February 26, 1992


**MEDICAID DRUG REBATE PROGRAM Release No. 4**

*** * * IMMEDIATE ATTENTION REQUIRED * * ***

**NOTE TO: All Participating Drug Manufacturers**

## UPDATING INDIVIDUAL CONTACT INFORMATION

There continue to be large numbers of discrepancies between the HCFA list of labeler contacts (financial, legal and technical) and that which labelers have requested States to use. Please remember that **ALL** correspondence from both HCFA **and** States is derived from the information you submitted with your signed rebate agreement. **The HCFA list is the official list to be used by States for drug labeler contacts.**

If there is a change in any contact information (name, address, telephone number), that change **MUST** be submitted to HCFA rather than sending it to individual States. HCFA will notify each State and maintain the data on a computerized master file. Each change must be submitted to HCFA in writing and sent to HCFA via mail or facsimile transmission at either (410) 966-0390 or 966-3252.
**Do not** request States to send invoices to persons other than those supplied to us. If you want invoices to go to someone other than currently listed, send the change to HCFA and we will make the change and inform each State.

## TELEPHONE AREA CODE CHANGES

Many localities are being affected by changes in area telephone codes. The eastern half of Maryland, which includes HCFA, is going through a transition from area code 301 to area code 410. Also, we are aware of an area code change in New Jersey. If your area code changed since submitting the rebate agreement, please inform us, immediately, so that we can update your contact information.

## DESI DRUG INDICATOR CONVERSION

As we alerted you in Release Number 3 dated December 26, we are advising you of a mandatory change that must be made for every NDC belonging to your labeler code. Attached you will find detailed definitions pertaining to the new table of values for the DESI DRUG INDICATOR field. This change was prompted by the receipt of a list of drug products which have been designated by the Food and Drug Administration (FDA) as Less-Than-Effective (LTE) and/or Identical, Related or Similar (IRS).

**THIS REQUIREMENT IS MANDATORY AND MUST BE COMPLETED AND RETURNED TO HCFA NO LATER THAN MARCH 31, 1992. DRUG PRODUCTS NOT CONTAINING THE NEW DESI VALUES WILL BE AUTOMATICALLY CHANGED TO A LTE (5 or 6) DESIGNATION UNTIL SUCH TIME THAT THE AFFECTED DRUG LABELER COMPLIES WITH THIS REQUIREMENT. THIS COULD RESULT IN ALL OR SOME OF YOUR DRUG PRODUCTS NOT BEING PURCHASED BY STATE MEDICAID AGENCIES.**

Additionally, some of you will receive an attachment to this note which lists those drug products belonging to your labeler code that the FDA has ruled to be LTE or IRS. We are aware that many drug products shown on the FDA list are obsolete or were purposely excluded from your data transmissions to HCFA since you were aware of the FDA ruling on them. Each drug product on the FDA list is identified by a 9 position NDC, FDA Drug Product Name, the NOOH date and the number assigned by the FDA. If you receive a listing of LTE drug products attached to this note, be advised that the DESI DRUG INDICATOR for these drug products is expected to be one of the LTE values (5 or 6) shown in the attached specification. Any disagreement should be referred to the FDA not HCFA. We will review each NDC on the FDA listing for compliance by drug labelers.

Finally, we have included with this note revised data definitions that show the new table of values for the DESI DRUG INDICATOR field.

## LATE DATA SUBMISSIONS TO HCFA

We are taking this opportunity to remind you of your responsibility to submit quarterly prices for your drug products within 30 days after the end of each calendar quarter. There are a number of drug labelers that submit their prices late every quarter and must be called numerous times. Per Section §1927(b)(3)(C) of the Social Security Act, failure to provide timely information can result in a daily penalty of $10,000 being assessed or the suspension of the agreement for not less than 30 days. We strongly urge your compliance with that requirement.

**MONTHLY CONSUMER PRICE INDEX (URBAN) (CPI-U)**

The latest CPI-U values are as follows:

| | | | | | |
|---|---|---|---|---|---|
| 09/90 | 132.7 | 02/91 | 134.8 | 07/91 | 136.2 |
| 10/90 | 133.5 | 03/91 | 135.0 | 08/91 | 136.6 |
| 11/90 | 133.8 | 04/91 | 135.2 | 09/91 | 137.2 |
| 12/90 | 133.8 | 05/91 | 135.6 | 10/91 | 137.4 |
| 01/91 | 134.6 | 06/91 | 136.0 | 11/91 | 137.8 |
| 12/91 | 137.9 | | | | |

Please continue to refer your questions to us by calling the drug rebate hotline at (410) 966-3249.

