DEPARTMENT OF HEALTH ANDHUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

FORM APPROVED
OMB No. 0938-0193

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL

FOR: CENTERS FOR MEDICARE & MEDICAID SERVICES

1. TRANSMITTAL NUMBER
23 — 0029

2. STATE
MI

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

TO: CENTER DIRECTOR
CENTERS FOR MEDICAID & CHIP SERVICES
DEPARTMENT OF HEALTH AND HUMAN SERVICES

3. PROPOSED EFFECTIVE DATE
October 1, 2023

5. FEDERAL STATUTE/REGULATION CITATION
42 CFR 447

6. FEDERAL BUDGET IMPACT (Amounts in WHOLE dollars)
a. FFY 2024 $0
b. FFY 2025 $0

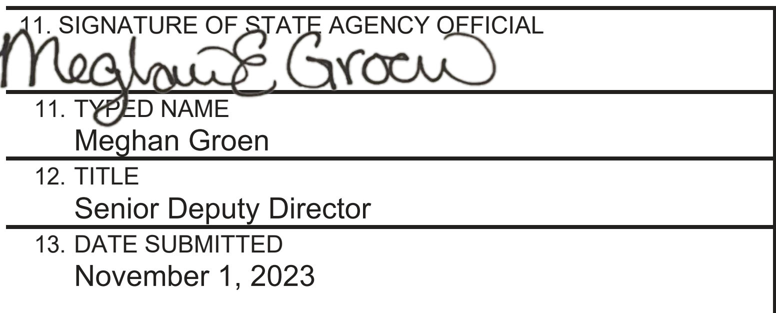
7. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT
Attachment 4.19--A Page 11a

8. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT *(If Applicable)*
Attachment 4.19--A Page 11a (TN# 21-0010)

9. SUBJECT OF AMENDMENT
This SPA provides authority to establish hospital reimbursement, separate from the Diagnosis Related Group (DRG) payment, for Spinraza and drugs for which the State has entered CMS approved outcomes-based contract arrangements with drug manufacturers for drugs provided to Medicaid beneficiaries.

10. 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
- [x] OTHER, AS SPECIFIED:

11. SIGNATURE OF STATE AGENCY OFFICIAL



11. TYPED NAME
Meghan Groen

12. TITLE
Senior Deputy Director

13. DATE SUBMITTED
November 1, 2023

15. RETURN TO

Behavioral and Physical Health and Aging Services Administration
Office of Strategic Partnerships & Medicaid Administrative Services – Federal Liaison
Capitol Commons Center – 7th Floor
400 South Pine
Lansing, Michigan 48933

Attn: Erin Black

FOR CMS USE ONLY

16. DATE RECEIVED

17. DATE APPROVED

PLAN APPROVED - ONE COPY ATTACHED

18. EFFECTIVE DATE OF APPROVED MATERIAL

19. SIGNATURE OF APPROVING OFFICIAL

20. TYPED NAME OF APPROVING OFFICIAL

21. TITLE OF APPROVING OFFICIAL

22. REMARKS

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

State of MICHIGAN

Policy and Methods for Establishing Rates
Inpatient Hospital

I. Hospital Rapid Whole Genome Sequencing (rWGS) Testing Reimbursement

Rapid whole genome sequencing testing provided in the inpatient hospital setting is excluded from the DRG payment. An additional payment for medically necessary rWGS will be made to a hospital when established clinical criteria is met. Costs associated with rWGS are to be billed separately from the inpatient episode. Hospital reimbursement will be made according to the Medicaid laboratory fee schedule.

J. SPINRAZA

SPINRAZA PROVIDED IN THE INPATIENT HOSPITAL SETTING IS EXCLUDED FROM THE DRG PAYMENT. AN ADDITIONAL PAYMENT FOR MEDICALLY NECESSARY SPINRAZA WILL BE MADE TO A HOSPITAL WHEN ESTABLISHED CLINICAL CRITERIA IS MET. COSTS ASSOCIATED WITH SPINRAZA ARE TO BE BILLED SEPARATELY FROM THE INPATIENT EPISODE. HOSPITAL REIMBURSEMENT WILL BE MADE ACCORDING TO THE MEDICAID FEE SCHEDULE.

