

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
OFFICE OF DIRECTOR

ACTION REFERRAL

TO <i>Giese</i>	DATE <i>10-25-11</i>
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DIRECTOR'S USE ONLY	ACTION REQUESTED
1. LOG NUMBER <i>100-179</i>	<input type="checkbox"/> Prepare reply for the Director's signature DATE DUE _____
2. DATE SIGNED BY DIRECTOR <i>cc: Mr. Keck, Supra</i> <i>Cleared 11/14/11, letter attached.</i>	<input checked="" type="checkbox"/> Prepare reply for appropriate signature DATE DUE <i>11-4-11</i>  <input type="checkbox"/> FOIA DATE DUE _____  <input type="checkbox"/> Necessary Action

APPROVALS (Only when prepared for director's signature)	APPROVE	* DISAPPROVE (Note reason for disapproval and return to preparer.)	COMMENT
1.			
2.			
3.			
4.			



Amgen USA Inc.  
One Amgen Center Drive  
Thousand Oaks, CA 91320-1799  
805.447.1000  
www.amgen.com

October 21, 2011

Mr. Tony Keck  
Director  
1801 Main Street  
Columbia, SC 29201

**RECEIVED**

OCT 25 2011

Department of Health & Human Services  
OFFICE OF THE DIRECTOR

Dear Mr. Keck,

I am writing to bring to your immediate attention two important issues regarding the Medicaid utilization data contained in the data file that South Carolina sends to CMS each quarter. Effective 2011, this data file is being used to calculate the Medicaid utilization from South Carolina attributable to each manufacturer for purposes of calculating the annual branded prescription drug fee assessed on each manufacturer under the Affordable Care Act. It is therefore essential that the Medicaid utilization data that South Carolina reports to CMS be as accurate and up-to-date as possible.

First, we urge South Carolina to update the original utilization file for each quarter sent to CMS to address any errors in rebate invoices that are later corrected and agreed to by the South Carolina through unit adjustments or dispute resolution. CMS made clear in State Release 72 (enclosed) that it is mandatory for states to update the quarterly utilization file sent to CMS to reflect any corrections or adjustments made to utilization data for a prior quarter. Although these errors usually are corrected by the state in separate documentation exchanged with Amgen, it appears that states are not submitting these corrections to CMS as well. Because the industry fee is based in part on these utilization reports, a state's failure to meet its obligation to correct erroneous reports could lead to the overstatement of Amgen's Medicaid utilization, and therefore the fee amount assessed.

Second, in light of the increased importance of reporting accurate Medicaid utilization data, we would like to remind you that the Medicaid drug rebate statute (Section 1927 of the Social Security Act) specifically excludes from rebate liability any drug for which separate reimbursement is not provided and where the drug instead is paid for and provided as part of or incident to and in the same setting as certain health services, including inpatient and outpatient hospital services, physicians' services, and renal dialysis. This issue is particularly important for Amgen's product EPOGEN<sup>®</sup>, which (as of January 2011) is often paid for under a bundled rate for ESRD patients. We attach a list of the EPOGEN<sup>®</sup> NDCs for your reference. CMS has affirmed the exclusion of such utilization from rebate claims in State Release 33, when it stated that "all-inclusive claims are excluded from drug utilization data used to calculate rebates due from manufacturers." Therefore, South Carolina should not include in its invoice to Amgen or in the utilization file sent to CMS any units for drugs that are not separately payable, including drug utilization where the payment for the drug is bundled into the payment for another health service.

Thank you in advance for your attention to these important issues. We will be following up with you in the coming weeks to see if you have any questions about this letter or the issues raised herein. Of course, if you have any questions in the interim, please do not hesitate to contact me.

Sincerely,

Duane Doucette  
AMGEN Medicaid Drug Rebate Program  
duaned@amgen.com

Enclosure  
Cc: James M. Assey  
Rhonda Morrison

## **MEDICAID DRUG REBATE PROGRAM**

**Release Number 72**

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



**NOTE TO: All State Medicaid Directors**

### **DRUG LABELERS**

#### **Termination of Halsey Drug Company, Incorporated (Labeler Code 00879)**

As the result of a hearing decision, the drug rebate agreement with the Halsey Drug Company, Incorporated (Labeler Code 00879) is being terminated effective January 1, 1998. States are asked to implement this change no later than January 9, 1998.

#### **New Drug Labeler**

The following labeler has entered into a drug rebate agreement with an effective date of participation in the rebate program of April 1, 1998:

Hyperion Medical, Inc. (Labeler Code 54002).

### **UTILIZATION CORRECTION RECORDS**

There seems to be some confusion over when and when not to include correction records on your quarterly utilization summary file submission to HCFA. This is the file you send that contains one record for each NDC record you submit to every labeler on your quarterly invoices. That record is to contain the summarized utilization for each NDC plus additional fields such as the **total reimbursement amount, number of prescriptions**, the current qtr/yr and a "0" in the correction flag field.

