beginning July 1, 1990, without regard to whether or not the drug has been sold or transferred to an entity, including a division or subsidiary of the

manufacturer, after the first day of such rebate period.

Base CPI-U—The base CPI-U means the CPI-U in effect for September 1990; for example, the CPI-U in effect that month was 132.7.

## 2. For Drugs Approved After October 1, 1990

For drugs approved by the FDA after October 1, 1990, OBRA '93 defines base date AMP and base CPI-U different from how they are defined in OBRA '90. These changes affect how additional rebates are calculated for single source and innovator multiple source drugs approved after October 1, 1990. Generally, the base date AMP is the AMP in effect for the first full rebate period after the day the drug was first marketed. The base CPI-U is the CPI-U in effect for the month prior to the first full rebate period after the day the drug was first marketed.

HCFA adopted on October 1, 1993 effective date for these changes to section 1927(c). Therefore, these changes are effective with rebate periods beginning on or after October 1, 1993, and additional rebates will be calculated differently for these drugs for the period of January 1, 1991 through September 30 1993 and rebate periods beginning on or after October 1, 1993. Therefore, to be consistent with the statute, we have defined the following terms to be used in the formulas for calculating additional rebates. HCFA will issue specific instructions to manufacturers and States on how to calculate additional rebates for these different periods.

Base Date AMP for rebate periods beginning on or after January 1, 1991 through September 30 1993—The original policy in effect under OBRA '90 will continue to be used for base date AMP. That is, for this period, the base date AMP will continue to be that for the first day of the first full month in which the drug was first marketed.

Base CPI-U for rebate periods beginning January 1, 1991 through September 30, 1993—The original policy in effect under OBRA '90 will be used for the base CPI-U. That is, the base CPI-U continues to be the CPI-U in effect for the month before the month in which the drug was first marketed.

Base Date AMP for rebate periods beginning on or after October 1, 1993—In accordance with section 1927(c)(2)(B), the base date AMP is the AMP in effect for the first full rebate period after the day on which the drug was first marketed.

Base CPI-U for rebate periods beginning on or after October 1, 1993—The base CPI-U means the CPI-U in

effect for the month prior to the month of the first full rebate period after the day on which the drug was first marketed.

## VII. Payment Limitations for Covered Drugs

### A. Applying Federal Reimbursement Upper Limits

OBRA '93 amended section 1927 of the Act regarding pharmacy reimbursement limits. Section 13602(a)(1) of OBRA '93 amended section 1927(f) by redesignating it as section 1927(e) and modifying the language in several subsections. OBRA '93 revised and redesignated section 1927(f)(1) of OBRA '90 as sections 1927(e)(1) and (e)(2), added section 1927(e)(3), and redesignated section 1927(f)(2) of OBRA '93 as section 1927(f)(4) of the Act.

Existing regulations at 42 CFR 447.331 through 447.334 establish methodologies for upper limits for payment of drugs covered under the Medicaid program, in accordance with section 1902(a)(30)(A) of the Act. Section 1927(e)(1) of the Act (redesignated from section 1927 (f)(1) under OBRA '90) imposed a moratorium period beginning January 1, 1991, and ending on December 31, 1994 with regard to pharmacy reimbursement limits. During this moratorium period, in accordance with section 1927(e)(1)(a), a State cannot reduce its reimbursement limits for covered outpatient drugs or the dispensing fees for these drugs in effect as of January 1, 1991 which were established in accordance with 42 CFR 447.331 through 447.334. In accordance with the statute, up to January 1, 1991, States retained the right to reduce payments to pharmacies.

Section 1927(e)(2) establishes a special rule for States that were not in compliance with these regulations. If a State is not in compliance with §§ 447.331 through 447.334, the provisions in section 1927(e)(1)(A) do not apply to the State until it is in compliance. That is, States which reduce reimbursement rates during January 1, 1991 through December 31, 1994 to comply with the regulations will not be violating the moratorium provision under section 1927(e)(1).

Since the statute refers specifically to States "in compliance," States that were not in compliance with the regulations on January 1, 1991, are still required to come into compliance with the regulations and reduce reimbursement limits, as required by these regulations, after January 1, 1991. To be in compliance with the regulations, the State must demonstrate that the

estimated acquisition cost (EAC) is set at the State Medicaid agency's "best estimate" of the prices that pharmacists in the State are generally and currently paying. (Section 447.301 contains the definition of EAC.)

Section 1927(e)(1)(B) of the Act provides that the Secretary may not modify by regulation the Federal upper limits formula used to determine reimbursement limits in §§ 447.331 through 447.334 to reduce the reimbursement limits for covered outpatient drugs. This provision applies to the Federal upper limits formula that was in effect on November 5, 1990 (the date of enactment of OBRA '90).

In accordance with section 1927(e)(3) of the Act (as added by OBRA '93), the moratorium provisions will not supersede or affect provisions in effect for State maximum allowable cost (MAC) limitations prior to January 1, 1991, or after December 31, 1994. MAC programs established by States prior to January 1, 1991, or after December 31, 1994 are allowable under the statute and are not considered a reduction in pharmacy reimbursement. States may continue to operate MAC programs in effect prior to January 1, 1991 in accordance with the terms of that program, e.g., States may adjust limits and add drugs within the requirements of the MAC programs in effect prior to January 1, 1991.

### B. Multiple Source Drugs

#### 1. Drugs Subject to Federal Upper Limits Under Section 447.332 (Upper Limits for Multiple Source Drugs)

Under existing § 447.332(a), an upper limit for a multiple source drug may be established if the following requirements are met:

- All of the formulations of the drug approved by the FDA have been evaluated as therapeutically equivalent in the current edition of the FDA publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*; and

- At least three suppliers list the drug (which has been classified by the FDA as category "A") in the current editions (or updates) of published compendia of cost information for drugs available for sale nationally.

Under these existing provisions of § 447.332, a State agency's payment for multiple source drugs must not exceed in the aggregate the payment levels determined by applying for each drug a reasonable dispensing fee established by the agency plus an amount established by HCFA that is equal to 150 percent of the published price for the least costly therapeutic equivalent (using all

available national compendia) that can be purchased by pharmacists in quantities of 100 tablets (or capsules) or the commonly listed size. Upper limits do not apply to brand name drugs if a physician certifies in his or her own handwriting on the prescription that a specific brand is medically necessary for the recipient. HCFA identifies the multiple source drugs that are subject to upper limits and their prices on a periodic basis in the *State Medicaid Manual* under Part 6, Payment for Services.

## 2. Drugs Subject to Federal Upper Limits Under Section 1927(e)(4) of the Act

Section 1927(e)(4) of the Act (redesignated from section 1927(f)(2) under OBRA '93) contains a provision that establishes new conditions for determining which multiple source drugs are subject to upper limits and, thus, establishes a new group of drugs subject to upper limits. Section 1927(e)(4) requires HCFA to establish an upper reimbursement limit for each multiple source drug when there are at least three therapeutically and pharmaceutically equivalent (A-rated by the FDA) multiple source drugs. When this condition is met, an upper limit will be applied to the multiple source drug whether or not the FDA rating of the additional formulations of the drug are either A-rated or B-rated drugs. (§ 447.335.)

Given the moratorium provisions in section 1927(e)(1)(B) of the Act (discussed in section VII.A. of this preamble), we view section 1927(e)(4) of the Act as authority to establish upper payment limits for additional multiple source drugs, rather than a mandate to change the formula set forth in § 447.332. Any modification to existing § 447.332 during the moratorium period of January 1, 1991, to December 31, 1994, would conflict with section 1927(e)(1)(B) of the Act, which prohibits the Secretary from modifying by regulation the Federal upper limits formula in §§ 447.331 through 447.334. By prohibiting a change in the reimbursement methodology under section 1927(e)(1)(B), we believe that the Congress recognizes and approves of the current method of establishing upper limits under § 447.332.

In accordance with the moratorium provisions in section 1927(e)(1)(B) of the Act, we would not change the formula used to determine reimbursement limits that is presently set forth in §§ 447.331 through 447.334. However, we do not believe the moratorium provisions prevent HCFA from applying the existing upper

payment limit formula to existing and additional drugs as required by section 1927(e)(4) of the Act.

To comply with the requirements of both 42 CFR 447.332 and section 1927(e)(4) of the Act, HCFA would establish an upper reimbursement limit for multiple source drugs using both sets of criteria found at the existing § 447.332 and the new § 447.335. We would specify in regulations at § 447.335 the conditions under which covered outpatient drugs will be subject to the Federal upper limits under section 1927(e)(4) of the Act. On a periodic basis, HCFA would consolidate both groups of drugs, including their prices, into one listing of drugs that are subject to the Federal upper limits. HCFA will issue this listing to the States in an electronic medium and in the *State Medicaid Manual* under Part 6, Payment for Services.

## 3. Inclusion of A- and B-Rated Drugs

The FDA publication, Approved Drug Products with Therapeutic Equivalence Evaluations, lists the application holders for the drugs and the accompanying A or B drug rating. This publication, however, does not list the current owner of the drug or distributors, that is, packagers or relabelers, and there is no Federal requirement that these repackagers or relabelers identify the source of their drug product. Therefore, the A and B rating is lost for all such drugs in the marketplace once they are repackaged or relabeled.

Because we are unable to identify an A or B rating for what we believe are the majority of drugs sold at the retail level of trade, we are including all drugs (A and B rated) in the rebate program. Otherwise, since there is no method to identify A-rated drugs, we would have to require all manufacturers that participate in the drug rebate program to sell only A-rated drugs to all its customers (as there is no method to determine which particular drug will be dispensed to a Medicaid recipient). This requirement would be the only feasible way to ensure that Medicaid recipients receive only A-rated drugs. However, such a requirement is not authorized under the provisions of section 1927 of the Act and would be contrary to FDA's current drug approval process which allows B-rated drugs to be marketed. Such a requirement would also not be consistent with our understanding of Congressional intent of the drug rebate program since it might reduce the number of manufacturers participating in the program that sell only B-rated products or a combination of A- and B-rated products, which could then

decrease the availability of needed drugs to Medicaid recipients.

## C. Denial of FFP When a Generic Substitution is Available

Section 1903(i)(10) of the Act provides that payment will not be made to a State for an innovator multiple source drug dispensed on or after July 1, 1991 if, under applicable State law, a less expensive noninnovator multiple source drug could have been dispensed but only to the extent that such amount exceeds the upper payment limit for such multiple source drugs. Consistent with our understanding of the statute and Congressional intent, we would interpret this provision in our regulations at § 447.550(b) to apply to drugs subject to the Federal upper limits under § 447.332(a). Therefore, we would include in regulations at § 447.335 that therapeutic equivalent drugs for upper limits under section 1903(i)(10) of the Act means drugs rated A or B by the FDA. We would apply this policy to only those drugs subject to the Federal upper limits to provide an established drug data base available to all States for determining if generic substitution is appropriate. The Federal upper limits program offers both pharmacists and the State Medicaid agencies a familiar, regularly updated guideline that can be easily used to compare the innovator and noninnovator drug prices.

We considered using national compendia prices or pharmacy charges in applying the generic substitution requirements; however, either alternative would be difficult to administer. Both alternatives would require the comparison of prices for the innovator and noninnovator multiple source drugs. These prices frequently change and, therefore, would require frequent update by the State Medicaid agency, possibly resulting in different lists in each State. Such alternatives could also disadvantage Medicaid recipients by substituting the regular medication they receive due to constant fluctuations in price which would determine whether the innovator multiple source drug could be dispensed at a given point in time.

Section 1903(i)(10) of the Act specifies that the substitution will be under applicable State law. FFP will be available for the dispensing of the innovator drug where the prescription has been hand annotated by the prescriber either as "brand medically necessary" or other such words to that effect as may be required under State law. Current regulations under § 447.331(c)(3) prohibit the use of a checkoff box on a form but allow the use

of a notation such as "brand medically necessary."

#### VIII. Compliance Action

A State's failure to comply with the reporting or drug access requirements of section 1927 of the Act is cause for compliance action against the State. Accordingly, we would specify in § 447.538 that a manufacturer may request HCFA to initiate compliance action against a State if the State fails to comply with the drug access requirements of section 1927 of the Act. A manufacturer may also request compliance action against a State if the manufacturer can show a pattern or history of inaccuracy in the drug utilization information provided by the State. It is incumbent upon the State to report accurate utilization data to ensure that rebates are paid in accordance with the statute.

Compliance actions taken by HCFA will not relieve the manufacturer from its obligation of making the rebate payment to States as set forth in section 1927 of the Act and will not bar the manufacturer from taking other actions against the State that are legally available to the manufacturer.

#### IX. Drug Rebate Agreement Provisions Not Addressed in This Document

On November 2, 1992, we published in the Federal Register (57 FR 49397) an interim final rule with comment period that addressed the following provisions of section 1927 of the Act:

- Drug Use Review—Section 1927(g) of the Act provides that a State must have, by January 1, 1993, a drug use review program for covered outpatient drugs that meet certain statutory requirements.

- Electronic Claims Management—Section 1927(h) of the Act provides that the Secretary shall encourage each State Medicaid agency to establish, as its principal means of processing claims for covered outpatient drugs under drug rebate agreements, a point-of-sale electronic claims management system, for the purpose of performing on-line, real time eligibility verifications, claims data capture, and adjudication of claims, and assisting pharmacists and other authorized persons in applying for and receiving payment.

A document that addresses public comments and finalizes rules is under development.

#### X. Summary of Public Comments on Notice and Departmental Responses

We received 20 timely pieces of correspondence from manufacturers, State agencies, a pharmaceutical manufacturer association, and other

parties on the notice published in the Federal Register on February 21, 1991 (56 FR 7049) that reprinted the text of the national drug rebate agreement. A summary of these comments and the Department's responses follow:

##### A. Enforcement of Enhanced Access Provisions

###### 1. Restrictive Formularies

*Comment:* The majority of the commenters stated that the rebate agreement, State instructions, and regulations implementing the drug rebate program should prohibit States from developing restrictive formularies.

