

Region 10 2201 Sixth Avenue, MS/RX-43 Seattle, Washington 98121

JAN 2 0 2011

Bruce Goldberg, MD, Director Department of Human Services Human Services Building 500 Summer Street Northeast, E-15 Salem, Oregon 97301-1097

RE: Oregon State Plan Amendment 10-013

Dear Dr. Goldberg:

The Centers for Medicare & Medicaid Services (CMS) Pharmacy Team recently approved Oregon State Plan Amendment (SPA) 10-013.

Although the Pharmacy Team has already sent the State a copy of the approval letter for this SPA, the Seattle Regional office is following up with a copy of the complete approval package for the reason that we were in receipt of the original, signed amendment request.

Therefore, enclosed you will find a copy of the official CMS form 179, amended page(s), and copy of the approval letter from the Pharmacy Team for your records.

If you have any questions concerning the Seattle Regional office role in the processing of this state plan amendment, please contact Jan Mertel at (206) 615-2317 or Jan.Mertel@cms.hhs.gov.

Sincerely,

Barbara K. Richards Associate Regional Administrator Division of Medicaid and Children's Health Operations

Enclosure

Cc: Judy Mohr Peterson, Administrator

DEPARTMENT OF HEALTH & HUMAN SERVICES Centers for Medicare & Medicaid Services 7500 Security Boulevard, Mail Stop S2-14-26 Baltimore, Maryland 21244-1850



Region 10

Center for Medicaid, CHIP, and Survey & Certification

Disabled and Elderly Health Programs Group

JAN 0 6 2011

Bruce Goldberg, MD, Director Department of Human Services Human Services Building 500 Summer Street Northeast E-15 Salem, OR 97301-1097

Dear Dr. Goldberg:

We have reviewed Oregon State Plan Amendment (SPA) 10-13, Prescribed Drugs, received in the Regional Office on August 5, 2010. We are pleased to inform you that the amendment is approved, effective January 1, 2011.

This amendment changes the ingredient cost reimbursement from the Average Wholesale Price (AWP) to the Average Acquisition Cost (AAC) or the Wholesale Acquisition Cost (WAC) for those drugs for which an AAC cannot be calculated. This amendment also, proposes to change the dispensing fee from one based on the type of pharmacy, to one based on a three tiered structure based on the annual volume of prescriptions a pharmacy fills. Additionally, the SPA revised the collection of supplemental rebates for individuals enrolled with a Medicaid managed care organization (MCO). In addition, per our discussion with your staff on December 6, 2010, we made the requested change to CMS-179, Block 10.

A copy of the CMS-179 form, as well as the pages approved for incorporation into the Oregon's state plan will be forwarded by the Seattle Regional Office. If you have any questions regarding this approval, please contact Steven Johnson at (410) 786-3332.

Larry Reed
Director
Division of Pharmacy

Judy Mohr Peterson, Administrator
Jesse Anderson, State Plan Coordinator
Barbara Richards, ARA Seattle Regional Office
Maria Garza, Seattle Regional Office

cc:

