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State/Territory Name: Idaho

State Plan Amendment (SPA) #: 17-0014

This file contains the following documents in the order listed:

1) Supplemental Letter
2) Approval Letter
3) CMS 179 Form
4) Approved SPA Pages

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

November 13, 2017

Russell S. Barron, Director
Department of Health and Welfare
Towers Building - Tenth Floor
PO Box 83720
Boise, ID 83720-0036

RE: Idaho State Plan Amendment (SPA) Transmittal Number 17-0014

Dear Mr. Barron:

The Centers for Medicare & Medicaid Services (CMS) has approved State Plan Amendment (SPA) 17-0014. This transmittal aligns the Idaho state plan in accordance with the Covered Outpatient Drug final rule, specifically the reimbursement of Physician Administered Drugs, and 340B contract drugs.

This SPA was approved on November 9, 2017, with the effective date of July 17, 2017.

Enclosed you will find a copy of the official CMS Form 179, amended state plan page(s), and copy of the 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,

[redacted]

David L. Meacham
Associate Regional Administrator

cc:
Clay Lord, Alternative Care Coordinator
Tami Eide, Medicaid Pharmacy Program Manager

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

November 9, 2017

Russell S. Barron, Director
Department of Health and Welfare Towers
Building - Tenth Floor
P.O. Box 83720
Boise, ID 83720-0036

Dear Mr. Barron:

We have reviewed Idaho's State Plan Amendment (SPA) 17-0014 received in the Seattle Regional Office on August 24, 2017. This SPA proposes to bring Idaho into compliance with the reimbursement requirements in the Covered Outpatient Drug final rule with comment period (CMS-2345-FC), concerning reimbursement for Physician Administered Drugs, 340B contract pharmacies, and clotting factor drugs.

Based on the information provided and consistent with the regulations at 42 CFR 430.20, we are pleased to inform you that SPA 17-0014 is approved with an effective date of July 17, 2017. A copy of the signed CMS-179 form, as well as the pages approved for incorporation into Idaho'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 Khau
Deputy Director
Division of Pharmacy

cc: Lisa Hettinger, Deputy Director, Idaho Department of Health and Welfare
David Meacham, ARA, CMS, Seattle Regional Office
Maria Garza, CMS, Seattle Regional Office

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: **ID-17-0014**

2. STATE: IDAHO

3. PROGRAM IDENTIFICATION: TITLE XIX OF THE SOCIAL SECURITY ACT (MEDICAID)

TO: REGIONAL ADMINISTRATOR
HEALTH CARE FINANCING ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

4. PROPOSED EFFECTIVE DATE
~~July 1, 2017~~ **(P&I) July 17, 2017**

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:
CFR §§ 447.512 and 447.518

7. FEDERAL BUDGET IMPACT:
0

8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT:
Attachment 4.19-B, pages 22a, 22b, 22c

9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT *(If Applicable)*:
Attachment 4.19-B, pages 22a, 22b, 22c

10. SUBJECT OF AMENDMENT:
Aligning State Plan with provisions enacted in the Covered Outpatient Drugs final rule

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:

12. SIGNATURE OF STATE AGENCY OFFICIAL:
[redacted]

13. TYPED NAME:
LISA HETTINGER

14. TITLE:
Deputy Director

15. DATE SUBMITTED: 8/24/2017

16. RETURN TO:
Lisa Hettinger, Deputy Director
Idaho Department of Health and Welfare
Division of Medicaid
PO Box 83720
Boise ID 83720-0009

FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED: 8/24/2017

18. DATE APPROVED: 11/9/17

PLAN APPROVED – ONE COPY ATTACHED

19. EFFECTIVE DATE OF APPROVED MATERIAL: 7/17/17

20. SIGNATURE OF REGIONAL OFFICIAL:
[redacted]

21. TYPED NAME: David L. Meacham

22. TITLE: Associate Regional Administrator

23. REMARKS:
8/30/17: State authorized P&I change to box 4

FORM HCFA-179 (07-92)

12. a. Prescription Drugs:

i. Reimbursement is restricted to those drugs supplied from labelers that are participating in the CMS Medicaid Drug Rebate Program.

ii. Reimbursement for all covered outpatient drugs shall be limited to the lowest of the following:
   a) Idaho Actual Acquisition Cost (AAC), plus the assigned professional dispensing fee.
   b) In cases where no AAC is available, Wholesale Acquisition Cost (WAC) will be used, plus the assigned professional dispensing fee. 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 compendium of drug pricing on the last day of the calendar quarter that corresponds to the calendar quarter.
   c) State Maximum Allowable Cost (SMAC) as established by the Department, plus the assigned professional dispensing fee.
   d) Federal Upper Limit (FUL) as established by CMS, plus the professional dispensing fee assigned by the Department.
   e) The provider's usual and customary charge to the general public.

