

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

FOR: HEALTH CARE FINANCING ADMINISTRATION

1. TRANSMITTAL NUMBER:

19 - 0013

2. STATE:

Michigan

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

TITLE XIX OF THE SOCIAL SECURITY ACT (MEDICAID)

TO: REGIONAL ADMINISTRATOR
HEALTH FINANCING ADMINISTRATION
DEPARTMENT OF HUMAN SERVICES

4. PROPOSED EFFECTIVE DATE

October 1, 2019

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:

CMS-2345-FC, 81 Fed. Reg. 5169

7. FEDERAL BUDGET IMPACT:

a. FFY 2020 \$0

b. FFY 2021 \$0

8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT:

Supplement to Attachment 3.1-A Page 24.1

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 PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (*If Applicable*):

Supplement to Attachment 3.1-A Page 24.1

10. SUBJECT OF AMENDMENT:

The purpose of this SPA is to clarify coverage of certain Active Pharmaceutical Ingredients (APIs) and Excipients when billed as part of a compounded drug claim.

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:

Kate Massey, Director

Medical Services Administration

12. SIGNATURE OF STATE AGENCY OFFICIAL:



13. TYPED NAME:

Kate Massey

14. TITLE:

Director, Medical Services Administration

15. DATE SUBMITTED:

December 19, 2019

16. RETURN TO:

Medical Services Administration
Actuarial Division - Federal Liaison
Capitol Commons Center - 7th Floor
400 South Pine
Lansing, Michigan 48933

Attn: Erin Black

FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED:

18. DATE APPROVED:

PLAN APPROVED – ONE COPY ATTACHED

19. EFFECTIVE DATE OF APPROVED MATERIAL:

20. SIGNATURE OF REGIONAL OFFICIAL:

21. TYPE NAME:

22. TITLE:

23. REMARKS:

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
State of **MICHIGAN**

***Amount, Duration and Scope of Medical and Remedial Care
Services Provided to the Categorically and Medically Needy***

12. Drug Products, Dentures, Prosthetic and Orthotic Devices, Eyeglasses (continued)
- a. Drug Products (continued)
7. A drug use review program, including prospective and retrospective drug utilization review, has been implemented in compliance with federal law.
 8. Claims management is electronic, in compliance with federal law.
 9. The State is in compliance with Section 1927 of the Social Security Act Based on the requirements for Section 1927 of the Act, the state has the following policies for the supplemental rebate program for the Medicaid population:
 - (A)
 - (I) CMS has authorized the State of Michigan to enter into the Michigan multi-state pooling agreement (MMSPA) also referred to as the National Medicaid Pooling Initiative (NMPI) for drugs provided to Medicaid beneficiaries. The NMPI Supplemental Rebate Agreement (SRA) and the Amendment to the SRA submitted to CMS on February 1, 2008, have been authorized for pharmaceutical manufacturers' existing agreements through their current expiration dates. The updated NMPI SRA submitted to CMS on September 25, 2013, has been authorized for renewal and new agreements with pharmaceutical manufacturers for drugs provided to Medicaid beneficiaries.
 - (II) CMS has authorized the State of Michigan to enter into outcomes-based contract arrangements with drug manufacturers for drugs provided to Medicaid beneficiaries. These contracts will be executed on the contract template titled "Outcomes-Based Supplemental Rebate Agreement" submitted to CMS and authorized for use beginning September 30, 2018.
 - (B) New contracts will be submitted to CMS for prior approval.
 - (C) 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 drug rebate agreement.
 - (D) All drugs covered by the program, irrespective of a prior authorization requirement, will comply with provisions of the national drug rebate agreement.
 10. COVERAGE OF SELECTED ACTIVE PHARMACEUTICAL INGREDIENTS (APIs) AND EXCIPIENTS THAT ARE ESSENTIAL TO THE HEALTH OF THE BENEFICIARY.
- b. Dentures
- Dentures are a covered benefit for recipients under the EPSDT program if determined necessary by a licensed dentist (Item 10 of this attachment) to correct masticatory deficiencies likely to impair general health. Prior authorization is required. If the client has an existing denture, replacement is permissible only if the existing denture cannot be relined or rebased, whether or not the existing denture was obtained through the Michigan Medical Assistance Program.
- Reimbursement for complete or partial dentures includes the costs of any necessary adjustments within six months of insertion. Dentures will be replaced when medically necessary. Prior authorization is required.
- c. Prosthetic and Orthotic Devices
- Such devices are provided under the following conditions only:
1. when provided to a hospital inpatient, upon a physician's order indicating that the device is essential to the client's medical treatment plan; or,
 2. when prior authorized as medically necessary and provided on an outpatient basis or for a recipient in a long-term care facility.



STATE OF MICHIGAN

DEPARTMENT OF HEALTH AND HUMAN SERVICES
LANSING

GRETCHEN WHITMER
GOVERNOR

ROBERT GORDON
DIRECTOR

September 24, 2019

NAME
TITLE
ADDRESS
CITY STATE ZIP

Dear Tribal Chair and Health Director:

RE: State Plan Amendment (SPA) for Active Pharmaceutical Product & Excipient Coverage Changes

This letter, in compliance with Section 1902(a)(73) and Section 2107(e)(1)(C) of the Social Security Act, serves as notice to all Tribal Chairs and Health Directors of the intent by the Michigan Department of Health and Human Services (MDHHS) to submit a SPA request to the Centers for Medicare & Medicaid Services (CMS).