DEPARTMENT OF HEALTH AND HUMAN SERVICES HEALTH CARE FINANCING ADMINISTRATION		FORM APPROVED OMB NO. 0938-0193		
TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL	1. TRANSMITTAL NUMBER: 10-13	2. STATE Oregon		
FOR: HEALTH CARE FINANCING ADMINISTRATION	3. PROGRAM IDENTIFICATION: TITLE XIX OF THE SOCIAL SECURITY ACT (MEDICAID) Medical Assistance			
TO: REGIONAL ADMINISTRATOR HEALTH CARE FINANCING ADMINISTRATION DEPARTMENT OF HEALTH AND HUMAN SERVICES	4. PROPOSED EFFECTIVE DATE 1/1/11			
5. TYPE OF PLAN MATERIAL (Check One):				
☐ NEW STATE PLAN ☐ AMENDMENT TO BE	CONSIDERED AS NEW PLAN			
COMPLETE BLOCKS 6 THRU 10 IF THIS IS AN AME	NDMENT (Separate Transmittal for each	amendment)		
6. FEDERAL STATUTE/REGULATION CITATION:	7. FEDERAL BUDGET IMPACT:			
1902(a)(30)(A), 1927 of the ACT, 42 CFR 440.120	a. 2011 \$ (1,734,782)			
	b. 2012 \$ (2,313,043)			
8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT:	9. PAGE NUMBER OF THE SUPERS			
Au 1	OR ATTACHMENT (If Applicable)			
Attachment 3.1-A, page 5-b, 5-c and Attachment 4.19-B,	Attachment 2.1 A maga 6.5 6	a and Attachment		
page 3, 3-a, 3-b, 3-c	Attachment 3.1-A, page 5-b, 5-	c and Attachment		
	4.19-B, page 3, 3-a, 3-b			
10. SUBJECT OF AMENDMENT: This transmittal is being subm	itted to revise an attachment for th	e supplemental rebate		
program and revise the pharmacy rate method for prescription				
WAC+6.25%. The dispensing fee will also change with this				
11. GOVERNOR'S REVIEW (Check One):				
GOVERNOR'S OFFICE REPORTED NO COMMENT	🛛 OTHER, AS SPEC	IFIED:		
COMMENTS OF GOVERNOR'S OFFICE ENCLOSED	· .			
☐ NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL				
12. SIGNATURE OF STATE AGENCY OFFICIAL:	16. RETURN TO:			
	Division of Medical Assista	nce Programs		
12 TYPED NAME Judy Mohr Peterson Bruce Goldberg, MD	Department of Human Servi	•		
19 11125 William Vally Mont Totalion (N-151400 Goldoorg, M25	500 Summer Street NE E-3			
14. TITLE: Administrator, DMAP Director, DHS	Salem, OR 97301	~. :		
16 DAME OF THE COMMENT		•		
15. DATE SUBMITTED: 8-5-10	ATTN: Jesse Anderson, Sta	te Plan Manager		
FOR REGIONAL OF	RICE USE ONLY			
17 DATE RECEIVED AUGUST 6 2010	18 DATE APPROVED:			
	JAN - 3	ZUI SEE		
PLAN APPROVED - ONE 19. EFFECTIVE DATE OF APPROVED MATERIAL	20. SIGNATURE OF REGIONAL OF	TOTAL		
AN UTZON	ZV. SIOPA I VALSOFIEDDO VALSAR	Harane Bar		
21. TYPEDNAME:	22 TIPLE:			
Bornan K. Richards	Associate Regional A	Olfundado.		
23. RPWARKS:	Division of Med			
	Children's H			
pen and intechanges authorized my that state on 12/8/10.				
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Transmittal #10-13 Attachment 3.1-A Page 5-b

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT Medical Assistance Program

State/Territory: OREGON

AMOUNT, DURATION, AND SCOPE OF MEDICAL AND REMEDIAL CARE AND SERVICES PROVIDED TO THE CATEGORICALLY NEEDY

LIMITATIONS ON SERVICES (Cont.)

12.a. <u>Prescribed Drugs</u>

Rebate Agreement:

The state is in compliance with section 1927 of the Social Security Act. The state will cover drugs of manufacturers participating in the Medicaid Drug Rebate Program. The state has the following policies for drug rebate agreements:

- Manufacturers are allowed to audit utilization rates;
- The unit rebate amount is confidential and cannot be disclosed for purposes other than rebate invoicing and verification, in accordance with Section 1927 (b)(3)(D);
- The state is in compliance with reporting requirements for utilization and restrictions to coverage;
- All drugs covered by the program, irrespective of a prior authorization agreement, will comply with the provisions of the national drug rebate agreement;
- Funds received from supplemental rebates will be reported to CMS;
- The state will remit the federal portion of any supplemental rebates collected at the same percentage basis as applied under the national rebate agreement.

Supplemental Rebate Agreement:

The state will be negotiating supplemental rebates in addition to the federal rebates provided for in Title XIX under the national rebate program. Supplemental rebate agreements between the state and a pharmaceutical manufacturer will be separate from the federal rebates received under the national rebate program.

CMS has authorized Oregon to enter into "The Sovereign States Drug Consortium (SSDC)" Medicaid Multi-State purchasing pool in relation to supplemental rebates.