*Response:* We agree that prior to OBRA '93, section 1902(a)(54) of the Act generally prohibited restrictive formularies (that is, formularies that impose access limitations for covered outpatient drugs covered under a rebate agreement). OBRA '93 revised section 1902(a)(54) to require that States comply with the applicable requirements of section 1927 and added section 1927(d)(4) which allows States to establish a drug formulary, effective October 1, 1993, which meets specific requirements. A State formulary must include covered outpatient drugs other than: (1) those drugs excluded under section 1927(d)(2); and (2) those drugs (with respect to the treatment of a specific disease or condition for an identified population) where the drug's labeling or compendia-based medically accepted indication does not have a significant, clinically meaningful therapeutic advantage, in terms of safety, effectiveness, or clinical outcome over other drugs included in the formulary.

We would require States to list in their State plans those drugs in section 1927(d) that they are excluding or restricting from coverage and also describe limitations or conditions of coverage (not including prior authorization programs). We would not require States to list in their State plans those drugs they are excluding or restricting from coverage with respect to the treatment of a specific disease or condition since States must have available to the public a written explanation of reasons for excluding the drugs. We believe requiring States to amend their State plans to include these drugs would be an unnecessary use of State resources.

###### 2. Prior Authorization

*Comment:* The majority of commenters were adamant that States be required to implement what they characterized as statutorily acceptable prior authorization programs. They believed that medical factors should be

the only criteria for approving or denying drugs subject to prior authorization and suggested that HCFA establish standards for State prior authorization programs to prevent abusive restrictions. One commenter was concerned that States would place on prior authorization: (1) All but the least expensive product in a therapeutic class; (2) the drugs of a manufacturer that does not provide an additional rebate above the amount required in the national agreement; and (3) the most expensive drug in a therapeutic class without regard for improved outcomes or reduction in total treatment costs associated with the more expensive drug therapy.

*Response:* Section 1927(d)(1)(A) of the Act provides that a State may subject any covered outpatient drug to prior authorization; that is, require approval of the drug before its dispensing for any medically accepted indication. In accordance with section 1927(d)(4)(E), a State's prior authorization formula is not considered a formulary subject to the requirements specified in section 1927(d)(4). The prior authorization system must meet two conditions specified under section 1927(d)(5) of the Act.

These proposed regulations would implement these provisions of section 1927 and allow States to maintain their prior authorization programs as they currently exist except that—

- A State must respond to a prior authorization request within 24 hours of the request; and
- A State must provide for the dispensing of at least a 72-hour supply of the drug in emergency situations.

In response to items numbered (1) and (3) in the comment, we believe that States should be able to consider both clinical and economic criteria in their prior authorization programs as long as medically necessary drugs are not denied. Prior to the drug rebate provisions, States could consider such criteria. We believe that OBRA '90 did not change that provision. We recognize, however, that the Congress, in passing the statutory provisions of the drug rebate program, was concerned with ensuring recipient access to medically necessary drugs. We would, therefore, require assurances from States that their prior authorization programs do not prevent access to medically necessary drugs.

In regard to item numbered (2) in this comment, States may, in accordance with sections 1927(a) (1) and (4) of the Act, negotiate separate agreements for additional rebates as long as they can establish that the requirements in section 1927 (as discussed in section II.

of this preamble) have been met. We will monitor the prior authorization programs to ensure that States are in compliance with these regulations.

We do not believe that, in light of the provisions of section 1927(d)(1)(A) of the Act, the Congress intended to set up any further requirements than those explicitly stated in the statute that would preclude States from requiring that prior authorization be obtained for any medically accepted indications, or requiring that the physician provide medical justification for using a particular drug within a therapeutic class, as long as access to medically necessary drugs is ensured. In accordance with the statute, we believe that a State continues to maintain the authority to prior authorize drugs provided the State approves the drug if medically necessary.

Additionally, section 4401(d)(3) of OBRA '90 requires that the Secretary, acting in consultation with the Comptroller General, study prior approval procedures utilized by State Medicaid programs conducted under title XIX of the Act. We will review the results of this study and, if necessary, consider additional changes to prior authorization programs at that time.

*Comment:* One commenter suggested that (1) a State should use a review board (similar to the drug utilization board) to establish criteria for selecting drugs subject to prior authorization; (2) the manufacturer should have input before a drug is placed on prior authorization or petition a State to remove a drug from prior authorization status; (3) the prior authorization process should be subject to the State Administrative Procedures Act; and (4) the prior authorization process should apply only for new prescriptions.

*Response:* We would require in § 447.526 that State staff who place drugs in a prior authorization system must be licensed to prescribe or dispense drugs, for example, physicians or pharmacists. We would provide, however, that State staff who respond to prior authorization requests need not be limited to persons licensed to prescribe or dispense drugs as long as all responses are made in consultation with these licensed professionals, or are made under guidelines promulgated by these licensed professionals and they are available for consultation in difficult or unusual cases. We believe that a State might benefit from a formulary committee for determining drugs that will be subjected to prior authorization but are not mandating this. However, we do not believe that we should limit the States' flexibility in operating their prior authorization programs to accommodate

the commenter's other concerns since the statute supports the States' authority to maintain their prior authorization programs as they currently exist.

*Comment:* One commenter suggested that States should be required to disclose all information regarding the basis for selecting drugs and for denying drugs subject to prior authorization, and to generate a report for HCFA on all claims that were denied.

*Response:* In accordance with section 1927(d)(5) of the Act and our understanding of the legislative intent of OBRA '90, we expect States to operate their prior authorization programs in a manner that does not preclude access to medically necessary drugs. We believe States will be consistent in applying criteria as to how drugs are selected for prior authorization. We would also require annual assurances that a State's prior authorization program does not prevent access to medically necessary drugs. States may continue to disclose their records for prior authorization in the same manner that they did before the change in statute, as the statute made no changes in this area. We believe it would be overly burdensome to require States to generate specific reports on prior authorization claims and would be of nominal benefit to HCFA.

*Comment:* Several commenters believed that, if a State does not comply with the prior authorization requirements that the commenters believe are appropriate (as discussed above in other comments on prior authorization), the manufacturer should be able to withhold the rebate due the State.

*Response:* The statute requires a manufacturer to provide a rebate to the State for each rebate period based on utilization data submitted by the State. The rebate must be paid by the manufacturer to the State no later than 30 days after the date of receipt of the State's utilization data. There is no authority for the Secretary to permit a manufacturer to withhold a rebate (nor for a manufacturer to unilaterally withhold such a rebate) where a State does not comply with prior authorization requirements. We have a compliance process to ensure that States comply with all provisions of the Medicaid program and, as noted in the rebate agreement, manufacturers may notify the appropriate HCFA RO if they believe a State is not complying with a provision of the drug rebate program.

#### B. New Drug Coverage

*Comment:* Several commenters were concerned that States would not allow unrestricted access to new drugs. Some

commenters believed that the new drug coverage protection afforded by section 1927(d)(6) prior to OBRA '93 should have provided that the 6 months of coverage for a new drug begin with the date when it is first marketed, and not from the date it is approved by the FDA. One commenter asserted that the Congress inadvertently reduced the time to less than 6 months because it may take several weeks, if not months, to bring a new drug on the market and suggested that HCFA support a technical amendment to the law. This commenter believed that prior to OBRA '93, section 1927(d)(6) of the Act encouraged manufacturers to bring new drugs to market prematurely since a manufacturer may need to educate and train physicians on a drug's use or administration once the drug is approved. Also, the commenter suggested that the FDA's approval of promotional materials and manufacturing specifications may not coincide with the drug approval date.

*Response:* OBRA '93 deleted section 1927(d)(6) and special coverage provisions for new drugs. Prior to OBRA '93, section 1927(d)(6) of the Act provided that a State may not exclude from coverage, subject to prior authorization or otherwise restrict any new drug or biological approved by the FDA for a 6-month period following the date of FDA approval. Effective October 1, 1993, these requirements no longer exist. New drugs approved by the FDA prior to October 1, 1993 will only receive the unrestricted coverage as specified in section 1927(d)(6) of the Act prior to OBRA '93 through September 30, 1993.

Based on our understanding of Congressional intent, we believe this 6-month period was specifically intended to be effective from the date of FDA approval to make prescribers familiar with a new drug and allow it to be introduced into the market place before it might require prior authorization by a State. Because this date was statutorily mandated, HCFA lacked authority to change this requirement to the date the drug was marketed.

Generally, with the exception of certain biological products, the approval of a new drug by the FDA under the NDA process does not include the approval of promotional materials. However, since the mid-1970s, the FDA has offered voluntary review and recommendations on proposed launch promotional materials to all sponsors. This review is utilized by well over 90 percent of the companies when marketing new products. With regard to manufacturing specifications, there are a few cases where compliance with the

manufacturing specifications was part of a post-NDA approval agreement that would be completed prior to marketing the product. However, since there are so few exceptions in this area and because we are bound to follow the statute, HCFA considered the 6-month period effective from the date the drug is approved by the FDA.

#### *C. Confidentiality of Manufacturer Price Information*

*Comment:* Many of the commenters believed that States should not have access to manufacturers' price information, including unit rebate amounts, since HCFA has access to this information. The commenters stated that the risk of disclosure and use of information for other purposes is too great.

*Response:* We have agreed not to disclose AMP and best price to States but maintain that the statute contemplates the disclosure of manufacturer pricing data to States. Section 1927(b)(3)(D) of the Act provides that information concerning drug prices must not be disclosed by "the Secretary or a State agency (or contractor therewith)." By including States within the confidentiality provisions, we believe that the Congress intended that States have the right to access of sufficient pricing information to calculate their rebates as required by the statute. The unit rebate amount, which provides the rebate due per tablet, etc., and which is the end result of the manufacturer's calculation, is, in our opinion, the minimum amount of information States need to accomplish this. At the same time, the statute protects the manufacturer's pricing data from disclosure. In accordance with section 1927(b)(3)(D) of the Act, information disclosed by manufacturers in connection with the rebate agreement is confidential and, notwithstanding other provisions of law (including the Freedom of Information Act, 5 U.S.C. 552) must not be disclosed by HCFA, the State agency, or its contractors in a form that reveals the manufacturer, except as necessary for the Secretary of HHS to carry out the provisions of section 1927 and for the Comptroller General or the Director of the Congressional Budget Office to review the information provided.

#### *D. Unit Rebate Amounts*

*Comment:* Several commenters believed that HCFA is not authorized by the statute to calculate the unit rebate amount since the law clearly states that the manufacturers will compute the information. They indicated that the penalties that may be imposed on

manufacturers and HCFA's audit authority are sufficient to ensure that manufacturers make accurate and timely calculations.

*Response:* In accordance with sections 1902(a)(4), 1903, and 1927 of the Act, we believe that the Secretary has the authority and duty to implement and oversee various aspects of the drug rebate program. The Secretary has delegated this responsibility to HCFA. In accordance with this authority, HCFA is not precluded from calculating the unit rebate amount. We agree that manufacturers are responsible for calculating and paying rebates correctly. However, we believe that the administrative approach of HCFA supplying the States with unit rebate information to verify rebates is a practical and acceptable administrative oversight responsibility to ensure that States receive correct rebate payments and that the proper amount of FFP is made available to States.

#### *E. Manufacturer's Requirements To List All Drugs*

*Comment:* One commenter asserted that a manufacturer should not have to provide to HCFA a list of all of its covered outpatient drugs since some of its drugs may not be covered under Medicaid, that is, those drugs that a State may restrict or exclude from coverage under section 1927(d)(2) of the Act. The commenter believed that the requirement to list all of its drugs places an unnecessary administrative burden on the manufacturers and States. The commenter also believed that HCFA should review and evaluate each manufacturer's list of covered drugs after several rebate periods of experience in the drug rebate program and delete those drugs that are not covered under Medicaid or delete drugs that provide a minimal rebate.

*Response:* Under the terms of the national rebate agreement, a manufacturer is required to provide to HCFA rebates for all its covered outpatient drugs dispensed under the plan. Thus, in our opinion, there is no authority under the statute to delete drugs from the list of covered outpatient drugs where those drugs provide a minimal rebate from the drug rebate program.

#### *F. Enforcement of State's Obligations*

*Comment:* Several commenters asserted that HCFA's compliance action initiated against a State that fails to meet the various requirements under the drug rebate program, (for example, covering all drugs or new drugs from the date of FDA approval) is an ineffective and inadequate means of ensuring that

States obey the requirements of sections 1902(a)(54) and 1927 of the Act.

The majority of commenters believed that manufacturers should be able to withhold rebate payments to a State until the State conforms its policies to the law. One commenter suggested that manufacturers should be allowed to withhold rebate payments in an amount equal to the sales lost during a rebate period, which would be estimated by the manufacturer, as a result of a State not properly covering drugs. Otherwise, the commenter was concerned that a State could "reap a windfall" since it would receive rebates and, at the same time, avoid paying for selected products that the State was required by statute to cover.

*Response:* Section 1904 of the Act and regulations at 42 CFR part 430, subpart C, provide that we may initiate a noncompliance action if States do not comply with all provisions of the Medicaid program. As noted in the rebate agreement, manufacturers may notify HCFA if they believe a State is not complying with a provision of the drug rebate program. The statute requires a manufacturer to provide a rebate to the State for each calendar rebate period based on utilization data submitted by the State. The rebate must be paid by the manufacturer to the State not later than 30 days after the date of receipt of the State's utilization data. Section 1927 of the Act does not contemplate that manufacturers can withhold rebates in those situations where a State does not comply with all of the provisions of the Medicaid program.

#### *G. Adequacy of State Medicaid Utilization Data*

*Comment:* One commenter asserted that section II. (b) of the national rebate agreement requires manufacturers to pay rebates to the States even if a State has failed to report all of the utilization data required by the statute and the agreement. The commenter believed this requirement is an attempt to relieve States of one of their primary responsibilities under the statute.