When you make a utilization correction on an invoice (called a utilization adjustment) for a prior quarter, you are supposed to include a correction record (correction flag = "1") for the affected quarter (**NOT** current quarter) with the **total units reimbursed** field containing **THE CORRECTED AMOUNT** (direct OVERLAY), not **ADJUSTED AMOUNT**. This is a mandatory update. We also request that you send a correction record when you adjust the **number of prescriptions** or **total reimbursement amount** fields. Again, these would be direct overlays, not adjusted amounts. In any case, the qtr/yr field reflects the quarter and year the change is for and the correction flag is set to "1." In all other cases, current qtr/yr is to be in all records and the correction field is to contain a "0." Please direct all questions regarding this issue to Vince Powell on (410) 786-3314.

### NEW RECORD SPECIFICATIONS FOR STATE MEDICAID AGENCIES

Enclosed are new record specifications that expand all date fields to allow for a four position year made necessary by the coming millennium. The new utilization record layout will be required for all data submitted to HCFA on January 1, 1999 or later. The change to the rebate tape file produced by HCFA will be effective with the rebates for the fourth quarter of calendar year 1998 which will be generated on or about February 15, 1999. States are directed to review the utilization reporting instructions located on pages F20 - F25 of the Medicaid Drug Rebate Operational Training Guide to ensure that proper naming conventions for utilization tapes and cartridges are used.

### OTHER ATTACHMENTS

Copies of the topic index and a listing of the 90-day treasury bill auction rates for the period of September 15, 1997 through December 8, 1997 are 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 or in State release #53.

Sally K. Richardson  
Director  
Center for Medicaid and State Operations

#### 5 Attachments

cc:

All State Technical Contacts

All Regional Administrators

All Associate Regional Administrators, Division of Medicaid

## EPOGEN NDC's

NDC	Dosage/package size
55513-0126-01	2,000 U, 1 mL vial
55513-0126-10	
55513-0144-01	10,000 U 1 mL vial
55513-0144-10	
55513-0148-01	4,000 U, 1 mL vial
55513-0148-10	
55513-0267-01	3,000 U, 1 mL vial
55513-0267-10	
55513-0283-01	20,000 U 2 mL vial
55513-0283-10	
55513-0478-01	20,000 U, 1 mL vial
55513-0478-10	
55513-0823-01	40,000 U, 1 mL vial
55513-0823-10	

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**  
**OFFICE OF DIRECTOR**

**ACTION REFERRAL**

TO	DATE
<i>Giese/Williams</i>	<i>10-25-11</i>

DIRECTOR'S USE ONLY	ACTION REQUESTED
1. LOG NUMBER <div style="text-align: right;"><i>000179</i></div>	<input type="checkbox"/> Prepare reply for the Director's signature <div style="text-align: right;">DATE DUE _____</div>
2. DATE SIGNED BY DIRECTOR <div style="border-bottom: 1px solid black; padding-top: 5px;"><i>cc: Mr. Keck, Supra</i></div>	<input checked="" type="checkbox"/> Prepare reply for appropriate signature <div style="text-align: right;">DATE DUE <i>11-4-11</i></div>
	<input type="checkbox"/> FOIA <div style="text-align: right;">DATE DUE _____</div>
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APPROVALS <small>(Only when prepared for director's signature)</small>	APPROVE	* DISAPPROVE <small>(Note reason for disapproval and return to preparer.)</small>	COMMENT
1. <i>[Signature]</i>	<i>11/8/11</i> <i>10/31/11</i>		
2. <i>[Signature]</i>	<i>11/14 OK</i>	<i>11/1 11/13</i>	
3.			
4.			



November 14, 2011

Mr. Duane Doucette  
Amgen USA Incorporated  
One Amgen Center Drive  
Thousand Oaks, California 91320-1799

Dear Mr. Doucette:

Thank you for your letter regarding the AMGEM drug rebate program. In addressing your first issue, South Carolina Medicaid does comply with Centers for Medicare and Medicaid Services (CMS) State Release 72, and provides utilization changes on prior quarters to CMS. The data provided is as accurate and up-to-date as possible. This file is prepared with the assistance of our rebate contractor, Magellan Medicaid Administration.

In response to the second issue, a rebate invoice is only generated when a provider reimbursement is captured at the drug level. South Carolina Medicaid fee for service (FFS) utilizes this policy. This information has been communicated to our providers, and the isolation of reimbursement at the drug level only is being transmitted to Magellan for rebate processing. When a beneficiary goes to dialysis treatment, the amount the provider was paid for the EPOGEN itself is isolated on the claim. This policy also applies to our Managed Care Organizations (MCOs), as we incorporate their drug specific activity into our calculation. We find virtually no utilization of EPOGEN in the data provided by the four (4) South Carolina MCOs serving our Medicaid beneficiaries.

I hope this information is helpful to you. If you have further questions or concerns about this matter, please do not hesitate to contact Mr. James Assey, R.Ph. in the Office of Physicians, Pharmacy, and Enhanced Care Services at (803) 898-2875.

Sincerely,



Melanie "BZ" Giese, RN  
Deputy Director

MG/as