

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

Center for Medicaid and State Operations

March 1, 2001

MEDICAID DRUG REBATE PROGRAM RELEASE #105

For State Medicaid Directors

ZENITH-GOLDLINE INCORRECT TERMINATION DATES

In State release #103, dated 12-13-2000, you were told about a problem with the Zenith-Goldline data file for labeler code #00172 where 51 NDCs incorrectly contained termination dates. This was to be corrected and, with the 4Q/2000 tape, product correction records (correction flag = 1) would be included. Unfortunately, this did NOT happen, thus these 51 NDCs for labeler code #00172 still contain invalid termination dates. **Please use the attached NDC list to correct your files so that these products can be dispensed and paid for by you.** The system problem has been fixed and the correction records will be on the next State type (1q/2001) due to you mid-May. Please direct any questions to Vince Powell on (410) 786-3314.

NEW UTILIZATION TAPE SUBMISSION INSTRUCTIONS (Please read carefully.)

Attached as revisions to the Operational Training Guide (pages F20-F22 and F27) are new instructions regarding quarterly utilization tape submission to HCFA. Please read carefully and begin using these procedures immediately. If you do not follow these new instructions, it is very likely that your tape will be rejected and will have to be resubmitted.

Questions regarding this matter should be directed to Kay Alexander at 410-786-0252 or kalexander@hcfa.gov.

LIMITED REVISIONS TO THE OPERATIONAL TRAINING GUIDE

In an effort to maintain an accurate drug rebate agreement on the Internet we have updated the signature line and accordingly are replacing Section C in the Operational Training Guide. Attached are updated pages for section C and section M of the guide.

The agreement has been updated to reflect the current HCFA address and organizational structure. In addition, we have deleted our cover letter to the agreement. Enclosure B to the agreement (pages M4-M7 in the guide) has been updated to eliminate the page that indicates which states have signed rebate agreements with labelers.

FYI, we intend to reprint the entire training guide this Fall to incorporate numerous revisions and additions. At that time, we will automatically send each State Technical Contact a copy of the revised training guide.

NEW WEBSITE FOR DRUG REBATE PROGRAM

Effective immediately, there is a new website for HCFA's Drug Rebate Program. To access the drug rebate files on the Internet please use www.hcfa.gov/medicaid/drugs/druginfo.htm.

NEW LABELERS

Mandatory Coverage Optional Coverage

Labeler Name/Labeler Code Date Date

D&K HealthCare Resources, Inc. 04/01/2001 12/22/2000

(Labeler Code 31096)

Heran Pharmaceutical Co., Inc. 04/01/2001 01/16/2001

(Labeler Code 50434)

Gemini Pharmaceuticals, Inc. 04/01/2001 12/11/2000

(Labeler Code 51645)

Baxter Healthcare Corporation 04/01/2001 11/17/2000

(Labeler Code 54643)

Peters Laboratories, Inc. 04/01/2001 01/17/2001

(Labeler Code 58728)

Danco Laboratories, LLC 04/01/2001 01/21/2001

(Labeler Code 64875)

Amarin Pharmaceuticals, Inc. 04/01/2001 01/29/2001

(Labeler Code 65234)

NEW LABELERS (Cont'd)

Mandatory Coverage Optional Coverage

Labeler Name/Labeler Code Date Date

Aslung Pharmaceutical LP 04/01/2001 12/29/2000

(Labeler Code 65271)

The Medicines Company 07/01/2001 02/22/2001

(Labeler Code 65293)

DrugAbuse Sciences, Inc. 04/01/2001 01/18/2001

(Labeler Code 65694)

Contact information for these new labelers is attached for your convenience.

TERMINATED LABELERS

The following labeler is being terminated effective April 1, 2001:

Medical Resources, Inc. (Labeler Code 64065).

The following labeler is being voluntarily terminated effective April 1, 2001:

Fujisawa (Labeler Code 57317).

OTHER ATTACHMENTS

A copy of the topic index and a current listing of the 90-day treasury bill auction rates beginning with the period June 7, 1999, is attached.

Please remember to direct your drug rebate questions to a staff member listed in section "O" of the Medicaid Drug Rebate Operational Training Guide.