Christine Nye
Director
Medicaid Bureau

Attachment

cc: Regional Administrators, HCFA

## THE DRUG EFFICACY STUDY AND IMPLEMENTATION (DESI) AND THE IDENTICAL, RELATED OR SIMILAR (IRS) DRUGS UNDER THE MEDICAID PROGRAM

The rebate agreement requires that the manufacturer's list of covered outpatient drugs include the national drug code (NDC) numbers for all drugs currently and previously marketed by the manufacturer. To comply with these requirements, manufacturers must also include on their lists of covered outpatient drugs **all** DESI/IRS drugs. The following sections will facilitate manufacturer and State identification and reporting of DESI/IRS drugs: I-Overview of the DESI Program, II-Description and Coverage of DESI/IRS Drug Groups, and III-Reporting DESI/IRS Drugs.

### I.OVERVIEW OF THE DESI PROGRAM

The Drug Efficacy Study and Implementation (DESI) program was the result of the Drug Amendments of 1962 (Pub. L. 87-781) enacted on October 10, 1962. The Drug Amendments of 1962 was enacted to require that manufacturers prospectively prove that a drug is both safe and effective before it could be marketed. Before the Drug Amendments of 1962, drugs could be marketed as long as the manufacturer could prove that the drug was safe for its labeled indications. Because drugs approved prior to October 10, 1962 (pre-62 drugs) were only approved as safe, the DESI program was established under which the FDA would review the effectiveness of drugs approved prior to 1962. During this review process, manufacturers were permitted to continue to market these pre-62 drugs. These drugs that are subject to review by the FDA are referred to as DESI drugs.

If the DESI review shows that a drug is not effective for some or all of its labeled indications, the Secretary of Health and Human Services publishes a Notice of Opportunity for a Hearing (NOOH) in the Federal Register. At that time, a manufacturer of that drug or identical, related or similar (IRS) drugs has the opportunity to convince the FDA that the drug is effective for its labeled indications or the FDA will require the manufacturer to withdraw the drug from the market. Drugs for which a NOOH has been issued are referred to as less than effective (LTE) DESI drugs. The IRS drug counterpart of a LTE DESI drug is also considered LTE.

Under section 1903(i)(5) of the Act, Medicaid FFP is not available for LTE DESI/IRS drug for which a NOOH is issued for **all** labeled indications. Under the drug rebate program, a drug is not

considered a covered outpatient drug for its unapproved indications if a NOOH is issued for **some or all** labeled indications.

## II.DESCRIPTION AND COVERAGE OF DESI/IRS DRUG GROUPS

At the present time, drugs subject to the DESI review process are in various stages of review. The drugs that fall within the various stages are described below. The mandatory and optional State coverage requirements and FFP restrictions are discussed for each of these groups. The term "DESI/IRS drugs" is used when discussing coverage of a DESI drug and its IRS counterparts.

The code that manufacturers must use in the DESI DRUG INDICATOR field when reporting these drugs is indicated for each group. Codes 2 through 6 are used to indicate the status of a DESI/IRS drug in the DESI DRUG INDICATOR field. Codes 0 and 1 are reserved and may not be used in this field as we want to assure that manufacturers reexamine all their drugs and properly classify them in accordance with these instructions.

### oDESI/IRS Drugs Determined Safe and Effective--CODE 2

Non-DESI/IRS drugs and pre-62 drugs that have undergone the DESI review process and have been determined by the Food and Drug Administration (FDA) to be effective for their labeled uses under section 505 of the Federal Food, Drug and Cosmetic Act meet the definition of a covered outpatient drug. Therefore, these DESI/IRS drugs of a participating manufacturer must be covered under the drug rebate program, are subject to rebate, and Federal financial participation (FFP) is available.

NOTE:Manufacturer data records must indicate a code "2" in the DESI DRUG INDICATOR field when reporting these drugs.

### oDESI/IRS Drugs Under Review (No Notice of Opportunity for a Hearing [NOOH] Issued)--CODE 3

Section 1927(d)(2)(I) gives States the option to exclude or restrict from coverage DESI or IRS drugs. As with all drugs covered under the rebate program, section 1927(d)(2)(I) is limited to those drugs that meet the definition of a covered outpatient drug in section 1927(k)(2)(a)(iii).