*Response:* Section 1927(b)(2)(A) of the Act requires that States use a standard reporting format established by the Secretary. In accordance with the statute, HCFA has defined the format for utilization data to include, in part, the use of NDC numbers. Given the provisions of the statute and our regulations at § 447.530, States would be required to report, at a minimum, the utilization data indicating the NDC number for the covered outpatient drugs and the total number of units of the drugs paid for during a rebate period. In

accordance with the statute, manufacturers must calculate and pay the rebate amounts within 30 days of the receipt of these two items of information. Furthermore, a manufacturer may audit these data that a State provides or is required to provide. If a manufacturer believes that a State has reported erroneous utilization data, the manufacturer is not required to pay a rebate on the portion of drugs for which the data are in question until the dispute is resolved.

*Comment:* Several commenters believed that Medicaid utilization data that States are required to supply to manufacturers are inadequate. They suggested that States should provide data at zip code level, and at a more detailed level if a manufacturer needs it, such as a claims history file that includes recipient, pharmacy, dispensing date and other claim information. They asserted that if States do not currently have this capability, we should require them to do so. These commenters also suggested that State utilization data should include monthly totals by NDC number and a rebate period summary, and that States should also be required to maintain the date that the drug was dispensed.

Several commenters stated that manufacturers should have the right to audit pharmacies and HCFA should ensure State cooperation with manufacturers in conducting these audits.

*Response:* We believe the data that the States provide under this regulation would be adequate for purposes of calculating the rebate. In addition, the manufacturer has the right, by law, to audit these data and adjustments to rebate amounts will be made to the extent that the data indicate that utilization was greater or less than the amount previously indicated. We would not require States to submit additional data, such as zip code-level information or a claims history, with their rebate period information. However, in the event of a dispute, we would require States to provide the manufacturer with this type of data if State confidentiality laws allow. (Section V.F. of the preamble contains further discussion on this issue.) Specific claim information that identifies a recipient is generally prohibited from being released to the public under the authority of section 1902(a)(7) of the Act and regulations at 42 CFR 431.300 through 431.307.

Manufacturers do not have the authority to audit pharmacies under section 1927 of the Act, but we expect States to audit pharmacy data in response to manufacturer requests when warranted.

#### H. Dispute Mechanism

*Comment:* One commenter believed that the timeframe of 30 days after receipt of a State's data is inadequate for a manufacturer to challenge errors made by the State. The commenter believed that the 30-day timeframe is unfair and may encourage premature challenges by manufacturers seeking to preserve their rights to use the dispute resolution process described in section V. of the rebate agreement.

*Response:* Section 1927(b)(1)(A) of the Act requires that manufacturers provide rebates within 30 days of receipt of State utilization data. In accordance with this requirement, we believe that the 30-day timeframe is reasonable for manufacturers to distinguish between legitimate disputed items and data inconsistencies and to attempt to resolve those disputes since data used to contest State data are similar to that needed to pay the rebate. If a manufacturer and State are unable to resolve discrepancies within the 30-day timeframe, the manufacturer must pay the rebate on the undisputed data and provide written notice of any discrepancies by submitting the RAR to the State agency. We would view it as a violation of these regulations and the rebate agreement if a manufacturer challenges the data simply as a method to extend the time period for reviewing data and avoid paying a rebate. The manufacturer also will be responsible for paying interest, as set forth in section 1903(d)(5) of the Act, on the disputed portion of the rebate if the State's data are not erroneous. (Section V.F. of the preamble contains a detailed discussion of the dispute resolution process.)

*Comment:* One commenter asserted that the dispute resolution process leaves States at financial risk when a dispute arises since HCFA will require its portion of the rebate payments from the States even though a manufacturer will withhold payments. The commenter believed that HCFA should assume some financial risk as well as play a more significant role in the dispute resolution.

*Response:* Manufacturers must pay States a rebate on the portion of the State utilization data that is not in dispute. We do not require the State to pay HCFA the Federal portion of the rate on the amount that is in dispute. Rather, we are requiring payment on those amounts that States receive in accordance with section 1927(b)(1)(B) of the Act. As a general rule, we believe we play a significant part as an overseer of the dispute resolution process between manufacturers and States. However,

since both of these parties are directly responsible for the data they generate, we believe they must primarily work together to reconcile any differences.

#### I. Separate State Agreements

*Comment:* Several commenters believed that: (1) Modifications to existing State agreements are not permitted under the statute; (2) a State agreement may not legally provide for a different rebate amount than the amount in the national agreement; and (3) approval of an agreement under which a State exempts products from prior approval restrictions in exchange for rebates greater than those provided in the national agreement would be an abuse of HCFA's discretion even if the greater rebates were legal.

*Response:* We do not agree that modifications to existing agreements are prohibited under the statute. Section 1927(a)(4) of the Act specifies conditions that existing agreements must meet to be in compliance with the law. (Section II.A. of this preamble contains a discussion of the provisions of section 1927(a)(4).) Section 1927(a)(4) does not preclude modifications to existing agreements, such as allowing greater rebates.

We disagree that there is no legal authority to approve a separate agreement that provides for a different rebate amount than the amount in the national agreement. Section 1927(a)(1) of the Act recognizes the Secretary's authority to authorize individual State agreements and does not require that the individual State agreements incorporate the rebate amount requirements set forth in the national agreement. Thus, rebates under the individual State agreements need not match the rebates mandated under the national agreement. However, for the Secretary to accept them, as discussed in section II. of this preamble, they must be at least as large as the amount specified in the national agreement.

HCFA has the authority under the statute to approve individual State agreements and will review the agreements to ensure that the State is operating its prior authorization program in a manner consistent with the statute and regulations. However, given the provisions of section 1927(a) of the Act, we disagree that a State may not negotiate a separate rebate agreement that requires a higher rebate in exchange for removing drugs from the State's prior authorization program, provided that medically necessary drugs continue to be available to Medicaid recipients.

*Comment:* Several States contend that the 60-day timeframe allowed for the resolution of disputes is inadequate.

The States suggested that we expand the timeframe to approximately 120 days as a more realistic standard.

*Response:* We acknowledge that this timeframe is not adequate due to the complexity of resolving disputes. Therefore, we have revised the dispute resolution process, as discussed in section V.F. of the preamble, to reasonably accommodate all of the steps necessary to resolve a dispute. We are proposing to extend the entire timeframe to 240 days after the State receives the manufacturer's RAR for a State and manufacturer to settle the dispute. After this point, both parties may use arbitration, mediation, or the State hearing mechanism to settle the dispute. As discussed in section V.F. of the preamble, we established this timeframe after much discussion with States, manufacturers, and pharmacy groups. We believe the proposed dispute resolution process and the expanded timeframes meet the needs of both States and manufacturers.

#### *J. Right of the Secretary to Audit AMP and Best Price Data*

*Comment:* One commenter claimed that the statute does not give the Secretary an unqualified right to audit a manufacturer's data regarding AMP and best price calculations, as stated in the rebate agreement.

*Response:* Section 1927(b)(3)(B) of the Act clearly states that the Secretary has the right to survey wholesalers and manufacturers to verify manufacturer prices reported on AMP and best price. We believe this provision includes the right to audit pricing data, since an audit is often necessary to verify such pricing data.

#### *K. Nonrenewal and Termination of Agreements*

*Comment:* One commenter recommended that the national rebate agreement should be modified to specify that the effective date of manufacturer initiated termination/nonrenewal is the "earlier" of 60 days after a notice or the ending date of the term of contract if proper notice is given. The language of the published national agreement indicated that it is the "later" of these events.

*Response:* This was an error in the national agreement and will be corrected in the next revision of the national rebate agreement. We will honor nonrenewals up to 60 days before the end of the current period of the agreement and terminations up to 60 days before the end of the current rebate period (effective at the end of that rebate period). We have indicated the correct date in the regulations at § 447.514(c).

#### *L. Administrative Procedure Act*

*Comment:* Several commenters stated that they believed HCFA violated the Administrative Procedure Act (APA), 5 U.S.C. section 553, by using a model rebate agreement to implement the drug rebate program instead of developing formal regulations that allowed for public comment. They indicated that HCFA did not have adequate input from the States, manufacturers, pharmacy organizations, and the public while developing the policies that govern the rebate program. One commenter believed that failure to develop regulations or allow amendments to the national rebate agreement puts manufacturers in the untenable situation of having to sign an agreement without fully understanding the terms or risk losing their drug coverage under Medicaid.

*Response:* Section 4401 of OBRA '90 requires manufacturers to enter into and comply with the terms of the national rebate agreement by March 1, 1991, in order for payment to be made available under section 1903 of the Act for covered outpatient drugs. (As noted earlier, this date was extended to April 30, 1991, under the extenuating circumstances provision of section 1927(a)(3) of the Act.) Because of the short timeframe imposed by the Congress to implement the drug rebate provisions, it was impossible to issue regulations prior to the date that the national rebate agreement was required to be signed. In light of these short timeframes, and in the interest of receiving public comments, the contents of the rebate agreement were developed in direct consultation with representatives of drug manufacturers, States, and other interested parties. We considered this process an adequate means of providing actual notice and for obtaining public comments of affected parties within the time constraints. We believe that, given the circumstances, this approach was consistent with the provisions of the APA.

In addition, section 4207(j) of OBRA '90 authorizes the Secretary to issue regulations on an interim or other basis as may be necessary to implement the amendments made by the provisions of OBRA '90. In developing this proposed rule with comment period, we have taken into consideration, as appropriate, the public comments we received on the February 21, 1991, Federal Register notice, which included the contents of the national rebate agreement.

#### *M. Timeframes for Signing Rebate Agreements*

*Comment:* The majority of commenters indicated that manufacturers did not have adequate time to analyze and sign the national rebate agreement if they wanted their drugs covered retroactively to January 1, 1991. If they did not sign the agreement by the given deadline, their drugs would not be covered until July 1, 1991, thereby resulting in a large span of time within which drugs would not be covered.

*Response:* We realized that the timeframe that manufacturers had to analyze and sign the rebate agreement for their drugs to be covered retroactively to January 1, 1991 was very limited. The majority of manufacturers were able to sign the rebate agreement by the deadline. However, for those few that did not, we extended, under the extenuating circumstances clause in section 1927(a)(3)(B) of the Act, the original deadline of February 28, 1991, to April 30, 1991, for manufacturers to enter into a rebate agreement effective for drug coverage retroactive to January 1, 1991.

#### *N. Amending the Language of the Rebate Agreement*

*Comment:* One commenter recommended that HCFA include in regulations the process and timeframes that will be used to make changes to the national rebate agreement.

*Response:* We plan to periodically revise the rebate agreement language as needed. However, we believe that a scheduled timeframe for publication is not warranted since manufacturers have entered into the rebate agreement with coverage beginning in different rebate periods. We will further consider all comments from the February 21, 1991 notice and this proposed rule when we revise the national rebate agreement language.

#### *O. Definition of Terms in the National Rebate Agreement*

*Comment:* We received numerous comments on the definitions included in section I. of the national rebate agreement. Commenters claimed that our definitions were not in compliance with the statute.

*Response:* We considered comments on definitions when developing this proposed rule. Where we believed changes were necessary, we included them in the definitions contained in this proposed rule. After publication of the final rule, we intend to amend the national rebate agreement to reflect any new regulatory requirements and definitions.

*P. National Drug Code*

*Comment:* Several commenters recommended that States be required to maintain their records of NDC numbers by full 11-digit NDC numbers after a reasonable transition time period. The commenters also suggested that if a State does not comply with the 11-digit NDC number requirement by the specified deadline, manufacturers should have no responsibility to pay the rebate amounts until such a system is in place.

*Response:* OBRA '93 amended section 1927(b)(2)(A) of the Act to require that States report to manufacturers information on the total number of units of each dosage form and strength and package size of each covered outpatient drug, that is, States must use an 11-digit NDC number. This change is effective as if it was included in OBRA '90.

Prior to the enactment of OBRA '93, we agreed that States should maintain their records by the full 11-digit NDC number that indicates the manufacturer, product, and package size of a drug. In accordance with sections 1902(a)(54) and 1927(b)(2) of the Act, we began requiring States to report drug utilization data to HCFA and manufacturers using the 11-digit NDC numbers for claims paid on and after March 1, 1992. (During a transitional period of January 1, 1991 through February 29, 1992, we allowed States that did not have the technical capability to report the 11-digit NDC number to use the 9-digit number (that is, the NDC number without the package size.)

We disagree, however, with the statement that a manufacturer should be able to withhold rebates. As stated earlier, the statute requires manufacturers to pay a rebate within 30 days of receiving State utilization data and does not authorize manufacturers to withhold a rebate when the State has submitted utilization data to the manufacturer. We will consider any State that does not maintain an 11-digit NDC number to be out of compliance.

*Q. Definition of Nominal Price*

*Comment:* One commenter contended that the definition of "nominal price" should not be predicated on a fixed percentage of 10 percent since this definition is not authorized by law and ignores the unique marketing and pricing practices of each drug manufacturer. This commenter believed that the company that claims a nominal price for a drug should have the burden of demonstrating to HCFA that the facts and circumstances concerning the drug render the price as nominal. The

commenter stated that the standards and procedures to demonstrate a nominal price should be specified in the regulations. Another commenter agreed with the nominal price definition in the rebate agreement of "any price less than 10 percent of the AMP."

*Response:* We originally gave consideration to a definition that a nominal price be less than 1 percent of AMP. However, after discussions with manufacturers, States, and other parties, we believe the current definition of "less than 10 percent of AMP" to be sufficient to encompass the nominal prices offered by manufacturers. Prices greater than this appear to be for sales of the type meeting the definition for inclusion of AMP or best price.

We believe the administrative costs and burdens are too great to justify a policy that would require HCFA to review each manufacturer's case of why a nominal price for a drug is warranted and would offer no greater assurance of more accurately defining nominal price.