iii. Professional Dispensing Fee:
Based upon the annual volume of the enrolled pharmacy, the professional dispensing fee will be as follows:
   - Fewer than 40,000 claims a year = $15.11
   - Between 40,000 and 69,999 claims per year = $12.35
   - 70,000 or more claims per year = $11.51

iv. 340B Covered Entity Reimbursement
   a) Reimbursement to 340B covered entities is limited to the actual 340B drug acquisition cost submitted (not to exceed the 340B ceiling price) plus the assigned professional dispensing fee as described in 12.a.iii.
   b) Drugs acquired through the federal 340B drug pricing program and dispensed by 340B contract pharmacies are not covered.
   c) An entity that does not use 340B covered outpatient drugs for all dispensed or administered drugs, including those dispensed through the 340B covered entity's retail pharmacy or administered in an outpatient clinic, will be considered as carved out of the 340B drug pricing program and shall be reimbursed for brand and generic drugs as provided in subsection 12.a.ii.

v. Reimbursement for Drugs Dispensed by Other Provider Types
   a) Drugs acquired through non-340B Indian Health Service, Tribal or Urban Indian pharmacies will be reimbursed at the actual acquisition cost to the entity, plus the assigned professional dispensing fee as described in 12.a.iii.

b) Drugs acquired via the Federal Supply Schedule (FSS) will be reimbursed at the FSS actual acquisition cost, plus the assigned professional dispensing fee as described in 12.a.iii.
c) Drugs acquired at nominal price, which is defined as pricing that is outside of 340B regulations or FSS, will be reimbursed at the actual acquisition cost, plus the assigned professional dispensing fee as described in 12.a.iii.
d) Specialty drugs not dispensed by retail community pharmacies and dispensed primarily through the mail will be reimbursed at the Idaho actual acquisition cost, if such cost is available, plus the professional dispensing fee as described in 12.a.iii. If the actual acquisition cost is not available, drugs will be reimbursed at the lower of the Wholesale Acquisition Cost (WAC) or State Maximum Allowable Cost (SMAC) as established by the Department, plus the assigned professional dispensing fee.
e) Drugs not distributed by a retail community pharmacy, such as drugs dispensed in a long-term care facility or dispensed to participants receiving swing-bed services, will be reimbursed at the actual ingredient cost, plus the assigned professional dispensing fee.

vi. Physician Administered Drugs
a) Payment to a Medicaid provider will be ninety percent (90%) of the ASP+6% rate.
b) If the ASP+6% rate is not available, the payment will be at the Wholesale Acquisition Cost (WAC).
c) Payment to 340B providers will be the actual 340B drug acquisition cost submitted (not to exceed the 340B ceiling price).

vii. Clotting Factor Reimbursement
Reimbursement for clotting factor, including those dispensed by specialty pharmacies, as well as those dispensed by hemophilia treatment centers and Centers of Excellence, will be at a state-based price equivalent to the published Medicare ASP+6% price, plus the assigned professional dispensing fee as described in 12.a.iii.

viii. Investigational Drugs
Investigational drugs are not a covered service under Idaho's Medicaid pharmacy program. The Department may consider Medicaid coverage on a case-by-case basis for life-threatening medical illnesses when no other treatment options are available. When approved for payment, reimbursement will be at actual acquisition cost plus the assigned professional dispensing fee.

ix. Supplemental Rebate Agreement:
Based on the requirements in Section 1927 of the Act, the state has the following policies for the supplemental drug rebate program for Medicaid participants.
a) The model rebate agreement between the state and drug manufacturers for drugs provided to Medicaid participants, submitted to CMS on April 23, 2004 and entitled "Supplemental Rebate Agreement" has been authorized by CMS.

b) The model rebate agreement between the state and drug manufacturers for drugs provided to Medicaid participants, submitted to CMS on February 27, 2004 and entitled "Merck Agreement" has been authorized by CMS.
c) Supplemental drug rebates received by the state in excess of those required under the national drug rebate agreement will be shared with the Federal government on the same percentage basis as applied under the national drug rebate agreement.
d) Manufacturers are allowed to audit utilization rates.
e) The unit rebate amount is confidential and cannot be disclosed for purposes other than rebate invoicing and verification, in accordance with 1927(b)(3)(D).
f) Payment of a supplemental rebate may not exempt a drug from prior authorization. It is one factor but is secondary to considerations of the safety, effectiveness, and clinical outcomes of the drug in comparison with other therapeutically interchangeable alternative drugs, and the net economic impact of inclusion or exclusion of the drug from prior authorization.
g) Manufacturers who do not participate in the supplemental rebate program will have their drugs made available to Medicaid participants through either the preferred drug list or the prior authorization process, depending on the results of the Pharmacy and Therapeutics Committee recommendations and Departmental review.
h) In addition to the supplemental rebate agreements listed above, CMS has authorized the state of Idaho to enter into The Optimal PDL Solution (TOP$), submitted to CMS on September 19, 2013, and effective on October 1, 2013, for the state of Idaho.

   Idaho will participate in a multi-state pooling program that will negotiate supplemental rebates in addition to federal rebates provided for in Title XIX. This multi-state pooling program is known as The Optimal PDL Solution (TOP$). TOP$^{sm} rebate agreements will be separate from the federal rebates. TOP$^{sm} supplemental rebates received by the State in excess of those required under the federal drug rebate agreement will be shared with the federal government on the same percentage basis as applied under the federal rebate agreement. Idaho will continue to utilize CMS-approved state-specific supplemental rebate agreements as listed above.