David McNally, Deputy Director

Finance, Systems and Quality Group

7 Attachments

cc:

All State Drug Rebate Technical Contacts

All Regional Administrators

All Associate Regional Administrators, Division of Medicaid

SENDING UTILIZATION DATA (Cont'd.)

e TO HCFA

States are required to report their utilization data to HCFA using magnetic media. States must send either a tape, or cartridge with an IBM Standard Label. The characteristics of this media are:

u Data Set Name: RBTE.Qq.Yyyyy.xx

Where q = quarter

yyyy = year

xx = State postal abbreviation

u Record Profile: 82 characters, fixed block, 9,266 characters per block.

**. NOTE: If the standards outlined above are not met,
THE TAPE WILL NOT BE PROCESSED.**

Send the **tape or cartridge** to: Health Care Financing Administration

Attention: Tape Library

7500 Security Boulevard

Baltimore, Maryland 21244

. NOTE: When HCFA completes its processing of State utilization tapes,

the tapes/cartridges are not returned to the States. Likewise, States are not required to return quarterly tapes/cartridges to HCFA.

**ONLY ONE (1) UTILIZATION DATA TAPE PER
QUARTER IS TO BE SUBMITTED TO HCFA.**

Rev. 02/01 **F20**

SENDING UTILIZATION DATA TO HCFA (Cont'd.)

States are required to send a tape confirmation letter indicating the data set name, volume serial number, and the date the tape was sent to HCFA. **(A copy of this letter should also be enclosed with the tape/cartridge.)**

Send the confirmation letter to: Health Care Financing Administration

Center for Medicaid and State Operations

Mail Stop S3-18-13

7500 Security Boulevard

Baltimore, Maryland 21244

Information from State utilization tapes is used to prepare HCFA's annual drug rebate Report to the Congress. Therefore, timely submission of these tapes is imperative.

In an effort to eliminate errors that hinder HCFA's processing of States' quarterly tapes/cartridges, a checklist was developed for State use. States should make every effort to comply with the checklist.

. NOTE: If the standards outlined on the checklist are not met, the HCFA tape librarians will not be able to determine that the tapes are drug rebate utilization tapes.

A copy of the checklist is provided on the following page.

MEDICAID DRUG REBATE PROGRAM

STATE UTILIZATION TAPE SUBMISSION CHECKLIST

The HCFA tape library receives a large quantity of tapes from many outside sources. To ensure that your tape is received and processed correctly, please follow the checklist below.

Assure that the correct naming convention is used for the data set on the tape.

RBTE.Qq.Yyyyy.xx Where q = quarter

yyyy
= year

x
x
=
S
t
a
t
e

p
o
s
t
a
l

a
b
b
r
e
v
i

DO NOT USE FOREIGN.OPCART.DRqyyyyy.xx or
FOREIGN.OPREEL.Dqyyyyy.xx

Is there an external label on the tape indicating that it is a drug rebate
tape? (A label with a data set name containing RBTE.Qq.Yyyyyy.xx is
necessary.)

If not already there, please include it now.

Did you generate a confirmation letter indicating the file name, volume
serial number, and the date the tape was sent? If not, please do so now.
This letter is to be sent to the following address:

Health Care Financing Administration
Center for Medicaid and State Operations
Mail Stop S3-18-13
7500 Security Boulevard
Baltimore, Maryland 21244

Please enclose a copy of the confirmation letter with the tape/cartridge.

___ Please assure that the tape/cartridge is addressed as follows:

Health Care Financing Administration
Office of Information Systems
Attention: Tape Library
7500 Security Boulevard
Baltimore, Maryland 21244

If you re-used a HCFA tape, YOU MUST REMOVE OR OBLITERATE ALL OF HCFA'S EXTERNAL LABELS AND PLACE A NEW LABEL ON THE TAPE/CARTRIDGE; otherwise, the tape/cartridge will be returned to blank stock and your data will not get processed. This will require a resubmission of your data.

Rev. 02/01 **F22**

MEDICAID DRUG REBATE PROGRAM

RECORD FORMAT

STATE INVOICE/UTILIZATION RECORD

(FORM HCFA-R-144)