*R. Additional Rebates Based on Rebate Period CPI-U Increases*

*Comment:* One commenter recommended that the additional rebates (for increases in drug costs in excess of the increase in the CPI-U) should not be computed on a rebate period basis because manufacturers do not raise prices each rebate period and the effects of a rebate period CPI-U calculation would be uneven. However, the commenter believed that if the additional rebate is computed on a rebate period basis, it should be reconciled at the end of the year based on the increase of CPI-U compared to the increase in price. The commenter also suggested that we should consider comparing increases in prices to the projected annual increase in the CPI-U.

*Response:* The revision to the additional rebate calculation suggested by the commenter is contrary to section 1927 of the Act, which provides that the additional rebate is computed on the increase in CPI-U from a base date to the month before the beginning of the rebate period. OBRA '93 amended section 1927(c)(2) and removed the reference that an alternate period could be considered. We believe the intent of the law is to ensure that, for Medicaid purposes, drug price increases are equal to or less than the increase in the CPI-U on a rebate period basis.

Both of the commenter's proposals would allow drug prices to increase in excess of the rebate period CPI-U until the CPI-U "caught up", for example, a price increase of 10 percent in December 1990 would not cause an additional rebate for all of 1991 if the

CPI-U increased 10 percent by December 1991.

*Comment:* One commenter suggested that the base CPI-U should be modified to use the June 1990 figure, the month before the rebate period used to determine the base AMP. The commenter believed this would make the time periods between the measurement of CPI-U and AMP the same.

*Response:* Section 1927(c)(2) of the Act provides that for drugs approved before October 1, 1990, we use the CPI-U from October 1, 1990. The CPI-U in effect on October 1, 1990, is the September 1990 CPI-U. For drugs approved after October 1, 1990, section VI. A. 2. of the preamble explains the criteria for determining the base CPI-U for the periods January 1, 1991—September 30, 1993, and October 1, 1993 and thereafter.

## XI. Responses to Public Comments

Because of the large number of items of correspondence we normally receive on a rule, we are not able to acknowledge or respond to written public comments individually. However, we will consider all comments that we receive by the date specified in the "Comment Date" section of this preamble and respond to them in the preamble to any final rule that we issue.

## XII. Paperwork Burden

Sections 447.508, 447.510, 447.514, 447.516(b), 447.524 (f) and (g), 447.526(c)(2)(i), 447.530, 447.534, 447.536, and 447.540(a)(2) of these proposed regulations contain requirements that are subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1980 (44 U.S.C. Chapter 35). These requirements have been approved by OMB under approval numbers 0938-0578 (for manufacturers) and 0938-0582 (for States).

Based on our experience with establishing new reporting systems, we estimate that the reporting requirements contained in these sections would be 39,289 burden hours per rebate period for manufacturers and 1,531 burden hours per rebate period for State Medicaid agencies.

## XIII. Impact Analysis

## A. Overall Impact

We generally prepare a regulatory flexibility analysis that is consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612), unless the Secretary certifies that a regulation will not have a significant impact on a

substantial number of small entities. For purposes of the RFA, States and individuals are not small entities, but we consider some participating manufacturers as small entities.

In addition, section 1102(b) of the Act requires the Secretary to prepare a regulatory impact analysis for any proposed rule that may have a significant impact on the operations of a substantial number of small rural hospitals. Such an analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 50 beds. We are not preparing a rural hospital impact statement because we have determined, and the Secretary certifies, that this proposed rule would not have a significant economic impact on the operations of a substantial number of small rural hospitals.

Although we view the anticipated results of these interim final regulations as beneficial to the Medicaid program as well as to Medicaid recipients and State governments, we recognize that some of the provisions could be controversial and may be responded to unfavorably by some affected entities. We also

recognize that not all of the potential effects of these provisions can be definitely anticipated, especially in view of their interaction with other Federal, State and local activities regarding outpatient prescription drug costs. In particular, considering the effects of our simultaneous efforts to improve the delivery of Medicaid-covered outpatient prescription drugs, it is impossible to quantify meaningfully a projection of the future effect of all of these provisions on State and manufacturers' operating costs or on the frequency of substantial noncompliance and termination proceedings.

However, in a General Accounting Office report entitled "Changes in Drug Prices Paid by Health Maintenance Organizations (HMOs) and Hospitals Since Enactment of Rebate Provisions" (January, 1993, GAO/HRD-93-43), there was very little evidence of a significant effect on small rural hospitals. This report compares the year before and year after rebates went into effect. It concludes that there were only negligible effects on drug costs to hospitals (in fact, a slight decrease for inpatient drugs), but that HMOs' costs went up about 8 percent.

It is clear that a large number of small entities, such as manufacturers and

pharmacies, will be affected by the implementation of these statutory provisions, and a substantial number of these entities may be required to make changes in their operations. For these reasons, we have prepared the following voluntary analysis. This analysis, in combination with the rest of the preamble, is consistent with the standards for analysis set forth by the RFA.

*B. Anticipated Effects*

1. Effects on the Medicaid Program

Primarily, the Medicaid drug rebate law was intended to reduce the amount State Medicaid programs pay for outpatient drugs by requiring manufacturers to offer States discounted prices for covered outpatient drugs. Below are estimates of Medicaid drug rebates. These estimates are based on data from actual rebates reported or paid for fiscal year 1992. These estimates also include the impact of section 601 of VHCA, which eliminated prices paid by the DVA and other entities from calculation of best price under the Medicaid drug rebate program. Projected Federal and State rebates have each been reduced by \$10 million per year to account for the impact of the VHCA provisions.

[\$ in millions]

	FY 94	FY 95	FY 96	FY 97
Federal .....	\$870	\$985	\$1135	\$1330
State .....	620	700	810	950

For fiscal year 1992, we estimated 12.76 percent rebate as a percentage of drug costs to the Medicaid program. Fiscal year 1993 data indicated an increase of the drug rebate of approximately 16 percent. Although we expect the percentage rebate to increase slightly over the estimable period reflected above, we are unable to do so with any degree of accuracy.

The estimates in the table represent savings generated from rebate payments from pharmaceutical manufacturers. They were the result of the following process:

- We developed a formula to estimate the manufacturer rebates as a percentage of Medicaid ingredient costs from a sample of drug claims drawn from the Medicaid Statistical Information System, otherwise known as MedStat.
- Average manufacturer prices were approximated by applying a discount to published average wholesale prices; the "best price" was developed from the DVA Federal supply schedule.

• The rebate formulas were modeled using a sample database from the data described above. The savings that resulted were expressed as a percentage of calculated Medicaid ingredient costs for the sample drugs.

• These saving percentages were applied to budget projections of Medicaid ingredient costs to obtain projected future savings. For this step the ingredient cost proportion of Medicaid drug spending and the distribution of brand name drugs versus generic drugs was derived from an analysis of data from the Pharmaceutical Data Service survey databases and MedStat data.

• The potential savings were reduced to account for rebate agreements that would have been negotiated between States and manufacturers in the absence of section 4401 of OBRA '90.

Further, section 13602 of OBRA '93 exhibited modifications to the Medicaid Drug Rebate law as previously indicated. We have made the following

estimates of savings as a result of these changes.

[\$ in millions]

	FY 94	FY 95	FY 96	FY 97	FY 98
Federal..	\$25	\$55	\$65	\$70	\$75
State .....	20	40	45	50	55

2. Effects on Pharmaceutical Manufacturers

Initially, it was anticipated that the outcome of these provisions would provide the Medicaid outpatient prescription drug program, representing 12 to 20 percent of all retail prescriptions in their respective States, with access to the best price for single source and innovator multiple source drugs. However, it was predicted in many circles that the pharmaceutical manufacturers would be unable to absorb these losses from 12 to 20 percent of retail sales and would respond by shifting the cost to other

non-Medicaid sectors of the prescription drug business. Various articles in newspapers and health journals have indicated that the pharmaceutical industry has elevated some prescription prices in non-Medicaid sectors. The overall impact of manufacturers raising drug prices for the non-Medicaid population cannot be accurately predicted.

Current data shows that approximately 515 manufacturers have signed agreements to participate in the Medicaid drug rebate program. Manufacturers appear to support the system and have minimal dissatisfaction. Recent studies done by the Office of Inspector General (OIG) show well over 90 percent of the drugs (and all major drugs) are covered compared to those covered prior to the program.

### 3. Effects on Non-Medicaid Sector

Reports indicate that some drug manufacturers are shifting higher drug costs to the DVA and the private sector. At one point, the DVA estimated that it would incur an additional \$150 million in drug costs in 1991 and believed that these increased drug costs would be the result of manufacturers attempting to level out their pricing structure to avoid paying Medicaid significantly discounted best prices. In part, as a result of these estimates, the DVA Appropriations Act was enacted, which temporarily excluded until June 30, 1992, prices paid for drugs by the DVA from the best price. In addition, VHCA was enacted on November 4, 1992, which amended section 1927 in several areas and excluded prices paid by numerous entities from the best price component of the Medicaid drug rebate calculation. However, sufficient data do not exist to make a comprehensive evaluation of the overall impact on the non-Medicaid sectors.

If manufacturers attempt to maintain revenues as predicted by some sources, there could be several entities of the non-Medicaid sector affected other than government. If all discounts and contracts were rescinded and one price instituted for all, the economic impact on the hospital industry, for example, would be substantially negative since the industry receives large discounts for drug purchases, but for some other purchasers, it would be substantially positive.

### C. Alternatives Considered

Section 1927 of the Act imposes strict legal and monetary savings requirements that the drug rebate program must meet. The only alternative to implementing the drug

rebate program is to repeal section 4401 of OBRA '90 and section 13602 of OBRA '93. However, a repeal would impose additional costs on the Medicaid program since the drug rebate program is expected to generate substantial savings. Also, Federal and State administrative costs would be incurred to reverse the policy and operational procedures that were established to implement the drug rebate program.

A cost/benefit analysis of repealing the legislation was not conducted since the primary effect of this program simply includes what economists term an economic "transfer"—reducing simultaneously and equally costs to the government and revenues of manufacturers through a change in purchasing procedures. The Congress passed this law to generate program savings from rebates to obtain price reduction that other sectors of the economy have received for years, and to provide the Medicaid population with equal access to the same prescription drugs that benefit the non-Medicaid population.

### D. Interaction With Other Activities

The drug rebate program, in combination with the reimbursement moratorium, prospective and retrospective drug use review, electronic claims processing system, and demonstration projects, should ensure that the Medicaid prescription drug program will operate in the most economical manner possible. These provisions should result in decreased costs for both States and pharmacies once all aspects of section 1927 of the Act are fully implemented.

### E. Conclusion

State and Federal Medicaid expenditures have grown at an extraordinary rate in recent years. Medicaid expenditures on prescription drugs, in particular, during the last half of the 1980s, grew at a rate greater than spending for many other Medicaid services. Therefore, we believe that the implementation of the above mentioned provisions in combination with measures that obtain an additional rebate based on the rate of growth of drug expenditures would help to reduce costs of the Medicaid program. We solicit public comments on the extent that any of the above mentioned entities are significantly economically affected by these provisions.

In accordance with the provisions of Executive Order 12866, this rule was reviewed by the Office of Management and Budget.

## List of Subjects

### 42 CFR Part 441

Family planning, Grant programs—health, Infants and children, Medicaid, Penalties, Prescription drugs, Reporting and recordkeeping requirements, Safety.

### 42 CFR Part 447

Accounting, Administrative practice and procedure, Grant programs—health, Health facilities, Health professions, Medicaid, Reporting and recordkeeping requirements, Rural areas.

42 CFR chapter IV, subchapter C would be amended as follows:

A. Part 441 is amended as follows:

### **PART 441—SERVICES: REQUIREMENTS AND LIMITS APPLICABLE TO SPECIFIC SERVICES**

1. The authority citation for part 441 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

2. In § 441.10, the introductory text is republished, and a new paragraph (j) is added to read as follows:

#### **§ 441.10 Basis.**

This subpart is based on the following sections of the Act which state requirements and limits on the services specified or provide Secretarial authority to prescribe regulations relating to services:

\* \* \* \* \*

(j) Sections 1903(a) and (i)(10) concerning FFP for State expenditures for drugs.

3. Section 441.25 is amended by adding a new paragraph (c) to read as follows:

#### **§ 441.25 Prohibition on FFP for certain prescribed drugs.**

\* \* \* \* \*

(c) FFP is not available in State expenditures for covered outpatient drugs unless the requirements and conditions specified in subpart E of part 447 of this subchapter are met.

B. Part 447 is amended as follows:

### **PART 447—PAYMENTS FOR SERVICES**

1. The authority citation for part 447 continues to read as follows:

Authority: Section 1102 of the Social Security Act (42 U.S.C. 1302).

2. Section 447.300 is revised to read as follows:

#### **§ 447.300 Basis and purpose.**

In this subpart—

(a) Sections 447.302 through 447.335 and 447.361 implement section

1902(a)(30) of the Act, which requires that payments be consistent with efficiency, economy, and quality of care; and section 1927(e)(4) of the Act, which specifies requirements for establishing upper limits on reimbursement for multiple source drugs dispensed under drug rebate agreements.

(b) Section 447.342 implements section 1902(a)(43) of the Act, which permits the State plan to provide for payment to a physician for laboratory services which the physician did not personally perform or supervise.

(c) Section 447.371 implements section 1902(a)(13)(F) of the Act, which requires that the State plan provide for payment for rural health clinic services in accordance with regulations prescribed by the Secretary.

3. Section 447.332 is revised to read as follows:

**§ 447.332 Upper limits for multiple source drugs.**

(a) *Establishment and issuance of listings.*

(1) HCFA will establish listings that identify and set upper limits for multiple source drugs that meet the following requirements:

(i) All of the formulations of the drug approved by the Food and Drug Administration (FDA) have been evaluated as therapeutically equivalent in the most current edition of its publication *Approved Drug Products with Therapeutic Equivalence Evaluations* (including supplements or in successor publications).

