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State/Territory Name: Oregon

State Plan Amendment (SPA) #: 17-0007

This file contains the following documents in the order listed:

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
Seattle Regional Office
701 Fifth Avenue, Suite 1600, MS/RX-200
Seattle, WA 98104

Division of Medicaid & Children's Health Operations

September 26, 2017

Pat Allen, Acting Director
Oregon Health Authority
500 Summer Street Northeast, E-15
Salem, OR 97301

RE: Oregon State Plan Amendment (SPA) Transmittal Number 17-0007

Dear Mr. Allen:

The Centers for Medicare & Medicaid Services (CMS) approved State Plan Amendment (SPA) 17-0007, in compliance with the requirements of the Final Covered Outpatient Drug Rule. This SPA amendment is effective April 22, 2017.

Enclosed you will find a copy of the official CMS Form 179, amended state plan pages, and copy of the September 20, 2017, approval letter from the CMS Pharmacy Team for your records.

If you have any questions, please contact me, or your staff may contact Maria Garza at maria.garza@cms.hhs.gov or (206) 615-2542.

Sincerely,

Digitally signed by David L. Meacham

[redacted]

Date: 2017.09.26 17:00:33 -07'00'

David L. Meacham
Associate Regional Administrator

Enclosure

cc:
Jesse Anderson, Oregon Health Authority

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

Center for Medicaid and CHIP Services

Disabled and Elderly Health Programs Group

September 20, 2017

Patrick Allen, Director
Oregon Health Authority
500 Summer Street Northeast, E-15
Salem, Oregon 97301-1079

Dear Mr. Allen:

We have reviewed Oregon's State Plan Amendment (SPA) 17-0007, Prescribed Drugs, received in the Seattle Regional Office on June 28, 2017. This SPA proposes to bring Seattle into compliance with the reimbursement requirements in the Covered Outpatient Drug final rule with comment period (CMS-2345-FC).

SPA 17-0007 establishes reimbursement for covered outpatient drugs using an actual acquisition cost methodology and with a tiered professional dispensing fee based on the annual volume of the enrolled pharmacy. Pharmacies with less than 30,000 claims per year will have a $14.01 professional dispensing fee. Pharmacies with between 30,000 and 49,999 claims per year will have a $10.14 professional dispensing fee. Finally, pharmacies with 50,000 or more claims per year will have a $9.68 professional dispensing fee. This SPA also includes reimbursement for 340B drugs, physician-administered drugs, clotting factor, federal supply schedule, and drugs purchased at nominal price. The state provided data and studies to demonstrate that the acquisition cost methodology and pharmacy dispensing fees being paid are sufficient to assure that Oregon's beneficiaries will have access to pharmacy services at least to the extent as the general population.

Based on the information provided and consistent with the regulations at 42 CFR 430.20, we are pleased to inform you that SPA 17-0007 is approved with an effective date of April 22, 2017. A copy of the revised signed CMS-179 form, as well as the pages approved for incorporation into Oregon's state plan will be forwarded by the Seattle Regional Office.

If you have any questions regarding this amendment, please contact Lisa Shochet at (410) 786-5445 or lisa.shochet@cms.hhs.gov.

Sincerely,

/s/

Meagan T. Khau
Deputy Director
Division of Pharmacy

cc: David Meacham, ARA, CMS, Seattle Regional Office
Maria Garza, CMS, Seattle Regional Office
Jesse Anderson, State Plan Manager, Oregon Health Authority

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

FOR: HEALTH CARE FINANCING ADMINISTRATION

1. TRANSMITTAL NUMBER: **17-0007**

2. STATE: Oregon

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
~~4/1/17~~ (P&I)
4/22/17

5. TYPE OF PLAN MATERIAL *(Check One)*:

☐ NEW STATE PLAN ☐ AMENDMENT TO BE CONSIDERED AS NEW PLAN ☒ AMENDMENT

COMPLETE BLOCKS 6 THRU 10 IF THIS IS AN AMENDMENT *(Separate Transmittal for each amendment)*

6. FEDERAL STATUTE/REGULATION CITATION:
Rx-1927 of the Social Security Act, 42 CFR Part 447
IHS- 42 CFR 431.110(b)
Part D-1927(d)(2) and 1935(d)(2) of the Act