Source: State Agencies

Target: HCFA and Manufacturers

| FIELD | SIZE | POSITION | REMARKS |
|-------------------------------|-------------|-----------------|---------------------------------------|
| Record ID | 4 | 1 - 4 | Constant of "01" |
| State Code | 2 | 5 - 6 | P.O. Abbreviation |
| Labeler Code | 5 | 7 - 11 | NDC #1 |
| Product Code | 4 | 12 - 15 | NDC #2 |
| Package Size Code | 2 | 16 - 17 | NDC #3 |
| Period Covered | 5 | 18 - 22 | QYYYY |
| Product FDA Registration Name | 10 | 23 - 32 | 1 st 10 characters as they |

| | | | |
|-----------------------------|----|---------|----------------------------|
| | | | appear on FDA registration |
| Rebate Amount Per Unit | 11 | 33 - 43 | 99999V999999 |
| Total Units Reimbursed | 12 | 44 - 55 | 999999999V999 |
| Total Rebate Amount Claimed | 9 | 56 - 64 | 9999999V99 |
| Number of Prescriptions | 6 | 65 - 70 | 999999 |
| Total Reimbursement Amount | 10 | 71 - 80 | 999999999V99 |
| Correction Flag | 1 | 81 - 81 | 0 = original |
| | | | 1 = correction record |
| Filler * | 1 | 82 - 82 | |

* This "filler" character is required only for the record format when States send utilization data to HCFA.

| Product | Termination Date | Description | Brand Comparable | Size | Status |
|---------------|------------------|-------------------------------|---|-----------|-----------|
| 00172-4266-60 | 02/02/2000 | ACYCLOVIR 200MG CAP | ZOVIRAX CAPS | 100 | Available |
| 00172-4266-70 | 02/02/2000 | ACYCLOVIR 200MG CAP | ZOVIRAX CAPS | 500 | Available |
| 00172-4267-60 | 05/26/2001 | ACYCLOVIR 400MG TAB | ZOVIRAX TABS | 100 | Available |
| 00172-4267-70 | 05/26/2001 | ACYCLOVIR 400MG TAB | ZOVIRAX TABS | 500 | Available |
| 00172-4268-60 | 01/09/2000 | ACYCLOVIR 800MG TAB | ZOVIRAX TABS | 100 | Available |
| 00172-4268-70 | 01/09/2000 | ACYCLOVIR 800MG TAB | ZOVIRAX TABS | 500 | Available |
| 00172-6405-44 | 10/06/1999 | ALBUTEROL SULF 0.83% NH50L UD | VENTOLIN/PROVENTIL NHAL SOLN 2.5/3ML UD | 60/3ML UD | Available |
| 00172-6405-49 | 10/06/1999 | ALBUTEROL SULF 0.83% NH50L UD | VENTOLIN/PROVENTIL NHAL SOLN 60/3ML UD | 60/3ML UD | Available |
| 00172-4234-70 | 01/28/2000 | BIUMETANIDE 2MG TAB | BIUMEX TABS | 500 | Available |
| 00172-2615-60 | 12/14/2001 | CAPTROPURILCTZ 25/25MG TAB | CAPOZIDE TABS | 100 | Available |
| 00172-2625-60 | 12/14/2001 | CAPTROPURILCTZ 25/25MG TAB | CAPOZIDE TABS | 100 | Available |
| 00172-5015-60 | 10/06/1999 | CAPTROPURILCTZ 50/25MG TAB | CAPOZIDE TABS | 100 | Available |
| 00172-5025-60 | 10/06/1999 | CAPTROPURILCTZ 50/25MG TAB | CAPOZIDE TABS | 100 | Available |
| 00172-4772-22 | 10/06/1999 | CEFACLOR 125MG/5ML ORAL SUS | CECLOR SUSPENSION | 75ML | Available |
| 00172-4772-23 | 10/06/1999 | CEFACLOR 125MG/5ML ORAL SUS | CECLOR SUSPENSION | 150ML | Available |
| 00172-4773-20 | 10/06/1999 | CEFACLOR 187MG/5ML ORAL SUS | CECLOR SUSPENSION | 50ML | Available |
| 00172-4773-21 | 10/06/1999 | CEFACLOR 187MG/5ML ORAL SUS | CECLOR SUSPENSION | 100ML | Available |
| 00172-4770-60 | 10/06/1999 | CEFACLOR 250MG CAP | CECLOR CAPS | 100 | Available |
| 00172-4774-22 | 10/06/1999 | CEFACLOR 250MG/5ML ORAL SUS | CECLOR SUSPENSION | 75ML | Available |
| 00172-4774-23 | 10/06/1999 | CEFACLOR 250MG/5ML ORAL SUS | CECLOR SUSPENSION | 150ML | Available |
| 00172-4775-20 | 10/06/1999 | CEFACLOR 375MG/5ML ORAL SUS | CECLOR SUSPENSION | 50ML | Available |
| 00172-4775-21 | 10/06/1999 | CEFACLOR 375MG/5ML ORAL SUS | CECLOR SUSPENSION | 100ML | Available |
| 00172-4771-60 | 10/06/1999 | CEFACLOR 500MG CAP | CECLOR CAPS | 100 | Available |
| 00172-4369-60 | 03/02/2001 | CLOZAPINE 100MG TAB | CLOZARIL TABS | 100 | Available |
| 00172-4369-70 | 03/02/2001 | CLOZAPINE 100MG TAB | CLOZARIL TABS | 500 | Available |
| 00172-4369-10 | 03/02/2001 | CLOZAPINE 100MG TAB UD | CLOZARIL TABS | UD-100 | Available |
| 00172-4369-60 | 03/02/2001 | CLOZAPINE 25MG TAB | CLOZARIL TABS | 100 | Available |
| 00172-4369-70 | 03/02/2001 | CLOZAPINE 25MG TAB | CLOZARIL TABS | 500 | Available |
| 00172-4369-10 | 03/02/2001 | CLOZAPINE 25MG TAB UD | CLOZARIL TABS | UD-100 | Available |
| 00172-3966-60 | 10/13/1999 | DIPHENOXHY/ATROP 2.5MG TAB CV | LONOTIL TAB CV | 100 | Available |
| 00172-3966-80 | 10/13/1999 | DIPHENOXHY/ATROP 2.5MG TAB CV | LONOTIL TAB CV | 1000 | Available |
| 00172-4036-60 | 10/13/1999 | ESTAZOLAM 1MG TAB CIV | PROSOM | 100 | Available |
| 00172-4037-60 | 10/13/1999 | ESTAZOLAM 2MG TAB CIV | PROSOM | 100 | Available |
| 00172-4175-60 | 10/27/1999 | EIDDOLAC 400MG TAB | LODINE TABS | 100 | Available |
| 00172-4175-70 | 10/27/1999 | EIDDOLAC 400MG TAB | LODINE TABS | 500 | Available |
| 00172-4174-60 | 10/27/1999 | EIDDOLAC 500MG TAB | LODINE TABS | 100 | Available |
| 00172-4174-70 | 10/27/1999 | EIDDOLAC 500MG TAB | LODINE TABS | 500 | Available |
| 00172-4364-60 | 03/02/2001 | LABETALOL HCL 100MG TAB | NORMODINE & TRANDATE TAB | 100 | Available |