(ii) At least three suppliers list the drug (which has been classified by the FDA as category "A" in its publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (including supplements or in successor publications)) based on all listings contained in current editions (or updates) of published compendia of cost information for drugs available for sale nationally.

(2) HCFA will publish the lists of multiple source drugs for which upper limits have been established and revisions to the lists in Medicaid program instructions.

(3) HCFA will identify the sources used in compiling these lists.

(b) *Specific upper limits.*

(1) The agency's payment for multiple source drugs identified and listed in accordance with paragraph (a) of this section must not exceed, in the aggregate, payment levels determined by applying for each drug entity a reasonable dispensing fee established by the agency plus an amount established by HCFA that is equal to 150 percent of the published price for the least costly

therapeutic equivalent drug (using all available national compendia) that can be purchased by pharmacists in quantities of 100 tablets or capsules (or, if the drug is not commonly available in quantities of 100, the package size commonly listed) or, in the case of liquids, the commonly listed size.

(2) For multiple source outpatient prescribed drugs identified in subpart E of this part, the formula specified in paragraph (b)(1) of this section is not subject to change by HCFA during the period January 1, 1991, through December 31, 1994.

(3) A State that is in compliance with the formula under paragraph (b)(1) of this section and § 447.331 may not reduce its reimbursement limits for covered outpatient drugs or dispensing fees for these drugs established under this formula during the period January 1, 1991, through December 31, 1994.

4. A new § 447.335 is added to read as follows:

**§ 447.335 Additional upper limits for multiple source drugs.**

(a) *Establishment and issuance of listings.*

(1) In addition to establishing listings specified in § 447.332, HCFA will establish listings that identify and set upper limits for multiple source drugs for which at least three of the formulations of the drug approved by the Food and Drug Administration (FDA) have been evaluated as therapeutically and pharmaceutically equivalent (category "A") in the most current edition of its publication *Approved Drug Products with Therapeutic Equivalence Evaluations* (including supplements or in successor publications), regardless of whether all additional formulations are rated as such.

(2) HCFA will publish the lists of multiple source drugs for which upper limits have been established and revisions to the lists in Medicaid program instructions.

(3) HCFA will identify the source(s) used in compiling these lists.

(b) *Specific upper limits.* The agency's payment for multiple source drugs identified and listed in accordance with paragraph (a) of this section must not exceed, in the aggregate, payment levels determined by applying for each drug entity a reasonable dispensing fee established by the agency plus an amount established by HCFA that is equal to 150 percent of the published price for the least costly therapeutic equivalent drug (using all available national compendia) that can be purchased by pharmacists in quantities of 100 tablets or capsules (or, if the drug

is not commonly available in quantities of 100, the package size commonly listed) or, in the case of liquids, the commonly listed size. For purposes of this paragraph, therapeutic equivalent drugs mean drugs rated A or B by the FDA.

5. A new subpart I, consisting of §§ 447.500–447.550, is added to read as follows:

**Subpart I—Payment for Outpatient Prescription Drugs Under Drug Rebate Agreements**

Sec.

- 447.500 Basis and purpose.
- 447.502 Applicability.
- 447.504 Definitions.
- 447.506 Requirement for rebate agreements as a condition for payment for outpatient prescription drugs.
- 447.508 State plan requirements.
- 447.510 Rebate agreements: General requirements.
- 447.512 Terms of agreements.
- 447.514 Termination and nonrenewal of national rebate agreements.
- 447.516 Outpatient drugs subject to rebates.
- 447.518 Outpatient drugs of manufacturers without rebate agreements.
- 447.520 New drugs subject to rebates.
- 447.522 Drugs not subject to rebates.
- 447.524 Exclusions and restrictions on drugs subject to rebates.
- 447.526 Prior authorization programs.
- 447.530 State reporting requirements.
- 447.534 Manufacturer reporting requirements.
- 447.536 Resolution of disputes relating to information reported.
- 447.538 Resolution of disputes relating to drug access and State systems.
- 447.540 Confidentiality of reported information.
- 447.542 Penalties for failure to report or reporting false information.
- 447.546 Payment of rebates.
- 447.548 Computation of unit rebate amount.
- 447.550 Denial of FFP.

**Subpart I—Payment for Outpatient Prescription Drugs Under Drug Rebate Agreements**

**§ 447.500 Basis and purpose.**

(a) *Basis.* This subpart—

(1) Interprets section 1927 of the Act which provides in part that, in order for payment to be made under Medicaid for covered outpatient drugs of a manufacturer, the manufacturer must enter into and comply with a rebate agreement with the Secretary of HHS on behalf of States (or with States directly under specific authorization of the Secretary);

(2) Implements section 1902(a)(54) of the Act which includes a State plan requirement that provides that if a State elects to cover prescription drugs, the State must comply with the

requirements of section 1927 of the Act; and

(3) Implements section 1903(i)(10) of the Act which provides for denial of FFP in expenditures—

(i) For covered outpatient drugs of a manufacturer dispensed in any State if the manufacturer does not enter into and comply with a rebate agreement, except as prescribed in section 1927(a)(3) of the Act; and

(ii) For any amount expended which exceeds the upper payment limit for an innovator multiple source drug dispensed on or after July 1, 1991, if under applicable State law, a less expensive multiple source drug could have been dispensed.

(b) *Purpose.* This subpart specifies the requirements for State Medicaid agencies and the conditions under which FFP will be made for covered outpatient prescription drugs dispensed on or after January 1, 1991, under drug rebate agreements with manufacturers. This subpart also specifies the conditions for approval and renewal of rebate agreements with drug manufacturers and manufacturer reporting requirements.

#### § 447.502 Applicability.

(a) The provisions of this subpart E apply to the 50 States (including any State that is furnishing medical assistance under a waiver granted under section 1115 of the Act) and the District of Columbia.

(b) The provisions of this subpart do not apply to covered outpatient drugs dispensed by:

(1) Health maintenance organizations (HMOs), including those organizations that contract with HCFA under section 1903(m) of the Act; and

(2) Hospitals that dispense covered outpatient drugs using drug formulary systems and bill Medicaid no more than the hospital's purchasing costs for these drugs as determined under the approved State plan.

#### § 447.504 Definitions.

As used in this subpart E—

*Covered outpatient prescription drugs* or *covered outpatient drugs* means those drugs as defined in sections 1927(k) (2) through (4) of the Act and specified in § 447.516.

*Depot* means any Federal warehousing facility and distribution arrangement, including the Department of Defense's Electronic Commerce Initiative (ECI), whether:

(1) Government owned and operated;

(2) Government owned and privately operated; or

(3) Privately owned and operated.

*Depot prices* mean prices available to any depot of the Federal Government for

purchase of drugs from a manufacturer through the depot system of procurement, irrespective of whether the drug products physically flow through the depot.

*FDA* refers to the Food and Drug Administration, Department of Health and Human Services.

*Innovator multiple source drug* means a multiple source drug from 1938 to present that was originally marketed under an original new drug application approved by the FDA.

*Manufacturer.* (1) A manufacturer means any entity that—

(i) Is engaged in 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;

(ii) Is engaged in the packaging, repackaging, labeling, relabeling, or distribution of prescription drug products and is not a wholesale distributor of drugs or a retail pharmacy licensed under State law; and

(iii) Possesses legal title to the National Drug Code (NDC) number for a covered drug, or biological product.

(2) In the case of a corporation that meets the conditions of paragraphs (1)(i) and (1)(ii) of this definition, the entity includes—

(i) Any corporation that owns at least 80 percent of the total combined voting power of all classes of stocks or 80 percent of the total value of shares of all classes of stock in the entity (that is, a parent corporation);

(ii) Any other corporation in which the parent corporation of the entity owns at least 80 percent of the total combined voting power of all classes of stock or 80 percent of the total value of shares of all classes of stock in the other corporation (that is, a brother-sister corporation); and

(iii) Any other corporation in which the entity owns at least 80 percent of the total combined voting power of all classes of stock or 80 percent of the total value of shares of all classes of stock in the other corporation (that is, a subsidiary corporation).

*Manufacturer-specific pricing* data includes the average manufacturer price (AMP) (as defined in § 447.534(c)(1)), base date AMP, best price, or unit rebate amount in connection with a rebate agreement.

*Marketed* means that a drug was first sold by a manufacturer in the United States after FDA approval.

*Medically accepted indication* means any use for a covered outpatient drug

approved under the Federal Food, Drug, and Cosmetic Act, or any use that is supported by one or more citations included or approved for inclusion in any of the following compendia: the American Hospital Formulary Service-Drug Information; the American Medical Association Drug Evaluations; and the United States Pharmacopeia-Drug Information.

*Multiple source drug* means a covered outpatient drug for which there are two or more drug products which—

(1) Are rated as therapeutically equivalent by the FDA in its current edition of its publication *Approved Drug Products with Therapeutic Equivalence Evaluations*;

(2) As determined by FDA, are pharmaceutically equivalent (the drug products contain identical amounts of the same active drug ingredient in the same dosage form and meet compendial or other applicable standards of strength, quality, purity, and identity) and are bioequivalent (the drugs do not present a known or potential bioequivalence problem, or if they do present such a problem, they are shown to meet an appropriate standard of bioequivalence). (This condition does not apply if FDA changes by regulation the requirement that in order for drug products to be rated as therapeutically equivalent, they must be pharmaceutically equivalent and bioequivalent);

(3) For purposes of coverage under the drug rebate program, are rated as "A" or "B" (therapeutic equivalence code) by the FDA in its current edition of its publication *Approved Drug Products with Therapeutic Equivalence Evaluations*; and

(4) Are sold or marketed in the State during a rebate period.

*National rebate agreement* means the rebate agreement developed by HCFA to implement section 1927 of the Act.

*NDC* refers to the National Drug Code number maintained by the FDA.

*Nominal price* refers to a price that is less than 10 percent of AMP.

*Noninnovator multiple source drug* means a multiple source drug that is not an innovator multiple source drug and that was marketed under an abbreviated new drug application approved by FDA, or any marketed, unapproved pre-1938 drug product for which the FDA has not made a final determination about its legal status. The term includes—

(1) All products approved under an abbreviated new drug application, paper new drug application under the FDA's former "Paper NDA" policy, or an application under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act; and

(2) Any marketed, unapproved pre-1938 drug product that has not been evaluated under the new drug provisions of the Federal Food, Drug and Cosmetic Act.

*Original New Drug Application (NDA)* means an FDA-approved drug or biological application that received one or more forms of patent protection, patent extension under title II of Public Law 98-417, the Drug Price Competition and Patent Term Restoration Act, or marketing exclusivity rights granted by the FDA. This definition includes a new drug application (NDA), an amended NDA, an antibiotic drug application (ADA), an amended ADA, a product license application (PLA), and an amended PLA.

*Single award contract prices* means prices under a contract between the Federal Government and a manufacturer resulting in a single supplier for a covered outpatient drug within a class of drugs.

*Single source drug* means a covered outpatient drug which is produced or distributed under an original new drug application approved by the FDA, including a drug product marketed by any cross-licensed producers or distributors operating under the new drug application.

*Wholesaler* means any entity (including a pharmacy or chain of pharmacies) to which the manufacturer sells the covered outpatient drugs, but that does not relabel or repackage the covered outpatient drug.

**§ 447.506 Requirement for rebate agreements as a condition for payment for outpatient prescription drugs.**

In order for payments to be made under Medicaid for covered outpatient prescribed drugs described in §§ 440.120 and 447.516 of this subchapter, except as provided in § 447.518, the manufacturers of the drugs must have entered into and comply with:

(a) A rebate agreement with the Secretary on behalf of States, or with States directly, that meets the requirements of this subpart.

(b) A pharmaceutical pricing agreement with the Public Health Service, in accordance with section 340B of the Public Health Service Act, for all covered outpatient drugs purchased by a covered entity (as described in section 340B(a)(4) of the Public Health Service Act) on or after December 1, 1992.

(c) A pharmaceutical pricing agreement with the Department of Veterans Affairs (DVA), in accordance with 38 U.S.C. 8126, for all single source drugs, innovator multiple source

drugs, biologicals, and insulin, effective January 1, 1993.

**§ 447.508 State plan requirements.**

A State Medicaid plan must provide that the Medicaid agency will comply with all of the applicable requirements of this subpart.

**§ 447.510 Rebate agreements: General requirements.**

(a) *Basic requirements.*

(1) Except as specified in paragraph (a)(2) of this section, a manufacturer of covered outpatient drugs that are dispensed under a State Medicaid program must have entered into and must comply with—

(i) A national rebate agreement authorized by HCFA; or

(ii) A State agreement that meets the conditions of paragraph (b) or (c) of this section and is authorized by HCFA.

(2) A manufacturer that has entered into a State agreement that meets the requirements of paragraph (b) or (c) of this section must also enter into the national rebate agreement.

(3) A manufacturer must include in its rebate agreement a list all of its drugs, by NDC numbers, that fall within the definition of covered outpatient drugs.

(4) A manufacturer may not specify that only a partial list of its covered outpatient drugs are subject to rebate under this subpart.

(b) *Existing State/manufacturer agreements.*

(1) HCFA will consider an individual drug rebate agreement between a manufacturer and a State Medicaid agency that is in effect on November 5, 1990, to be in compliance with the Federal requirements for drug rebates for the initial agreement period if—

(i) The initial term of the agreement provides for a minimum aggregate rebate of 10 percent of the average manufacturer price, as defined in § 447.534(c), for all of the manufacturer's drugs paid for by the State under Medicaid in a rebate period;

(ii) The State agency agrees to report to HCFA any rebates paid under the rebate agreement; and

(iii) The State agency submits to HCFA a written assurance from the manufacturer that the minimum 10-percent rebate was met under the agreement as of November 5, 1990.