TN No. <u>10-13</u> Supersedes TN No. 09-11 Approval Date:

Effective Date: 1/1/11

JAN - 3 2011

Transmittal #10-13 Attachment 3.1-A Page 5-c

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT Medical Assistance Program

State/Territory: <u>OREGON</u>

AMOUNT, DURATION, AND SCOPE OF MEDICAL AND REMEDIAL CARE AND SERVICES PROVIDED TO THE CATEGORICALLY NEEDY

<u>LIMITATIONS ON SERVICES</u> (Cont.)

12.a. <u>Prescribed Drugs</u>

Supplemental Rebate Agreement (Cont):

The Centers for Medicare and Medicaid Services (CMS) has authorized a rebate agreement between the state and a drug manufacturer that provides supplemental rebates for drugs provided to the Oregon Medicaid program as follows:

- A supplemental rebate agreement submitted to CMS on 6/19/2003 and entitled, "State of Oregon, Supplemental Rebate Agreement" has been authorized by CMS.
- A supplemental rebate agreement submitted to CMS on 7/15/09, amended the 6/19/03 version of the "State of Oregon, Supplemental Rebate Agreement" under Transmittal 03-02, has been authorized by CMS.
- A supplemental rebate agreement submitted to CMS on 8/2/10 amended the 7/15/09 version of the "State of Oregon, Supplemental Rebate Agreement" authorized under Transmittal 09-05, has been authorized by CMS.

The state will maintain the flexibility to negotiate supplemental rebate payments by manufacturers for Medicaid Managed Care Organization (MCO) utilization of products on the PDL regardless if the products are on the Medicaid MCO formularies (Version 1 of Attachment A, Transmittal 10-13).

TN No. <u>10-13</u> Supersedes TN No. 09-11 Approval Date:

JAN - 3 2011

Effective Date: 1/1/11

Transmittal # 10-13 Attachment 4.19-B Page 3

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT Medical Assistance Program

State/Territory: <u>OREGON</u>
METHODS AND STANDARDS FOR ESTABLISHING PAYMENT RATES
2. Prescribed Drugs

A. General

- (1) The Division of Medical Assistance will pay the lesser of the provider's usual charge to the general public for a drug or the estimated acquisition cost (EAC) plus a dispensing fee. The EAC is defined by the Division as the lesser of:
 - a. The Average Acquisition Cost (AAC) of the drug. The AAC will be established by the Division or its contractor by rolling surveys of enrolled pharmacies to verify the actual invoice amount paid by the pharmacy for the product and as such will serve as the basis for reimbursement;
 - b. In cases where no AAC is available, reimbursement will be Wholesale Acquisition Cost (WAC). WAC shall mean the price, paid by a wholesaler for the drugs purchased from the wholesaler's supplier, typically the manufacturer of the drug as published by a recognized compendia of drug pricing on the last day of the calendar quarter that corresponds to the calendar quarter;
 - c. The Division determines usual charge to be the lesser of the following unless prohibited from billing by federal statute or regulation:
 - i. The provider's charge per unit of service for the majority of non-Medical Assistance users of the same service based on the preceding month's charges;
 - ii. The provider's lowest charge per unit of service on the same date that is advertised quoted or posted. The lesser of these applies regardless of the payment source or means of payment;
 - iii. Where the provider has established a written sliding fee scale based upon income for individuals and families with income equal to or less than 200% of the federal poverty level, the fees paid by these individuals and families are not considered in determining the usual charge. Any amounts charged to third party resources are to be considered.

TN <u>10-13</u> Supersedes TN 09-01 Approval Date:

JAN - 3 2011

Effective Date: 1/1/11

Transmittal # 10-13 Attachment 4.19-B Page 3-a

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT Medical Assistance Program

State/Territory:	OREGON	

METHODS AND STANDARDS FOR ESTABLISHING PAYMENT RATES

12. Prescribed Drugs (continued)

- (2) The Division requires prior authorization of payment for selected therapeutic classes of drugs. These drug classes are listed in the Oregon Administrative Rules, Pharmaceutical Services Program. Exception to the prior authorization requirement may be made in medical emergencies.
- (3) The Division will reimburse providers only for drugs supplied from pharmaceutical manufacturers or labelers who have signed an agreement with CMS or who have a CMS approved agreement to provide drug price rebates to the Oregon Medicaid program.
- (4) The Division utilizes a contracted mail order vendor, the program is voluntary for the enrollees. The vendor is selected via a standard invitation to bid process. All Medicaid program rules apply to the vendor contract, payment rates are established during the bid process.