7. FEDERAL BUDGET IMPACT:
a. FFY 2017 $ 10,800,151
b. FFY 2018 $ 21,598,356

8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT:
Admin page 28
Attachment 3.1-A, page 5-a, 5a.1, 5-b, ~~5-c~~ (P&I)
Attachment 4.19-B, page 1a.5, ~~1a.7~~, 3 thru 3-d (P&I)

9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT *(If Applicable)*:
Admin page 28, 28a
Attachment 3.1-A.1, page 1-3
Attachment 3.1-A, page 5-a, 5a.1,5-b, 5-c
Attachment 4.19-B, page 3 thru 3-c

10. SUBJECT OF AMENDMENT: This transmittal is being submitted reflect the covered outpatient drug regulation final rule published in the Federal Register 2/1/16 and descriptions of reimbursement methods for all pharmacy types. Technical corrections also include: Reimbursement details for IHS facilities was filed on Admin page 28 in error in 1987, this submission will move those details to Attachment 4.19-B, page 1a.5; Coverage of Part D drug preprint was filed in a separate section in 2011. This submission will move it under the Pharmacy section 12.

11. GOVERNOR'S REVIEW *(Check One)*:
☐ GOVERNOR'S OFFICE REPORTED NO COMMENT
☐ COMMENTS OF GOVERNOR'S OFFICE ENCLOSED
☐ NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL
☒ OTHER, AS SPECIFIED: The Governor does not wish to review any plan materials.

12. SIGNATURE OF STATE AGENCY OFFICIAL:
[redacted]

13. TYPED NAME Lori Coyner, MA

14. TITLE: Medicaid Director, OHA

15. DATE SUBMITTED: 6/28/17

16. RETURN TO:
Oregon Health Authority
Medical Assistance Programs
500 Summer Street NE E-65
Salem, OR 97301

ATTN: Jesse Anderson, State Plan Manager

FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED: 6/28/17

18. DATE APPROVED: 9/20/17

PLAN APPROVED – ONE COPY ATTACHED

19. EFFECTIVE DATE OF APPROVED MATERIAL: 4/22/17

20. SIGNATU[redacted]

21. TYPED NAME: David L. Meacham

22. TITLE: Associate Regional Administrator

23. REMARKS:
9/14/17 - State authorized P&I change to box 4 and 8

FORM HCFA-179 (07-92)

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
State/Territory: __OREGON_____

SECTION 3 - SERVICES: GENERAL PROVISIONS

Citation(s)

3.1 (g) Participation by Indian Health Service Facilities

42 CFR 431.110(b)
AT-78-90

Indian Health Service facilities are accepted as providers, in accordance with 42 CFR 431.110(b), on the same basis as other qualified providers.

1902(e)(9) of the Act,
P.L. 99-509

(Section 9408)

(h) Respiratory Care Services for Ventilator-Dependent Individuals

Respiratory care services, as defined in section 1902(e)(9)(C) of the Act,
are provided under the plan to individuals who--

(1) Are medically dependent on a ventilator for life support at least six hours per day;

(2) Have been so dependent as inpatients during a single stay or a continuous stay in one or more hospitals, SNFs or ICFs for at least 30 consecutive days.

(3) Except for home respiratory care, would require respiratory care on an inpatient basis in a hospital, SNF, or ICF for which Medicaid payments would be made;

(4) Have adequate social support services to be cared for at home; and

(5) Wish to be cared for at home.

X Yes. The requirements of section 1902(e)(9) of the Act are met.

__ Not applicable. These services are not included in the plan.

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
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. Prescribed Drugs

Reimbursement is available to covered outpatient drugs of any manufacturer that has entered into and complied with an agreement under Section 1927(a) of Title XIX of the Social Security Act, which are prescribed for a medically accepted indication. Drugs subject to limitations are those outlined under Section 1927(d)(4) of Title XIX of the Social Security Act.

Pursuant to 42 U.S.C. section 1396r-8, the State established a preferred drug list to be known as the Practitioner Managed Preferred Drug List (PDL). OHA determines which prescription drugs may require prior authorization by reviewing the drug(s) for the following:

- Safety
- Potential for abuse or misuse
- Narrow therapeutic index
- High cost when less expensive alternatives are available

Prescribed Drugs may be subject to prior authorization by the agency to ensure that drugs are prescribed and dispensed appropriately and complies with requirements in Section 1927(d)(5) of the Act.

1935(d)(1) Effective January 1, 2006, the Medicaid agency will not cover any Part D drug for full-benefit dual eligible individuals who are entitled to receive Medicare benefits under Part A or Part B.