(2) HCFA will consider an existing individual State rebate agreement to be in compliance with Federal requirements for drug rebates throughout the initial period of the agreement only if the manufacturer continues to provide rebates that meet the minimum 10-percent rebate requirement specified in paragraph

(b)(1)(i) of this section throughout the initial period. If this requirement is not met, the manufacturer's drugs are subject to the terms of the national rebate agreement.

(3) A State and a manufacturer may amend the initial period of a rebate agreement that was in effect on November 5, 1990, that meets the requirements of paragraph (b)(1) of this section if the State and manufacturer are in agreement with all modifications and the terms of the agreement allow such modifications. Existing agreements may be amended to:

(i) Provide for a greater rebate; or

(ii) Add drugs if the minimum 10-percent aggregate rebate requirement is met.

(4) The manufacturer must have a rebate agreement that meets the requirements of section 1927(a) of the Act in every State and the District of Columbia for FFP to be available under Medicaid.

(c) *New State/manufacturer agreements.* If a State Medicaid agency did not have an existing agreement with its drug manufacturers in effect on November 5, 1990, it may enter into a new agreement under the conditions of this paragraph.

(1) The agreement must provide drug rebates as least as great as those required under the national rebate agreement.

(2) The State agency must agree to report to HCFA any rebates paid under the rebate agreement.

(3) The manufacturer must enter into the national rebate agreement.

(4) The State agency must provide to HCFA a written assurance from the manufacturer that the agreement provides rebates that equal or exceed the amounts in the national agreement.

(d) *Authorization by HCFA.* Existing and new agreements, and their renewals, must be specifically authorized by HCFA.

**§ 447.512 Terms of agreements.**

(a) *Initial period.*

(1) The initial period of an existing State/manufacturer agreement and a new State/manufacturer agreement is the period specified in the agreement. In the event no period is specified, the initial period is 1 year.

(2) The initial period of the national rebate agreement must be for at least 1 year.

(b) *Renewal of agreements.*

(1) An existing agreement may be renewed if—

(i) The agreement provides drug rebates as least as great as those required under the national rebate agreement;

(ii) The State agency agrees to report to HCFA any rebates paid under the rebate agreement;

(iii) The State agency provides to HCFA a written assurance from the manufacturer that the agreement provides rebates that equal or exceed the amounts in the national agreement; and

(iv) The manufacturer enters into the national rebate agreement.

(2) Each national agreement will be automatically renewed for successive periods of at least 1 year if the agreement continues to meet the conditions of the initial period of the agreement and requirements of these regulations, unless the manufacturer gives a written notice of intent not to renew the agreement or HCFA or the manufacturer terminates the agreement in accordance with § 447.514.

(c) *Effective dates of national rebate agreements.*

(1) A national rebate agreement that was entered into and authorized by HCFA between February 15, 1991, and April 30, 1991, is effective retroactive to January 1, 1991, unless the manufacturer requests a later effective date.

(2) A national rebate agreement that is entered into and authorized by HCFA on or after May 1, 1991, is effective the first day of the rebate period that begins more than 60 days after the date the agreement is entered into unless the manufacturer requests a later effective date.

**§ 447.514 Termination and nonrenewal of national rebate agreements.**

(a) *Who may terminate.* National rebate agreements may be terminated by HCFA or by the manufacturer as specified in paragraphs (b) and (c) of this section.

(b) *Termination by HCFA.*

(1) HCFA may terminate an agreement if the manufacturer violates the requirements of the rebate agreement or for "other good cause" shown. "Other good cause" includes, but is not limited to, any violations of the provisions of the national rebate agreement, section 1927 or the related regulations, or the persistent failure to provide timely information on pricing and other required information or to pay timely rebates.

(2) HCFA will send a written notice of the existence of a violation and the decision to terminate the agreement to the manufacturer and notify all State Medicaid agencies of the termination.

(3) The termination will be effective no earlier than 60 days after the date the notice of termination is sent to the manufacturer.

(4) If a manufacturer is dissatisfied with a termination decision made by HCFA, the manufacturer may request a

hearing to appeal the termination under the procedures established in the national rebate agreement. However, a request for a hearing will not delay the effective date of the termination.

(c) *Termination by the manufacturer.* A manufacturer may terminate an agreement for any reason.

(1) *Reasons other than nonrenewal—*  
(i) *Written notice.* To terminate an agreement for reasons other than nonrenewal, a manufacturer must provide a written notice of termination to HCFA at least 60 days before the beginning of the calendar quarter in which the termination will occur.

(ii) *Effective dates.* Termination will be effective on the first day of the first rebate period beginning at least 60 days after the manufacturer gives written notice requesting termination, or a later date if so specified by the manufacturer.

(2) *Nonrenewals—*(i) *Written notice.* A manufacturer that wishes not to renew an agreement must provide a written notice of nonrenewal of the agreement to HCFA at least 60 days before the end of the current agreement period.

(ii) *Effective dates.*

(A) Termination resulting from nonrenewal will be effective on the ending date of the term of the agreement if the manufacturer has given the 60-day advance notice.

(B) If the manufacturer has not given the 60-day advance notice, the effective dates of termination specified in paragraph (c)(1)(ii) of this section will apply.

(3) *Date of notice.* The postmark date of the U.S. Postal Service or common mail carrier will be considered as the date a manufacturer gives written notice.

(d) *Reinstatement after termination.* If an agreement is terminated by either HCFA or the manufacturer, another agreement with the manufacturer (or a successor manufacturer) may not be entered into until a period of one calendar quarter has elapsed from the date of the termination, unless HCFA finds good cause for an earlier reinstatement.

(e) *Effect of termination or nonrenewal on rebates due.* Any nonrenewal or termination of a rebate agreement will not affect rebates due before the effective date of nonrenewal termination.

(f) *Notification of termination.* HCFA will notify States of any termination of a manufacturer from the drug rebate program at least 30 days prior to the effective date of the termination.

**§ 447.516 Outpatient drugs subject to rebates.**

(a) Except for the drugs or items listed in § 447.522, the following covered

outpatient drugs are subject to rebates under this subpart:

(1) Drugs that are—

(i) Covered outpatient drugs of participating manufacturers under an approved State Medicaid plan; and

(ii) Dispensed by prescription (except certain over-the-counter drugs as specified in paragraph (a)(5) of this section);

(2) Drugs that meet the requirements of the Federal Food, Drug, and Cosmetic Act and the Drug Amendments of 1962 specified in section 1927(k)(2)(A) (i) through (iii) of the Act;

(3) A biological product other than a vaccine that may only be dispensed by prescription, is licensed under section 351 of the Public Health Service Act, and is produced at an establishment licensed under section 351 to produce such products;

(4) Insulin certified under section 506 of the Federal Food, Drug, and Cosmetic Act; and

(5) "Over-the-counter" drugs that are prescribed by a physician or other person authorized to prescribe drugs under State law, if the State provides for coverage of these drugs as prescribed drugs under its approved State Medicaid plan.

**§ 447.518 Outpatient drugs of manufacturers without rebate agreements.**

(a) *Definition.* For purposes of this section, *1-A rated drugs* means drugs classified as such by the FDA, prior to January 1, 1992, as new molecular or chemical entities that may provide effective therapy or diagnosis for a disease not adequately treated or diagnosed by any marketed drug, or provide improved treatment of a disease through improved effectiveness or safety (including decreased abuse potential) and identified in the FDA publication *Office of Drug Evaluation Statistical Report*, issued yearly. The term includes drugs rated as 1-A/AA.

(b) *Federal financial participation (FFP).* FFP is available for payments for single source and innovator multiple source 1-A rated drugs that are furnished by manufacturers without rebate agreements if—

(1) The State agency has determined that the availability of the drug is essential to the health of Medicaid recipients under the approved State plan;

(2) The prescribing physician has obtained approval for use of the drug before it is dispensed in accordance with a prior authorization program specified in § 447.526, or the Secretary has approved the State agency's determination regarding drug necessity under paragraph (b)(1) of this section.

**§ 447.520 New drugs subject to rebates.**

(a) Effective October 1, 1993, there is no special treatment for new drugs under the Medicaid drug rebate program.

(b) For the period January 1, 1991 through September 30, 1993—

(1) Subject only to the exclusions and restrictions specified in § 447.524 (a)(2) and (a)(3), a new drug of participating manufacturers must be covered for a period of 6 months after the date of approval of the drug by the FDA, regardless of when the manufacturer begins to market the drug.

(2) Except as specified in § 447.524(b), a State agency may not exclude, subject to the prior authorization conditions specified in § 447.526, or otherwise restrict the coverage of covered outpatient drugs under a drug rebate agreement any new drug or biological approved by the FDA for a period of 6 months after FDA approval.

(c) FFP is not available for coverage of new drugs furnished by manufacturers who do not have rebate agreements that were in effect for the 6-month period after FDA approval of the new drug, unless covered during the retroactive period of January 1, 1991, through March 31, 1991, or covered as a 1-A rated drug under § 447.518(b).

**§ 447.522 Drugs not subject to rebates.**

The following list indicates drugs or items that are not subject to rebates under this subpart:

(a) Any drug, biological product, or insulin provided as part of, or as incident to and in the same setting as any of the following (and for which Medicaid payment may be made as part of payment for the following and not as direct reimbursement for the drug):

(1) Inpatient hospital services;

(2) Hospice services;

(3) Dental services (except for drugs for which the approved State plan authorizes direct reimbursement to the dispensing dentist);

(4) Physician services;

(5) Outpatient hospital services;

(6) Nursing facility services and services provided by an intermediate care facility for the mentally retarded;

(7) Other laboratory and x-ray services; and

(8) Renal dialysis.

(b) Any drug, biological product, or insulin that is used for a medical indication that is not a medically accepted indication.

(c) Any drug, biological product, or insulin for which a NDC number is not required by the FDA.

(d) Medical supply items such as syringes (excluding insulin-filled syringes), urine and blood glucose

testing strips and devices, lancets, and inhalers.

(e) Enteral nutrition products that are not approved by FDA as a drug under sections 505, 506, and 507 of the Federal Food, Drug, and Cosmetic Act.

(f) Parenteral nutrition products that are not approved by the FDA under section 505 of the Federal Food, Drug, and Cosmetic Act and given by the intravenous route of administration.

(g) Investigational new drugs (for example, Treatment IND drugs, Group C cancer drugs, and Parallel Track drugs).

**§ 447.524 Exclusions and restrictions on drugs subject to rebates.**

(a) A State agency may limit coverage of outpatient drugs that are subject to rebate by—

(1) Implementing a prior authorization program, as specified in § 447.526;

(2) Restricting or excluding certain drugs from coverage as specified in paragraphs (b) and (c) of this section; and

(3) Restricting the quantity of drugs per prescription and the number of refills, as specified in paragraph (e) of this section.

(b) A State may exclude or restrict from coverage, as an outpatient drug subject to rebate, any drug if—

(1) The prescribed use of the drug is not for a medically accepted indication;

(2) The drug, the class of drug, or its medical use is contained on the list as specified in paragraph (c) of this section;

(3) The drug is subject to restrictions in an existing or new manufacturer rebate agreement with the State agency that has been authorized by HCFA in accordance with § 447.510; or

(4) The State has excluded coverage of the drug from its formulary established in accordance with section 1927(d)(4) of the Act.

(c) A State may exclude or restrict from coverage, as outpatient drugs subject to rebate, any of the prescribed drugs it has elected to cover under its approved State Medicaid plan that fall within the following descriptions of drugs, classes of drugs, or their medical uses:

(1) Agents when used for anorexia, weight loss, or weight gain.

(2) Agents when used to promote fertility.

(3) Agents when used for cosmetic purposes or hair growth.

(4) Agents when used for the symptomatic relief of cough or colds.

(5) Agents when used to promote smoking cessation.

(6) Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparation.

(7) Nonprescription drugs.

(8) Covered outpatient drugs for which the manufacturer seeks to require, as a condition of sale, that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee.

(9) Barbiturates.

(10) Benzodiazepines.

(d) HCFA will periodically update, by regulation, the list of drugs subject to restriction as specified in paragraph (c) of this section by adding drugs, classes of drugs, or medical uses if it determines that there is evidence of clinical abuse or inappropriate use. HCFA will make this determination on the basis of data collected by the State Medicaid agency's surveillance and utilization review (SUR) program under part 456 of this subchapter.

(e) A State may restrict the minimum and maximum quantities of covered outpatient drugs per prescription and the number of refills within a therapeutic class of drugs. A State may also restrict one or more package sizes of a drug to be dispensed as long as the restriction does not result in a participating manufacturer's drugs not being covered at all under the Medicaid program.

(f) The agency must specify in its State Medicaid plan that, except for the restrictions and exclusions specified in this section, and drugs excluded from its formulary which meets the requirements of section 1927(d)(4) of the Social Security Act, the formulary will permit coverage of covered outpatient drugs of manufacturers which have met the requirements of § 447.506 that are prescribed for a medically accepted indication.

(g) The agency must include in its State Medicaid plan a list of covered outpatient drugs, classes of drugs, or medical uses under paragraph (c) of this section that it is excluding or restricting from coverage under this section and specify the limitations or conditions on coverage.

**§ 447.526 Prior authorization programs.**

(a) A State agency may establish a prior authorization program for any covered outpatient drug under which the drug must be approved before it is dispensed for any medically accepted indication.

(b) A State agency may determine which persons (for example, physician, pharmacist) are permitted to request prior authorization of a drug.

(c) Under a prior authorization program, the State agency must—

(1) Provide for a response by telephone or telecommunications device to a request for prior authorization

within 24 hours of receipt of a request; and

(2) In emergency situations, provide for dispensing of at least a 72-hour supply of drugs, except for those drugs that are excluded or restricted as outpatient prescribed drugs under § 447.524.

(i) The State agency must specify in its State plan the process that will be used to determine what constitutes an emergency situation.

(ii) The State agency must ensure that its response to a prior authorization request is given to the dispenser before the emergency supply is exhausted.

(iii) In emergency situations, the State must provide a mechanism so that a dispenser or physician can make a prior authorization request 24 hours before the supply is exhausted and a response returned by the State within that 24-hour period.