K. OUTCOMES-BASED CONTRACT ARRANGEMENTS

DRUGS PROVIDED UNDER OUTCOMES-BASED CONTRACT ARRANGEMENTS WITH DRUG MANUFACTURERS FOR DRUGS PROVIDED TO MEDICAID BENEFICIARIES IN THE INPATIENT HOSPITAL SETTING ARE EXCLUDED FROM THE DRG PAYMENT. AN ADDITIONAL PAYMENT FOR DRUGS UNDER AN OUTCOMES-BASE CONTRACT ARRANGEMENT WILL BE MADE TO A HOSPITAL WHEN ESTABLISHISHED CLINICAL CRITERIA IS MET. COSTS ASSOCIATED WITH THESE DRUGS ARE TO BE BILLED SEPARETLY FROM THE INPATIENT EPISODE. HOSPITAL REIMBURSMENT WILL BE MADE ACCORDING TO THE MEDICAID FEE SCHEDULE.

Medicaid Hospital Upper Payment Limit Non-Federal Funding Questions

The following questions should be answered in relation to all payments made to all providers reimbursed pursuant to a methodology for each of the applicable services that are submitted pursuant to SMDL #13-003.

1. Section 1903(a)(1) provides that Federal matching funds are only available for expenditures made by States for services under the approved State plan. Do providers receive and retain the total Medicaid expenditures claimed by the State (includes normal per diem, supplemental, enhanced payments, other) or is any portion of the payments returned to the State, local governmental entity, or any other intermediary organization? If providers are required to return any portion of payments, please provide a full description of the repayment process. Include in your response a full description of the methodology for the return of any of the payments, a complete listing of providers that return a portion of their payments, the amount or percentage of payments that are returned and the disposition and use of the funds once they are returned to the State (i.e., general fund, medical services account, etc.)

   Response 4.19-A: *Providers will not return any portion of any Medicaid-related payments they receive.*

   Response 4.19-B: *Providers will not return any portion of any Medicaid-related payments they receive.*

2. Section 1902(a)(2) provides that the lack of adequate funds from local sources will not result in lowering the amount, duration, scope, or quality of care and services available under the plan. Please describe how the state share of each type of Medicaid payment (normal per diem, supplemental, enhanced, other) is funded. Please describe whether the state share is from appropriations from the legislature to the Medicaid agency, through intergovernmental transfer agreements (IGTs), certified public expenditures (CPEs), provider taxes, or any other mechanism used by the state to provide state share. Note that, if the appropriation is not to the Medicaid agency, the source of the state share would necessarily be derived through either through an IGT or CPE. In this case, please identify the agency to which the funds are appropriated. Please provide an estimate of total expenditure and State share amounts for each type of Medicaid payment. If any of the non-federal share is being provided using IGTs or CPEs, please fully describe the matching arrangement including when the state agency receives the transferred amounts from the local governmental entity transferring the funds. If CPEs are used, please describe the methodology used by the state to verify that the total expenditures being certified are eligible for Federal matching funds in accordance with 42 CFR 433.51(b). For any payment funded by CPEs or IGTs, please provide the following:
   i. a complete list of the names of entities transferring or certifying funds;
   ii. the operational nature of the entity (state, county, city, other);
   iii. the total amounts transferred or certified by each entity;
   iv. clarify whether the certifying or transferring entity has general taxing authority: and,

v. whether the certifying or transferring entity received appropriations (identify level of appropriations).

Response 4.19-A: *Funding for all hospital payments detailed below must be appropriated by the state legislature before expenditures can be incurred. The funding sources supporting appropriations for specific payments are itemized below.*

DRG Payments – Hospital DRG payments made under section 4.19-A are estimated to be $326.4 million for fiscal year 2021. State funding for these payments is estimated at $61.6 million for this time period.

Per Diem Payments – Hospital per diem payments made under section 4.19-A are estimated to be $7.7 million for fiscal year 2021. State funding for these payments is estimated at $1.1 million for this time period.

TEFRA Payments – Hospital TEFRA payments made under section 4.19-A are estimated to be $48.2 million for fiscal year 2021. State funding for these payments is estimated at $14.3 million for this time period.

Capital Payments – Hospital capital payments made under section 4.19-A are included in the DRG and Per Diem payments listed above for fiscal year 2021. State funding for these payments is listed above for this time period.