The purpose of this SPA is to include certain active pharmaceutical ingredients (bulk drug substances) and excipients (flavorings, transdermal vehicles) within the State Plan. This change will allow MDHHS to cover these as a Medicaid pharmacy benefit when part of a compounded prescription in accordance with 42 CFR 440.120, section 1905(a)(12) and clarified in CMS's Medicaid Drug Rebate Program Notice #158. Extending coverage of these products will benefit Medicaid beneficiaries who rely on them as part of their drug therapy. The anticipated effective date of this SPA is October 1, 2019.

There is no public hearing scheduled for this SPA. Input regarding this SPA is highly encouraged, and comments regarding this notice of intent may be submitted to Lorna Elliott-Egan, MDHHS Liaison to the Michigan tribes. Lorna can be reached at 517-284-4034, or via email at Elliott-EganL@michigan.gov. **Please provide all input by November 8, 2019.**

In addition, MDHHS is offering to set up group or individual consultation meetings to discuss the SPA, according to the tribes' preference. Consultation meetings allow tribes the opportunity to address any concerns and voice any suggestions, revisions, or objections to be relayed to the author of the proposal. If you would like additional information or wish to schedule a consultation meeting, please contact Lorna Elliott-Egan at the telephone number or email address provided above.

Distribution List for L 19-32
September 24, 2019

Mr. Bryan Newland, Tribal Chairman, Bay Mills Indian Community
Ms. Audrey Breakie, Health Director, Bay Mills (Ellen Marshall Memorial Center)
Mr. Thurlow Samuel McClellan, Chairman, Grand Traverse Band Ottawa & Chippewa Indians
Mr. Soumit Pendharkar, Health Director, Grand Traverse Band Ottawa/Chippewa
Mr. Kenneth Meshigaud, Tribal Chairman, Hannahville Indian Community
Ms. G. Susie Meshigaud, Health Director, Hannahville Health Center
Mr. Warren C. Swartz, Jr., President, Keweenaw Bay Indian Community
Ms. Kathy Mayo, Interim Health Director, Keweenaw Bay Indian Community - Donald Lapointe Health/Educ Facility
Mr. James Williams, Jr., Tribal Chairman, Lac Vieux Desert Band of Lake Superior Chippewa Indians
Ms. Sadie Valliere, Health & Human Services Director, Lac Vieux Desert Band
Mr. Larry Romanelli, Ogema, Little River Band of Ottawa Indians
Mr. Daryl Wever, Health Director, Little River Band of Ottawa Indians
Ms. Regina Gasco-Bentley, Tribal Chairman, Little Traverse Bay Band of Odawa Indians
Ms. Jodi Werner, Health Director, Little Traverse Bay Band of Odawa
Mr. Bob Peters, Chairman, Match-E-Be-Nash-She-Wish Potawatomi Indians (Gun Lake Band)
Ms. Kelly Wesaw, Health Director, Match-E-Be-Nash-She-Wish Potawatomi
Mr. Jamie Stuck, Tribal Chairman, Nottawaseppi Huron Band of Potawatomi Indians
Ms. Rosalind Johnston, Health Director, Huron Potawatomi Inc.- Tribal Health Department
Mr. Matthew Wesaw, Tribal Chairman, Pokagon Band of Potawatomi Indians
Mr. Matt Clay, Health Director, Pokagon Potawatomi Health Services
Mr. Ronald Ekdahl, Tribal Chief, Saginaw Chippewa Indian Tribe
Mrs. Karmen Fox, Executive Health Director, Nimkee Memorial Wellness Center
Mr. Aaron Payment, Tribal Chairman, Sault Ste. Marie Tribe of Chippewa Indians
Mr. Leonid Chugunov, Health Director, Sault Ste. Marie Tribe of Chippewa Indians - Health Center

CC: Tannisse Joyce, Region V, CMS
Keri Toback, Region V, CMS
Leslie Campbell, Region V, CMS
Justyna Redlinski, Region V, CMS
Ashley Tuomi, MHPA, Executive Director, American Indian Health and Family Services of Southeastern Michigan
L. John Lufkins, Executive Director, Inter-Tribal Council of Michigan, Inc.
Keith Longie, Director, Indian Health Service - Bemidji Area Office
Lorna Elliott-Egan, MDHHS

MDHHS appreciates the continued opportunity to work collaboratively with you to care for the residents of our state.

Sincerely,

A handwritten signature in black ink, appearing to read 'K. Massey', with a long horizontal line extending to the right.

Kate Massey, Director
Medical Services Administration

cc: Tannisse Joyce, CMS
Keri Toback, CMS
Leslie Campbell, CMS
Justyna Redlinski, CMS
Ashley Tuomi, MHPA, Executive Director, American Indian Health and Family
Services of Southeastern Michigan
L. John Lufkins, Executive Director, Inter-Tribal Council of Michigan, Inc.
Keith Longie, Director, Indian Health Service - Bemidji Area Office
Lorna Elliott-Egan, MDHHS