B. Payment Limits for Multiple Source Drugs

- (1) Reimbursement for multiple source drugs in the Medicaid Program shall not exceed the lowest of:
 - a. The federally mandated upper limit (FUL) for certain multiple source drugs as established and published by CMS plus a dispensing fee;
 - b. The Estimated Acquisition Cost (EAC) defined by the Medicaid as the Average Acquisition Cost (AAC) of the drug or, in cases where no AAC is available, Wholesale Acquisition Cost (WAC) plus a dispensing fee; or
 - c. The provider's Usual and Customary charge to the general public for the drug.
- (2) Payment for multiple-source drugs for which CMS has established upper limits will not exceed, in the aggregate, the set upper limits plus a dispensing fee.
- (3) Oregon state law requires that no payment shall be made for a multiple source drug having a federal upper limit (FUL) for payment if a less expensive multiple source drug could have been dispensed, unless the physician certifies in his or her own handwriting that a specific brand is medically necessary for a particular recipient.

TN No.<u>10-13</u> Supersedes TN No. 09-01 Approval Date:

Effective Date: 1/1/11

JAN - 3 2011

Transmittal #10-13 Attachment 4.19-B Page 3-b

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT Medical Assistance Program

State/Territory:	OREGON	

METHODS AND STANDARDS FOR ESTABLISHING PAYMENT RATES

12. Prescribed Drugs (continued)

- C. Payment Limits for Single-Source Drugs
 - (1) The Division established the payment amount for single-source drugs shall not exceed the lowest of:
 - a. The Estimated Acquisition Cost (EAC) defined by the Medicaid as the Average Acquisition Cost (AAC) of the drug; or
 - b. In cases where no AAC is available, Wholesale Acquisition Cost (WAC) plus a dispening fee; or
 - c. The provider's Usual and Customary charge to the general public for the drug.
 - (2) The upper payment limit established by the State EAC listing does not apply if a prescriber certifies that an innovator multi-source drug is medically necessary.
 - (3) Payments for single-source drugs shall not exceed, in the aggregate, the lesser of the estimated acquisition cost plus a reasonable dispensing fee or the provider's usual charge to the general public.
- D. Payment limit for 340B entity
 - (1) The Division established the payment amount for 340B entities shall not exceed the entity's actual acquisition cost plus a dispensing fee.
- E. Dispensing or Professional Fees
 - (1) The Division establishes pharmacy dispensing fee payments based on the results of surveys of pharmacies. The dispensing fee structure will be one of 3 rate tiers. The Division or its designated representative will conduct an annual survey of every enrolled pharmacy to determine which tier the pharmacy will be paid.

TN No. <u>10-13</u> Supersedes TN No. <u>09-01</u> Approval Date: **JAN - 3 2011**

Effective Date: 1/1/11

Transmittal # 10-13 Attachment 4.19-B Page 3-c

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT Medical Assistance Program

State/Territory:	OREGON	
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METHODS AND STANDARDS FOR ESTABLISHING PAYMENT RATES

12. Prescribed Drugs (continued)

- (2) Based upon the annual volume of the enrolled pharmacy, the dispensing fee will be as follows:
 - Less than 49,999 claims a year = \$14.01
 - Between 50,00 and 69,999 claims per year = \$10.14
 - 70,000 or more claims per year = \$9.68
- (3) Pharmacies that fail to respond to the annual survey will default to the \$9.68 dispensing fee.
- (4) Pharmacies dispensing through a unit dose or 30-day card system must bill the Division only one dispensing fee per medication dispensed in a 30-day period.
- (5) Dispensing fee tiers are applicable to all retail (chain and independent), Institutional, mail order, compounding and 340 programs.

TN No. <u>10-13</u> Supersedes TN No. 09-01 Approval Date:

Effective Date: 1/1/11

JAN - 3 2011