1927(d)(2) and 1935(d)(2) The Medicaid agency provides coverage for the following excluded or otherwise restricted drugs or classes of drugs, or their medical uses to all Medicaid recipients, including full benefit dual eligible beneficiaries under the Medicare Prescription Drug Benefit–Part D.

☒ The following excluded drugs are covered

☒ (a) agents when used for anorexia, weight loss, weight gain: Appetite Stimulants for Anorexia, Cachexia, Wasting.

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
State/Territory: OREGON

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

LIMITATIONS ON SERVICES (Cont.)

1927(d)(2) and 1935(d)(2)

☐ (b) agents when used to promote fertility

☒ (d) agents when used for the symptomatic relief cough and colds: Cough Preparations/Expectorants Cough & Cold Preps

☒ (e) prescription vitamins and mineral products, except prenatal vitamins and fluoride: Vitamin K, Folic Acid Preparations, Vitamin D.

☒ (f) nonprescription drugs: 1st Generation Antihistamines & Decongestant Combinations, Diphenhydramine, Antiulcer Preps/Gastrointestinal Preps, Non-Narcotic Analgesics

☐ (g) covered outpatient drugs 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.

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. Prescribed Drugs

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.

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).

9. Clinic Services:

Indian Health Service and Tribal Health Facilities (I/T)

Services provided by facilities of the Indian Health Service (IHS) which includes, at the option of the tribe, facilities operated by a tribe or tribal organization, and funded by Title I or III of the Indian Self Determination and Education Assistance Act (Public Law 93-638), are paid at the rates negotiated between the Health Care Financing Administration (HCFA) and the IHS and which are published in the Federal Register or Federal Register Notices.

The outpatient per visit rate is also known as the IHS encounter rate. The definition of an encounter is, "A face-to-face contact between a health care professional and an IHS beneficiary eligible for the Medical Assistance Program for the provision of Title XIX/CHIP defined services through an IHS, AI/AN Tribal Clinic or Health Center, or a Federally Qualified Health Clinic with a 638 designation within a 24-hour period ending at midnight, as documented in the client's medical record."

Payment for multiple encounters of medical, dental mental health/ substance use disorder, on the same date of service will be allowed only if the services are categorically different and/or are provided for a distinct and separate diagnosis.

Pharmacy encounters will be paid at the federal OMB clinic encounter rate as outlined in Attachment 4.19-B, section 12-prescribed drugs of this state plan.

The following provider types are allowable to be reimbursed under the IHS encounter rate: Physicians, Physician Assistants, Advanced Nurse Practitioners, Nurse Midwives, Dentists, Pharm D, Speech-Language Pathologist, Audiologist, Physical therapist, Occupational therapist, Podiatrist, Optometrist, Substance Use Disorder Counselors, Psychiatrist, Psychologist, Mental Health Professionals or other health care professionals.

These services are not limited except as directed by the Oregon Administrative Rule -General Rules - Excluded Services and Limitations, the American Indian/Alaska Native Billing Guide and the Health Evidence Review Committee (HERC) Prioritized List of Health Services (List) as follows: Coverage for diagnostic services and treatment for those services funded on the HERC List and Coverage for diagnostic services only, for those conditions that fall below the funded portion of the HERC List.

Medical Transportation services are outside the IHS encounter rate and are reimbursed under the OHA fee-for-service system.

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

A. General

(1) The Oregon Health Authority, Medical Assistance Program will pay the lesser of the provider's usual charge to the general public for a drug or the actual acquisition cost (AAC) plus a dispensing fee. The AAC is defined by the Authority as :

a. The Oregon-specific Average Acquisition Cost (OR-AAC) of the drug. The OR-AAC will be established by the Authority 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 OR-AAC is available, reimbursement will be at the National Average Drug Acquisition Cost (NADAC) developed by CMS;
c. In cases where no OR-AAC and no NADAC is available, reimbursement will be Wholesale Acquisition Cost (WAC) ;

B. Payment Limits for Single and Multiple Source Drugs

(1) Reimbursement for single source and multiple source drugs in the Medicaid Program shall follow the methodology outlined in section A.(1) of this state plan attachment.
a.
(2) The maximum allowable cost set by the Authority for multiple source drugs will not exceed, in aggregate, the upper limits established under 42 CFR 447.512.