Under this section, the following DESI/IRS drugs meet the definition of a covered outpatient drug and may be excluded or restricted from coverage at State option:

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 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.

Therefore, a State may exclude or restrict from coverage 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. This includes DESI/IRS drugs that have not been reviewed by the FDA or are still under review and, therefore, a NOOH has not been issued. If a State covers these DESI/IRS drugs, FFP is available for the drugs of participating manufacturers and the drugs are subject to a rebate. (This group does not include drugs under Code 2 (safe and effective)).

NOTE: Manufacturer data records must indicate a code "3" in the DESI DRUG INDICATOR field when reporting these drugs.

**o Less Than Effective (LTE) DESI/IRS Drugs For Some Indications--CODE 4**

Sections 1903(i)(5) and 1862(c) of the Act do not prohibit Federal payment if a DESI drug is effective for **at least one indication**. These drugs may be covered at State option and FFP is available.

Although these drugs may be covered at State option, there are situations when they may be subject to rebate. The definition of a covered outpatient drug in section 1927(k)(2)(A)(iii) 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 (LTE) for some or all of their prescribed uses.

However, when these drugs are considered safe and effective for an approved indication, they are considered a covered outpatient drug for that indication. Therefore, these drugs of participating manufacturers must be included in the drug rebate program for their approved indications (and other medically accepted indications), are subject to rebate, and FFP is available.

NOTE:Manufacturer data records must indicate a code "4" in the DESI DRUG INDICATOR field when reporting these drugs.

**oLTE DESI/IRS Drugs For All Indications--CODE 5**

Under section 1903(i)(5) of the Act, Federal payment 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 applies regardless of whether the manufacturer is appealing the NOOH for some or all of the drug's indications.

NOTE:Manufacturer data records must indicate a code "5" in the DESI DRUG INDICATOR field when reporting these drugs.

**oLTE DESI/IRS Drugs Withdrawn from the Market--CODE 6**

This group of LTE DESI/IRS drugs has been determined by the FDA to be LTE, a NOOH has been issued, and the manufacturer has voluntarily withdrawn the drug from the market. 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, FFP is not available for these drugs.

NOTE:Manufacturer data records must indicate a code "6" in the DESI DRUG INDICATOR field when reporting these drugs.

## III.REPORTING DESI/IRS DRUGS

The rebate agreement requires that the manufacturer's list of covered outpatient drugs include the national drug code (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 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 code to another code 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 from October 1, 1990 for these 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 reviewing DESI notices published in the Federal Register by the FDA and for identifying those DESI/IRS drugs which it produces that are the subject of a NOOH. (See January 15, 1987 Federal Register 52 FR 1663 and 1668.) Reporting false information to HCFA regarding the status of a DESI/IRS drug for coverage purposes is a violation of section 1927 of the Act and the rebate agreement. Thus, a manufacturer could be subject to civil money penalties and/or termination.

## COVERAGE AND PAYMENT FOR DESI/IRS DRUGS

| COVERAGE/REBATE/FFP REQUIREMENTS | DESI/IRS CODE | | | | |
|---|---|---|---|---|---|
| | 2 | 3 | 4 | 5 | 6 |
| Mandatory Coverage Under Medicaid Drug Rebate Program | X | | * | | |
| May be Excluded or Restricted Under Medicaid Drug Rebate Program | | X | | | |
| Optional Coverage under Medicaid | | X | X | X | |
| Subject to Rebate Payments | X | X | * | | |
| FFP Is Available | X | X | X | | |
| FFP Not Available | | | | X | X |

**GROUP DESCRIPTIONS:**

Group 2 - DESI/IRS Drugs Determined to be Safe and Effective **or** drugs are non-DESI
Group 3 - DESI/IRS Drugs Under Review (No NOOH Issued)
Group 4 - LTE DESI/IRS Drugs for Some Indications

*If a drug in this group has an FDA-approved labeled indication for which a NOOH has not been issued, the drug is covered for that indication and other medically accepted indications, and the drug is subject to rebate.

Group 5 - LTE DESI/IRS Drugs for All Indications
Group 6 - LTE DESI/IRS Withdrawn from the Market