GME Payments – Hospital GME payments made under section 4.19-A are estimated to be $52.2 million for fiscal year 2021. State funding for these payments is estimated at $19.8 million for this time period.

GME payments consisted of $31.2 million in GME Funds Pool and Primary Care Pool payments and $20.9 million in Innovations Pool payments. The latter were made to Pine Rest Christian Hospital, Hurley Medical Center, and Detroit Receiving Hospital under arrangements with Michigan State University and Wayne State University, respectively, whereby the universities provided the state share of approximately $10.5 million.

DSH Payments – Hospital DSH payments under 4.19-A are estimated to be $489.3 million for fiscal year 2021. The total non-federal share of hospital DSH payments was approximately $145.4 million for this time period. There are four components to the non-federal share of the payments:

1. Approximately $61.3 million was funded through state general fund tax dollars.

2. Approximately $1.0 million was funded through intergovernmental transfers (IGTs) from public entities. The state received the state share from public entities prior to issuing the DSH payment to the hospitals. Attachment A provides additional information related to these IGTs.

3. Approximately $28.1 million was funded through certified public expenditures (CPEs). The methodology for these payments is described on pages 24b and 24c of Section 4.19-A of Michigan's Medicaid State Plan. Attachment B provides additional information related to these CPEs.

4. Approximately $55.0 million was funded through a hospital provider tax to support the Outpatient Uncompensated Care DSH Pool.

<u>*Supplemental/Enhanced Payments*</u> *– Hospital supplemental payments made under section 4.19-A are estimated to be $399.9 million for fiscal year 2021. These payments consist of $398.8 million in Medicaid Access to Care Initiative (MACI) payments and $1.1 million in Rural Access Pool (RAP) payments. MACI payments are supported by a hospital provider tax. RAP payments are supported by the state general fund. The non-federal share of supplemental/enhanced payments is estimated at $87.1 million.*

<u>Response 4.19-B</u>*: Funding for all hospital payments detailed below must be appropriated by the state legislature before expenditures can be incurred. The funding sources supporting appropriations for specific payments are broken out below.*

Regular Outpatient Hospital Payments- Regular outpatient hospital payments made under section 4.19-B are estimated to be $104.8 million for fiscal year 2021. These payments are supported by state general fund. State funding for these payments is estimated at $12.4 million for this time period.

Supplemental/Enhanced Payments- Hospital supplemental payments made under section 4.19-B for fiscal year 2021 are estimated to be $131.3 million. These payments consist of $130.8 million in Medicaid Access to Care Initiative (MACI) payments and $0.5 million in Rural Access Pool (RAP) payments. MACI payments are supported by a hospital provider tax. RAP payments are supported by the state general fund. The non-federal share of supplemental/enhanced payments is estimated at $27.6 million.

3. Section 1902(a)(30) requires that payments for services be consistent with efficiency, economy, and quality of care. Section 1903(a)(1) provides for Federal financial participation to States for expenditures for services under an approved State plan. If supplemental or enhanced payments are made, please provide the total amount for each type of supplemental or enhanced payment made to each provider type.

   <u>Response 4.19-A</u>*: The Medicaid Access to Care Initiative (MACI) and Rural Access Pool (RAP) payments detailed in section 4.19-A are considered to be supplemental payments. Total supplemental inpatient payments made under section 4.19-A for fiscal year 2021 are approximately $398.8 million for MACI payments and $1.1 million for the RAP payments.*

   <u>Response 4.19-B</u>*: Medicaid Access to Care (MACI) and Rural Access Pool (RAP) hospital payments detailed in Attachment 4.19-B are considered to be supplemental payments. Total supplemental payments made under Attachment 4.19-B for fiscal year 2021 are approximately $130.8 million for MACI payments and $0.5 million for the RAP payments.*

4. For clinic or outpatient hospital services please provide a detailed description of the methodology used by the state to estimate the upper payment limit (UPL) for each class

of providers (State owned or operated, non-state government owned or operated, and privately owned or operated). Please provide a current (i.e., applicable to the current rate year) UPL demonstration.

Response: The answer to this question is provided in the State's response to the CMS formal UPL reporting requirements. The State's UPL packet includes a final copy of its fiscal year 2023 upper payment limit demonstration and the accompanying completed fillable documents.