(d) State staff who place drugs in a prior authorization system must be licensed to prescribe or dispense drugs in the State, for example, physicians or pharmacists.

(e) State staff who respond to prior authorization requests are not limited to persons licensed to prescribe or dispense drugs as long as all decisions involving drugs subject to prior authorization are made—

(i) In consultation with these licensed professionals; or

(ii) Under guidelines promulgated by such individuals as long as States provide access to these licensed professionals in difficult or unusual cases.

(f) The State agency must establish a process to ensure that recipients have access to medically necessary covered outpatient drugs and must provide annual written assurances to HCFA that its prior authorization program does not prevent recipients from gaining access to medically needed drugs.

#### § 447.530 State reporting requirements.

(a) *Basic requirement.* The State agency must provide to manufacturers with drug rebate agreements State drug utilization data specified in paragraph (b) of this section for which Medicaid payments have been made during a rebate period. For purposes of this section—

(1) The agency must use the 11-digit NDC number to report drug utilization data.

(2) *Unit* means the lowest commonly identifiable amount of a drug—for example, tablet or capsule for solid dosage forms, milliliter for liquid forms, and gram for ointments or creams, as described in the rebate agreement and accompanying appendices.

(b) *Type of data to be reported.* The State agency must submit to manufacturers the following information, based on claims paid by the agency during a rebate period:

(1) State identification;

(2) Rebate period and year for which data apply;

(3) The NDC number;

(4) Total units paid for during a rebate period by NDC.

(5) The product name (FDA registration name);

(6) Total amount of rebate that a State claims for each NDC;

(7) Total number of prescriptions paid for during the rebate period by NDC number; and

(8) The rebate amount per unit and the total amount paid for during the rebate period by NDC number to verify rebate payment.

(c) *Timeframe for reporting.*

(1) The State agency must report the utilization data no later than 60 days after the end of each rebate period.

(2) In the event that a due date falls on a weekend or Federal holiday, the report or other item will be due on the first business day following that weekend or Federal holiday.

(3) If a State does not submit its rebate period utilization data to the manufacturer within 1 year after the rebate period ends—

(i) A manufacturer is not required to pay a rebate on those drugs; and

(ii) A State may be considered out of compliance with section 1927 of the Act for failure to collect rebates.

(d) *Format of report.* The State agency must report the utilization data, using the NDC number, in a form prescribed by HCFA.

(e) *Administrative procedures for data collection.* The State agency must—

(1) Inform Medicaid participating drug dispensers that they are required to use accurate NDC numbers for the drugs dispensed in submitting their Medicaid claims and of potential payment denial, sanctions, including those for fraud and abuse, and possible termination of provider agreements, for incorrect coding of NDC numbers;

(2) Establish and implement an oversight and auditing plan to ensure proper pharmacy coding and reporting practices;

(3) Establish and implement procedures for investigating at the pharmacy level allegations of erroneous utilization data by manufacturers with rebate agreements; and

(4) Establish procedures for taking actions necessary to ensure accurate coding.

(f) *Use of data edits.* The State must verify the accuracy of utilization data

through the use of data edits such as, but not limited to—

(1) Unit types are appropriate for NDCs;

(2) Units match amount paid by the State; and

(3) Amount paid by the State is appropriate for the drug.

(g) *Use of rounding indicators.* States must identify by NDC number those drugs for which the number of units has been rounded by showing a rounding indicator for the number of units dispensed.

#### § 447.534 Manufacturer reporting requirements.

(a) *Basic requirements.* Under the terms of the drug rebate agreement, a manufacturer must—

(1) Supply HCFA with a list of all covered outpatient drugs (as specified in paragraph (c) of this section), the average manufacturer price, and, for single source and innovator multiple source drugs, the best price (as specified in paragraph (d) of this section) within 30 calendar days of entering into an agreement;

(2) Update the list of covered outpatient drugs as provided for in paragraph (b) of this section;

(3) Supply the information specified in paragraph (e) of this section for each rebate period in a format prescribed by HCFA in regulations or instructions; and

(4) Complete and submit to States the HCFA Form 302, the Remittance Advice Report (RAR), in a format prescribed by HCFA in regulations or instructions.

The RAR must include the information specified in paragraph (f) of this section, along with any rebate period rebates due within 30 days of receiving from the State Medicaid drug utilization data.

(b) *Update to manufacturer's drug list.* A manufacturer must update its list of all covered outpatient drugs for each rebate period, including the average manufacturer price of each drug, and, for single source and innovator multiple source drugs, the manufacturer's best price.

(1) The updated list must be reported by the manufacturer to HCFA no later than 30 days after the last day of each rebate period.

(2) The updated list reported by the manufacturer must include the NDC number for each covered outpatient drug currently marketed by the manufacturer and for all drugs that the manufacturer no longer markets until the supply of the drug under an NDC has expired, the drug has been taken off the market, or for any other reason, there no longer exists the potential that the drug may be paid for under the manufacturer's NDC number.

(c) "Average manufacturer price" defined.

(1) "Average manufacturer price" (AMP) means, with respect to a covered outpatient drug of the manufacturer for a rebate period, the average unit price paid to the manufacturer for the drug in the State by wholesalers for drugs distributed to the retail pharmacy class of trade (excluding sales to hospitals, health maintenance organizations and to wholesalers where the drug is relabeled under that distributor's NDC number), after deducting customary prompt pay discounts.

(2) Federal supply schedule prices are not included in the calculation of AMP.

(3) AMP includes cash discounts allowed and all other price reductions (other than rebates under this subpart), which reduce the actual price paid.

(4) AMP is calculated as a weighted average of prices for all the manufacturer's package sizes for each covered outpatient drug sold by the manufacturer during that rebate period. It is calculated as net sales divided by numbers of units sold, excluding goods or any other items given away, but not contingent on any purchase requirements. "Net sales" means quarterly gross sales revenues less cash discounts allowed and all other price reductions (other than rebates under section 1927 of the Act) which reduce the actual price paid. For bundled sales, the allocation of the discount is made proportionately to the dollar value of the units of each drug sold under the bundled arrangement. "Bundled sales" refers to the packaging of drugs of different types where the condition of rebate or discount is that more than one drug type is purchased, or where the resulting discount or rebate is greater than that which would have been received had the drug been purchased separately.

(5) The manufacturer must adjust the AMP for a rebate period if cumulative discounts or other arrangements subsequently adjust the prices actually realized.

(d) "Best price" defined.

(1) "Best price" means, with respect to single source and innovator multiple source drugs, the lowest single price at which the manufacturer sells the covered outpatient drug to any purchaser in the United States in any package size in any pricing structure (including capitated payments), in the same quarter for which the AMP is computed.

(2) To determine best price, use the following prices in the best price calculation:

(i) *Prices included in best price.*

(A) Except for those prices specifically exempted by law, as specified in paragraphs (d)(2)(i)(B) and (d)(2)(ii) of this section, best price includes prices to wholesalers, retailers, providers, HMOs, nonprofit entities, or governmental entities within the States (excluding depot prices and single award contract prices of any agency of the Federal Government).

(B) For periods January 1, 1991, through October 27, 1991, and July 1, 1992, through September 30, 1992, best price includes any prices charged under the Federal Supply Schedule of the General Services Administration, including prices for drugs and biologicals paid by the DVA and drugs and biologicals in contracts administered by the DVA.

(ii) *Prices excluded from best price.*

(A) For periods beginning on or after October 1, 1992, best price excludes any prices charged to the Indian Health Service, the DVA, a State home receiving funds under 38 U.S.C. 1741, the Department of Defense, the Public Health Service, or a covered entity described in section 1927(a)(5)(B) of the Social Security Act; any prices charged for drugs and biologicals under the Federal Supply Schedule of the General Services Administration; or any prices used under a State pharmaceutical assistance program.

(B) For the period October 28, 1991, through June 30, 1992, best price excludes any prices charged under the Federal Supply Schedule of the General Services Administration for drugs and biologicals paid by the DVA and drugs and biologicals in contracts administered by the DVA.

(3) Calculations of best prices must include cash discounts, free goods that are contingent on any purchase requirements, volume discounts, and rebates, other than rebates under section 1927 of the Act.

(4) Best price must be determined on a unit basis without regard to special packaging, labeling, or identifiers on the dosage form or product or package, and must not take into account prices that are nominal in amount.

(5) For bundled sales, the allocation of the discount is made proportionately to the dollar value of the units of each drug sold under the bundled arrangement.

(6) The manufacturer must adjust the best price for a rebate period if cumulative discounts, rebates, or other arrangements subsequently adjust the prices actually realized.

(7) For purpose of this section, *provider* means a physician, hospital and other health maintenance organizations or entities that treat individuals for illnesses or injuries or

provides services or items in the provisions of health care.

(e) *Contents of quarterly report.* The manufacturer's quarterly reports to HCFA must include—

(1) NDC number with labeler code, product code, and package size code;

(2) Period covered for rebates (rebate period and year);

(3) Product FDA registration name;

(4) Drug category of single source, innovator multiple source, or noninnovator multiple source;

(5) Indicator for drug reviewed under the Drug Efficacy Study Implementation (DESI) program;

(6) FDA therapeutic equivalence explanation code;

(7) Unit type;

(8) Units per package size;

(9) AMP;

(10) Basedate AMP;

(11) Best price;

(12) FDA approval date;

(13) Date drug entered market;

(14) Drug termination date;

(15) Drug type; and

(16) Correction record flag which signals that the record contains corrected information from a previous submission.

(f) *Contents of Remittance Advice Report (RAR) (HCFA Form 304).* The manufacturer's RARs to States must include—

(1) Manufacturer name, labeler code, address, and name, telephone number, and facsimile number of contact person;

(2) State;

(3) Rebate period and year for which the information applies;

(4) Invoice number, if State provided one;

(5) NDC number and product name;

(6) Rebate amount per unit;

(7) Units invoiced;

(8) Rebate amount invoiced;

(9) Rebate amount paid;

(10) Adjusted rebate per unit, if applicable;

(11) Adjustment code, if applicable;

(12) Credit/debit indicator, if applicable;

(13) Adjusted invoice amount, if applicable;

(14) Units disputed, if applicable;

(15) Dispute code, if applicable;

(16) Withheld invoice amount, if applicable;

(17) Total rebate amount invoiced;

(18) Total rebate amount paid;

(19) Total adjusted invoice amount, if applicable; and

(20) Total withheld invoice amount, if applicable.

(g) *Recordkeeping requirements.*

(1)(i) Except as set forth in paragraph (e) of this section, a manufacturer must retain records (written or electronic) for

3 years from the date the manufacturer reports that rebate period's data. The records must include the data and any other materials from which the calculations of the AMP and best price are derived, including a record of any assumptions made in the calculations.

(ii) A manufacturer must retain records beyond the 3-year period if audit findings have not been resolved.

(2) Both the State and manufacturer must retain supporting documentation (written or electronic) related to the dispute resolution process and the RAR for 3 years from the date a dispute is resolved between the manufacturer and State.

(h) *Timeframe for reporting revised AMP or best price.* A manufacturer must report changes to AMP or best price for 3 years after the quarter to which the data pertains.

**§ 447.536 Resolution of disputes relating to information reported.**

(a) *Resolving data inconsistencies.*

(1) The manufacturer must attempt to identify and resolve data inconsistencies in State Medicaid drug utilization data prior to initiating the dispute resolution process described in paragraphs (b) and (c) of this section.

(2) The manufacturer must attempt to resolve any data inconsistencies under paragraph (a)(1) of this section with the State by no later than 30 days after receipt of State Medicaid drug utilization data. The manufacturer may initiate this process through telephone contact with the State.

(3) If data inconsistencies are resolved by the manufacturer and State, the manufacturer must record this fact on the RAR and the State must maintain supporting documentation to substantiate the resolution of the data inconsistencies.

(b) *Reporting disputes.*

(1) If, in any rebate period, a manufacturer and the State are unable to resolve data inconsistencies under paragraph (a) of this section or other disputed items within 30 days after the manufacturer receives State Medicaid drug utilization data, the manufacturer must complete and submit the RAR to the State in accordance with § 447.534(a)(4) or the State's utilization data are considered final and binding and the entire rebate payment is due.

(2) The RAR must include the information specified in § 447.534(f) and identify by each NDC the reason(s) why the manufacturer is disputing the data.

(3) The manufacturer must submit to the State supporting documentation for certain types of disputes as indicated on the RAR. The manufacturer must submit

supporting documentation for certain types of disputes as indicated on the RAR if a State requests the documentation to verify information.

(4) The RAR must be postmarked by the United States Postal Service or common mail carrier on or prior to the due date for the rebate period payment of the rebates to the State agency.

(c) *Resolving disputes.*

(1) Within 90 days after the State receives the RAR, the State must contact the manufacturer in writing or by telephone to discuss the dispute and to present the State's preliminary response on the disputed items to the manufacturer. If the dispute is resolved, the manufacturer and the State must both maintain supporting documentation of the resolution for 3 years from the date the dispute is resolved.

(2) If the dispute is not resolved in accordance with paragraph (c)(1) of this section, the State must, within 150 days after the State receives the RAR and in accordance with State confidentiality laws—

(i) Provide the manufacturer with drug utilization data, such as zip code-level data, pharmacy-level data, sampling of pharmacy claims, or historical trends on those items in dispute; and

(ii) Submit to the manufacturer the same type of drug utilization data used by the manufacturer to identify disputed items.

(3) If State confidentiality laws prohibit the State from releasing the types of information in paragraph (c)(2) of this section, the State may require the manufacturer to provide the data upon which the manufacturer based the dispute to the State. Upon such request, the manufacturer must furnish such data to the State within 150 days after the State receives the RAR.

