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State/Territory: Indiana

State Plan Amendment (SPA)#: 20-0018

This file contains the following documents in the order listed:

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

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

February 17, 2021

Ms. Allison Taylor
Medicaid Director
Indiana Office of Medicaid Policy and Planning
402 W Washington St Rm W382
Indianapolis, IN 46204-2776

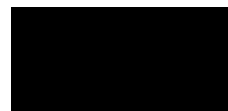
Dear Ms. Taylor:

The CMS Division of Pharmacy team has reviewed Indiana State Plan Amendment (SPA) 20-0018 received in the Division of Program Operations North Branch on November 20, 2020. This SPA proposes to make technical changes to the template utilized in administering the State's supplemental drug rebate program.

Based on the information provided and consistent with the regulations at 42 CFR 430.20, we are pleased to inform you that SPA 20-0018 is approved with an effective date of October 1, 2020. A copy of the updated signed CMS-179 form, as well as the pages approved for incorporation into Indiana's state plan will be forwarded by the Division of Program Operations North Branch.

If you have any questions regarding this request, please contact Justin Aplin at (410) 786-6901 or Justin.Aplin@cms.hhs.gov.

Sincerely,



Digitally signed by John
M. Coster -S
Date: 2021.02.17
10:22:33 -05'00'

John M. Coster, Ph.D., R.Ph.
Director, Division of Pharmacy
DEHPG/CMCS/CMS

cc: James G. Scott, Director Division of Program Operations
Mai Le-Yuen Division of Program Operations North Branch
Sara Albertson Indiana Office of Medicaid Policy and Planning

**TRANSMITTAL AND NOTICE OF APPROVAL OF
STATE PLAN MATERIAL**

1. TRANSMITTAL NUMBER:
20-018

2. STATE
Indiana

FOR: HEALTH CARE FINANCING ADMINISTRATION

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:
October 1, 2020

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:
42 CFR 447.505

7. FEDERAL BUDGET IMPACT (*thousands*):
a. FFY 2020 \$ 0
b. FFY 2021 \$ 0

8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT:

~~Attachment 3.19 page 7~~
Attachment 3.1-A page 7

9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION
OR ATTACHMENT (*If Applicable*):

~~Attachment 3.19 page 7~~
Attachment 3.1-A page 7

10. SUBJECT OF AMENDMENT:

This State Plan Amendment makes technical changes to the template utilized in administering the State's supplemental drug rebate program. In addition, the State is updating the date on an affected page within the state's State Plan. These changes are being made in order to bring about greater transparency pertaining to the supplemental drug rebate processes and procedures and to fully comply with applicable state requirements for supplemental rebates.

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:

**Indiana's Medicaid State Plan does not require the
Governor's review. See Section 7.4 of the State Plan**

12. SIGNATURE OF STATE AGENCY OFFICIAL:

13. TYPED NAME: Allison Taylor

14. TITLE: Medicaid Director

15. DATE SUBMITTED:

16. RETURN TO:

Allison Taylor
Medicaid Director
Indiana Office of Medicaid Policy and Planning
402 West Washington Street, Room W382
Indianapolis, IN 46204
ATTN: Sara Albertson, Federal Relations Lead

FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED:
November 20, 2020

18. DATE APPROVED:
February 17, 2021

PLAN APPROVED – ONE COPY ATTACHED

19. EFFECTIVE DATE OF APPROVED MATERIAL:
October 1, 2020

20. SIGNATURE OF REGIONAL OFFICIAL:

Digitally signed by John M. Coster -S
Date: 2021.02.17 10:23:17 -05'00'

21. TYPED NAME:
John M. Coster

22. TITLE:
Director, Division of Pharmacy, DEHPG/CMCS/CMS

23. REMARKS:

The state is requesting a pen & ink change to boxes 8 and 9 to read: "Attachment 3.1-A page 7".

12.a. Prescribed Drugs

Provided with limitations.

Reimbursement is available for prescribed drugs subject to the limitations set out in 405 IAC 5. The following are not covered: anorectics or any agent used to promote weight loss; topical minoxidil preparations; fertility enhancement drugs; drugs used to treat sexual or erectile dysfunction, as set forth in section 1927(d)(2)(K) of the Act, unless such drugs are used to treat conditions other than sexual or erectile dysfunction and such uses have been approved by the Food and Drug Administration; drugs prescribed solely or primarily for cosmetic purposes. All over-the-counter and non-legend items are subject to the limitations set out in 405 IAC 5-24.

In accordance with Section 4401 of P.L. 101-508 (Omnibus Budget Reconciliation Act of 1990), Indiana Medicaid will fully participate in the manufacturer rebate program. In doing so, all applicable provisions and restrictions of the legislation, as well as that of any subsequent rules and/or regulations, will be strictly adhered to. Specifically, Indiana Medicaid will reimburse for all rebating manufacturers' (as identified to the agency by CMS) products fully in accordance with the specifications of the legislation. The program will also adhere to all reporting requirements of the legislation.

Supplemental Rebates--The State is in compliance with section 1927 of the Social Security Act. The state will cover drugs of federal rebate participating manufacturers. The state is in compliance with reporting requirements for utilization and restrictions to coverage. Pharmaceutical manufacturers can audit utilization data. The unit rebate amount is confidential and cannot be disclosed for purposes other than rebate invoicing and verification.

The state will be negotiating supplemental rebates in addition to the federal rebates provided for in Title XIX. Rebate agreements between the state and a pharmaceutical manufacturer will be separate from the federal rebates. A rebate agreement between the State and a drug manufacturer for drugs provided to the Medicaid program, submitted to CMS on November 20, 2020 and entitled, State of Indiana Supplemental Rebate agreement, has been authorized by CMS.

Supplemental 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 rebate agreement.

All drugs covered by the program, irrespective of prior authorization requirement, will comply with the provisions of the national rebate agreement.

TN No. 20-018

Approval Date February 17, 2021Effective Date October 1, 2020

Supersedes TN No. 20-014