Zel ...oline Pharmaceuticals

Correct Termin: 69
Lancet 172

| NDC | Termination Date | Description | Brand Comparable | Size | Status |
|---------------|------------------|---------------------------|--------------------------|------|--------------|
| 00172-364-70 | 03/02/2001 | LABETALOL HCL 100MG TAB | NORMODYNE & TRANDATE TAB | 500 | Available |
| 00172-4365-60 | 03/02/2001 | LABETALOL HCL 200MG TAB | NORMODYNE & TRANDATE TAB | 100 | Available |
| 00172-4365-70 | 03/02/2001 | LABETALOL HCL 200MG TAB | NORMODYNE & TRANDATE TAB | 500 | Available |
| 00172-1366-60 | 03/02/2001 | LABETALOL HCL 300MG TAB | NORMODYNE & TRANDATE TAB | 100 | Available |
| 00172-4235-70 | 01/28/2000 | NAOOL 20MG TAB | CONGARD TABS | 500 | Available |
| 00172-4288-60 | 01/09/2000 | NICARDIPINE HCL 20MG CAP | CARDENE CAPS | 100 | Available |
| 00172-4288-70 | 01/09/2000 | NICARDIPINE HCL 20MG CAP | CARDENE CAPS | 500 | Available |
| 00172-4289-60 | 01/09/2000 | NICARDIPINE HCL 30MG CAP | CARDENE CAPS | 100 | Available |
| 00172-4289-70 | 01/09/2000 | NICARDIPINE HCL 30MG CAP | CARDENE CAPS | 500 | Available |
| 00172-4370-70 | 03/02/2001 | PHENYLENESIN LA TAB | ENTEX LA TABS | 500 | Available |
| 00172-3691-60 | 10/13/1999 | PROCHLORPERAZINE 10MG TAB | COMPAZINE TABS | 100 | Discontinued |
| 00172-3691-60 | 10/13/1999 | PROCHLORPERAZINE 5MG TAB | COMPAZINE TABS | 100 | Available |
| 00172-4286-60 | 01/09/2000 | VERAPAMIL 120MG ER TAB | CALAN SRISOPTIN SR TABS | 100 | Available |