(4) Within 240 days after the State receives the RAR, the State and manufacturer must complete negotiations. One of the following actions must occur:

(i) The State ceases the dispute resolution process based on a cost-effectiveness determination in accordance with paragraph (k) of this section;

(ii) The State and the manufacturer settle on the State Medicaid drug utilization data and agree to make appropriate adjustments to any rebate amounts;

(iii) The State and the manufacturer agree to a resolution based on mutually acceptable data which is more representative of actual Medicaid utilization;

(iv) If no resolution is reached, the State must schedule a hearing in accordance with paragraph (d) of this section or the State may be subject to a compliance action by HCFA; or

(v) In lieu of a State hearing, the State and manufacturer may agree to arbitration or mediation to settle the dispute.

(5) The State must maintain documentation which clearly describes its decision to—

(i) Cease the dispute resolution based on cost-effectiveness as specified in paragraph (k) of this section; or

(ii) Agree with the manufacturer on a settlement as specified in paragraphs (c)(4)(ii) or (c)(4)(iii) of this section.

(d) *State hearing.*

(1) If no settlement has been reached between the State and the manufacturer within 240 days after the State receives the RAR, the State, must within 30 days, schedule a hearing. The hearing must be conducted within 1 year from the 240th day after the State receives the manufacturer's RAR.

(2) The manufacturer may require a State to schedule a hearing at any stage of the process if the State does not take the required actions of the dispute process within the specified timeframes. The State must, within 30 days, schedule a hearing.

(3) If the manufacturer does not comply with its timeframes specified in the agreement, the State may—

(i) At any stage of the process schedule a hearing which must be conducted within 1 year from the 240th day after the State received the manufacturer's RAR;

(ii) Follow the administrative law or judicial process for collecting rebate payments; and/or

(iii) Request HCFA, through the Regional Office, to terminate the manufacturer's national rebate agreement.

(e) *Use of arbitration or mediation.*

(1) In lieu of a State hearing, the State and the manufacturer may agree to arbitration or mediation to resolve the dispute.

(2) The State must maintain documentation which clearly describes the agreement with the manufacturer to resolve the dispute through arbitration or mediation rather than a State hearing.

(3) The State must maintain documentation for a period of 3 years from the date the dispute is resolved through arbitration or mediation.

(f) *Payment of rebate pending resolution of disputes.*

(1) The manufacturer must pay the State agency that portion of the rebate claimed which is not in dispute by the due date of the required rebate period rebate payment.

(2) The manufacturer may, at its option, make payment on the disputed portion of the data.

(g) *Interest on disputed amounts.*

(1) The manufacturer or the State agency must pay or credit the balance due, if any, plus a rate of interest as specified in section 1903(d)(5) of the Act by the due date of the first rebate period payment after resolution of the dispute.

(2) For disputed amounts withheld by the manufacturer and due the State, the interest is computed from the 38th day after the State mails its Medicaid drug utilization data and stops accruing on the later of the date the dispute is resolved, and the date the disputed amount is paid or credited to the proper party.

(3) For amounts paid by the manufacturer on the disputed the amount, interest must be paid by the State when resolution results in payment to the manufacturer. Interest must be paid for the period from the date of receipt of payment for the disputed data to the date the dispute is resolved and the disputed amount is paid or credited to the manufacturer.

(h) *Adjustment of rebate payment.*

The State agency must adjust rebate payments if information indicates that Medicaid utilization data was greater or less than previously specified on the State's invoice for rebate payments.

(i) *Availability of FFP for rebates lost in a dispute.* FFP is available for otherwise properly dispensed drugs that involve disputed drug utilization data, and the Federal portion of the rebate is not required from the State, when—

(1) A dispute was terminated because the State determined and adequately documented that the dispute resolution process was not cost-effective as specified in paragraph (k) of this section; or

(2) Less than the full rebate resulted from a dispute resolution between a State and a manufacturer as specified in paragraph (c)(4)(ii) or (c)(4)(iii) of this section.

(j) *Rebate tolerances—(1)*

*Administrative cost tolerance.*

Generally, the State is not required to invoice manufacturers for rebates per labeler code which are less than the administrative cost tolerance of \$50 associated with the preparation of the invoice.

(2) *Updates to administrative cost tolerance.* HCFA will update the administrative cost tolerance through Medicaid program instructions.

(k) *Cost-effectiveness tolerance for disputed amounts—(1)*

*Cost-effectiveness tolerance.* Under paragraph (c)(4)(i) of this section, a State

may cease the dispute resolution process based on the following cost-effectiveness tolerances:

(i) The disputed amount is less than \$10,000 per labeler code; and

(ii) The disputed amount is less than \$1,000 per product code.

(2) *Updates to cost-effectiveness tolerance.* HCFA will update the cost-effectiveness tolerances through Medicaid program instructions.

**§ 447.538 Resolution of disputes relating to drug access and State systems.**

(a) A manufacturer may request HCFA to initiate compliance action against a State if the State fails to comply with section 1927 of the Act. The manufacturer may also request HCFA to initiate compliance action when the State agency shows a pattern or history of inaccuracy in reporting Medicaid drug utilization data.

(b) Any compliance action initiated by HCFA will not relieve the manufacturer from its obligation of making the rebate payment as provided in § 447.546.

**§ 447.540 Confidentiality of reported information.**

(a) *State agency requirements.*

(1) Except as specified in paragraph (a)(2) of this section and notwithstanding other laws, including, but not limited to, the Freedom of Information Act (5 U.S.C. 552), the State agency and its contractors must not disclose any manufacturer-specific pricing data collected or reported in connection with a rebate agreement in any form that reveals the manufacturer or wholesaler of a drug or prices for the drugs that are charged by the manufacturer or wholesaler.

(2) The State agency and its contractors must provide to HCFA information that is necessary to carry out the provisions of section 1927 of the Act and to permit review under section 1927 of the Act by the Comptroller General and the Director of the Congressional Budget Office.

(3) A State agency may release its utilization data, excluding manufacturer-specific pricing data, to the extent such release of information is allowed under a State's confidentiality laws.

(b) *Manufacturer requirements.*

(1) A manufacturer or its contractors must not disclose information contained in the State's drug utilization reports.

(2) A manufacturer must observe State confidentiality laws and regulations.

**§ 447.542 Penalties for failure to report or reporting false information.**

(a) *Surveys and audits.*

(1) HHS surveys wholesalers, manufacturers, and direct sellers that distribute covered outpatient drugs, when necessary, to verify manufacturer prices reported to HCFA.

(2) HHS may audit a manufacturer's calculations of AMP and best price of covered outpatient drugs, as necessary, to verify reported data.

(b) *Imposition of penalties.*

(1) The Secretary may impose on any wholesaler, manufacturer, or direct seller of a covered outpatient drug that refuses a request for information about charges or prices in connection with a survey or knowingly provides false information a civil monetary penalty in an amount not to exceed \$100,000 for each item.

(2) The Secretary may impose on a manufacturer who fails to provide the required information on AMP and best price or the list of covered outpatient drugs on a timely basis a civil money penalty of \$10,000 for each day beyond the due date that the information is not provided.

(i) If the information is not reported within 90 days of the due date, HCFA may suspend the drug rebate agreement after the end of the 90-day period.

(ii) The suspension is for a period of at least 30 days and continues until the information is provided.

(3) The Secretary may impose on a manufacturer that knowingly provides false information an additional penalty not to exceed \$100,000 for each item of false information. These civil money penalties are in addition to other penalties as may be prescribed by law.

(c) *Procedures for imposing penalties.* The imposition of a civil money penalty will be made in accordance with the provisions of sections 1128A and 1927(b)(3) of the Act.

**§ 447.546 Payment of rebates.**

(a) *Basic requirements.* In order for FFP to be available to a State for expenditures for covered outpatient drugs of a manufacturer, the manufacturer must agree to—

(1) Calculate a rebate payment using the formulas specified in paragraph (b) of this section and make a rebate payment to each State Medicaid agency for the manufacturer's covered outpatient drugs paid for by the State Medicaid agency during the rebate period;

(2) Make the rebate payments for each rebate period within 30 days after receiving from the State Medicaid drug utilization data on the total number of units of covered outpatient drugs, by NDC number, paid by the State under the plan during the rebate period, as

reported in accordance with § 447.530; and

(3) Continue to make rebate payments for all of its covered outpatient drugs for as long as an agreement is in force and drug utilization data reports are made and until—

(i) The entire supply of the drug under an NDC number has expired;

(ii) The drug has been taken off the market; or

(iii) For another reason, there no longer exists the potential that the drug may be paid for under the manufacturer's NDC number.

(b) *Formulas for rebates.*

(1) The basic rebate for single source drugs and innovator multiple source drugs is—

(i) For January 1, 1991, through December 31, 1991: The greater of 12.5 percent of the AMP or the AMP minus best price. (The rebate is capped at 25 percent of AMP.)

(ii) For January 1, 1992, through September 30, 1992: The greater of 12.5 percent of the AMP or the AMP minus best price. (The rebate is capped at 50 percent of AMP.)

(iii) For October 1, 1992, through December 31, 1993: The greater of 15.7 percent of the AMP or the AMP minus best price. (The rebate is capped at 50 percent of the AMP for the rebate period of October 1, 1992, through December 31, 1992.)

(iv) For January 1, 1994, through December 31, 1994: The greater of 15.4 percent of the AMP or the AMP minus best price.

(v) For January 1, 1995, through December 31, 1995: The greater of 15.2 percent of the AMP or the AMP minus best price.

(vi) For January 1, 1996, and thereafter: The greater of 15.1 percent of the AMP or the AMP minus best price.

(2) The additional rebate for single source and innovator multiple source drugs is for calendar years 1991 through 1993: On a drug-by-drug basis, the amount by which the increase in the AMP exceeds the increase in the Consumer Price Index-Urban (CPI-U) from October 1, 1990, to the month before the rebate period of the rebate.

(3) The rebate for noninnovator multiple source and other drugs is—

(i) For calendar years 1991 through 1993: 10 percent of the AMP.

(ii) For calendar years 1994 and thereafter: 11 percent of the AMP.

(c) *Late submittal of data.* The manufacturer is not required to pay a rebate if the State does not submit its rebate period utilization data to the manufacturer within 1 year after the rebate period ended.

**§ 447.548 Computation of unit rebate amount.**

(a) HCFA computes a per drug unit rebate amount on the basis of the formulas specified in § 447.546(b). The rebate amount will be based on unit pricing information supplied by the manufacturer in accordance with § 447.534.

(b) HCFA supplies the per drug unit rebate amount to each State on a rebate period basis. The State must compute the total rebate anticipated, based on its own utilization records, and send an invoice to the manufacturers for a total rebate amount due. However, the manufacturer remains responsible for correctly calculating the rebate amount based on State reported utilization data and its correct determination of AMP and, where applicable, base date AMP and best price, as defined in § 447.534.

**§ 447.550 Denial of FFP.**

(a) Except for those drugs described in § 447.518, FFP will be denied for payment of any dispensed covered outpatient drug of a manufacturer that does not have in effect and comply with:

(1) A drug rebate agreement, as specified in this subpart;

(2) A pharmaceutical pricing agreement with the Public Health Service, in accordance with section 340B of the Public Health Service Act, for all covered outpatient drugs purchased by a covered entity (as described in section 340B(a)(4) of the Public Health Service Act) on or after December 1, 1992; and

(3) A pharmaceutical pricing agreement with the DVA, in accordance with 38 U.S.C. 8126, for all single source drugs, innovator multiple source drugs, biologicals, and insulin, effective January 1, 1993.

(b) FFP is not available for payment for expenditures that exceed the upper payment limit for an innovator multiple source drug that is subject to the Federal upper limits in §§ 447.332(a) and 447.335 dispensed on or after July 1, 1991, if, under applicable State law, a less expensive noninnovator multiple source drug could have been dispensed.

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Programs)

Dated: April 12, 1995.

Bruce C. Vladeck,  
*Administrator, Health Care Financing Administration.*

Dated: August 31, 1995.

Donna E. Shalala,  
*Secretary.*

[FR Doc. 95-22860 Filed 9-18-95; 8:45 am]

BILLING CODE 4120-01-P

**FEDERAL COMMUNICATIONS COMMISSION**

**47 CFR Part 90**

[PR Docket No. 92-235, DA 95-1967]

**Examination of Exclusivity and Frequency Assignment Policies**

**AGENCY:** Federal Communications Commission.

**ACTION:** Proposed rule; extension of comment period.

**SUMMARY:** On June 15, 1995, the Commission adopted a *Further Notice of Proposed Rule Making* which seeks to introduce market forces into the Private Land Mobile Radio (PLMR) bands. The *Further Notice of Proposed Rule Making* proposed three options to introduce market forces into these bands: exclusivity, user fees, and competitive bidding. The Commission sought comment on each of these options in order to assist in the development and implementation of an overall strategy on how to promote greater efficiency in these bands. This proposed rule extends the period of time in which commenters have to file comments and reply comments.

**DATES:** Comments are to be filed on or before October 16, 1995, and reply comments are to be filed on or before November 20, 1995.

**FOR FURTHER INFORMATION CONTACT:** Mark Rubin of the Wireless Telecommunications Bureau at (202) 418-0680.

**SUPPLEMENTARY INFORMATION:**

Order Extending Comment and Reply Comment Period

Adopted: September 12, 1995

Released: September 13, 1995

By the Chief, Private Wireless Division:

1. On September 1, 1995, the American Public Transit Association (APTA) requested that the time for filing comments in response to the *Further Notice of Proposed Rule Making* in the above-captioned proceeding released by the Commission on June 23, 1995,<sup>1</sup> be extended from September 15, 1995, to October 16, 1995. Likewise, on September 5, 1995, the Land Mobile Communications Council (LMCC) filed a Motion For Extension Of Time until November 20, 1995, to file comments. LMCC also requested that the time for filing reply comments be extended from October 16, 1995, to January 5, 1996.

2. APTA, which represents approximately 400 American public and private mass transit systems, states that

<sup>1</sup> FCC 95-255, 60 Fed. Reg. 37148 (1995).