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 340B entity:

(1) 340B covered entity pharmacies who carve in for Medicaid, shall not exceed the entity's actual acquisition cost, plus the assigned professional dispensing fee.
(2) 340B covered entities that purchase drugs outside of the 340B program are reimbursed at the AAC rate defined in section A. (1) of this state plan attachment, plus the usual professional dispensing fee.
(3) Drugs acquired through the federal 340B drug pricing program and dispensed by 340B contract pharmacies are not covered.
(4) The professional dispensing fee allowed for a 340B covered entity is the same as for any enrolled pharmacy, according to claims volume as outlined in section J of this state plan.

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)

D. Indian Health Service/Tribal (I/T) Pharmacy:
An eligible I/T pharmacy may choose to participate in the Medicaid Program and receive reimbursement for Medicaid covered services under any of following options:

(1) I/T Pharmacy will receive reimbursement as a 340B entity outlined in this State Plan attachment section C (1) through (4);

(2) I/T pharmacy will receive the Indian Health Service (IHS) per visit outpatient encounter rate, called the All-Inclusive Rate (AIR). Under an encounter rate methodology, a single rate is be applied to "A face-to-face contact between a health care professional and an IHS beneficiary eligible for the Medical Assistance Program for services through an IHS, AI/AN Tribal Clinic or Health Center, or a Federally Qualified Health Clinic with a 638 designation within a 24-hour period ending at midnight, as documented in the client's medical record. The I/T Pharmacy will receive one encounter per prescription filled or refilled and will not be limited to a certain number of prescriptions per day.

(3) I/T Pharmacy operating as a non tribal retail pharmacy will receive reimbursement as outlined in Attachment 4.19-B of this state plan, section 12.A.
.

E. Pharmacies who purchase drugs at Nominal Price (outside of 340B or FSS) will be reimbursed their actual acquisition cost plus the usual professional dispensing fee.

F. Pharmacies who purchase drugs at the Federal Supply Schedule will be reimbursed their actual acquisition cost plus the usual professional dispensing fee.

G. Specialty Drugs (Not distributed by a Retail Pharmacy and distributed primarily through the Mail): The Authority reimburses at the AAC rate defined in this state plan attachment, plus the usual professional dispensing fee.

H. Long-Term Care Pharmacy: The Authority reimburses at the AAC rate defined in this state plan, plus the usual professional dispensing fee.

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

State/Territory: OREGON

METHODS AND STANDARDS FOR ESTABLISHING PAYMENT RATES

12. Prescribed Drugs (continued)

I. Physician Administered Drugs: reimbursement is based on Medicare's Average Sale Price (ASP) +6%. When no ASP rate is listed the rate shall be based upon the Wholesale Acquisition Price (WAC) plus 6.25%. If no WAC is available, then the rate shall be reimbursed at Acquisition Cost. 340B covered entities that bill for Physician Administered Drugs and carve in for Medicaid, shall not exceed the entity's actual acquisition cost.

J. Investigational Drugs – Investigational drugs are not a covered service under the Oregon Medical Assistance pharmacy program.

K. Clotting Factor from Specialty Pharmacies, Hemophilia Treatment Centers:
OHA contracts with a specialty provider of hemophilia treatment products subject to 1915(b)(4) waiver terms. Clotting factor payments outside of the contract, reimbursement is in accordance with section 12(A)(1) of this state.

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

State/Territory: OREGON

METHODS AND STANDARDS FOR ESTABLISHING PAYMENT RATES

12. Prescribed Drugs (continued)

L. Dispensing or Professional Fees

(1) The Authority 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 Authority or its designated representative will conduct an annual survey of every enrolled pharmacy to determine which tier the pharmacy will be paid.

(2) Based upon the annual volume of the enrolled pharmacy, the dispensing fee will be as follows:

- Less than 30,000 claims a year = $14.01
- Between 30,000 and 49,999 claims per year = $10.14
- 50,000 or more claims per year = $9.68

(3) Pharmacies that fail to respond to the annual survey will default to the highest volume tier dispensing fee.

(4) Pharmacies dispensing through a unit dose or 30-day card system must bill OHA only one dispensing fee per medication dispensed in a 30-day period.

(5) Dispensing fee tiers are applicable to all pharmacies: retail independent, Institutional, mail order, compounding and 340 programs. Retail chain affiliated pharmacy dispensing fee is paid at the lowest tier regardless of volume.

(6) Independently owned pharmacies in communities that are the only enrolled pharmacy within a fifteen (15) mile radius from another pharmacy shall be reimbursed at the lowest volume tier.