5. Does any governmental provider receive payments that in the aggregate (normal per diem, supplemental, enhanced, other) exceed their reasonable costs of providing services? If payments exceed the cost of services, do you recoup the excess and return the Federal share of the excess to CMS on the quarterly expenditure report?

   Response: In the aggregate, the payments are under the Medicare upper payment limit. They therefore do not exceed the hospital providers' reasonable costs of providing services. A mechanism has been implemented to recoup and return the federal share of overpayments in the event that overpayment occurs.

Public Notice

Michigan Department of Health and Human Services
Behavioral and Physical Health and Aging Services Administration

Hospital Reimbursement for Spinraza and Drugs Under Outcomes-based Contract Arrangements State Plan Amendment Request

The Michigan Department of Health and Human Services (MDHHS) plans to submit a State Plan Amendment (SPA) request to the Centers for Medicare & Medicaid Services (CMS) to establish hospital reimbursement, separate from the Diagnosis Related Group (DRG) payment, for Spinraza and drugs for which the state has entered CMS approved outcomes-based contract arrangements with drug manufacturers for drugs provided to Medicaid beneficiaries. Payment will be made for applicable drugs in accordance with the Medicaid fee schedule in effect on the date of service. The anticipated effective date for the hospital reimbursement for Spinraza and outcomes-based contracts SPA is October 1, 2023. The estimated gross savings to the State of Michigan for the SPA is $1.275 million per year.

There is no public meeting scheduled regarding this notice. Any interested party wishing to request a written copy of the SPA or wishing to submit comments may do so by sending an e-mail to MSADraftPolicy@michigan.gov or submitting a request in writing to: MDHHS/ Behavioral and Physical Health and Aging Services Administration, Program Policy Division, PO Box 30479, Lansing MI 48909-7979 by September 30, 2023. A copy of the proposed State Plan Amendment will also be available for review at: https://www.michigan.gov/mdhhs/inside-mdhhs/budgetfinance/264/state-plan-amendments.

RELEASED: September 13, 2023

STATE OF MICHIGAN
DEPARTMENT OF HEALTH AND HUMAN SERVICES
LANSING

GRETCHEN WHITMER
GOVERNOR

ELIZABETH HERTEL
DIRECTOR

October 17, 2023

NAME
TITLE
ADDRESS
CITY STATE ZIP

Dear Tribal Chair and Health Director:

RE: Hospital Reimbursement for Spinraza and Drugs Provided Under Outcomes-based Contract Arrangements

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 State Plan Amendment (SPA) request to the Centers for Medicare & Medicaid Services (CMS).

Pending CMS approval, MDHHS will provide reimbursement, separate from the Diagnosis Related Group (DRG) payment, for Spinraza and drugs for which the state has entered CMS approved outcomes-based contract arrangements with drug manufacturers for drugs provided to Medicaid beneficiaries. This change is expected to have no impact on tribal members. The anticipated effective date of this SPA is October 1, 2023.

There is no public hearing scheduled for this SPA. Due to the requirements within state contract arrangements for an effective date of October 1, 2023, it is not possible to adhere to the sixty (60) days notification. Input regarding this Amendment 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 517-512-4146, or via email at Elliott-EganL@michigan.gov. **Please provide all input by December 1, 2023.**

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.

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

An electronic copy of this letter is available at www.michigan.gov/medicaidproviders >> Policy, Letters & Forms.

Sincerely,

Meghan E. Groen, Director
Behavioral and Physical Health and Aging Services Administration

CC: Keri Toback, CMS
Nancy Grano, CMS
Chasity Dial, CEO, American Indian Health and Family Services of Southeastern Michigan
Daniel Frye, Director, Indian Health Service - Bemidji Area Office
Lorna Elliott-Egan, MDHHS

Distribution List for L 23-56
October 17, 2023

Ms. Whitney Gravelle, President, Bay Mills Indian Community
Ms. Audrey Breakie, Health Director, Bay Mills (Ellen Marshall Memorial Center)
Mr. David M. Arroyo, Chairman, Grand Traverse Band Ottawa & Chippewa Indians
Ms. Doris Winslow, Health Director, Grand Traverse Band Ottawa/Chippewa
Mr. Kenneth Meshigaud, Tribal Chairman, Hannahville Indian Community
Ms. G. Susie Meshigaud, Health Director, Hannahville Health Center
Ms. Doreen G. Blaker, Tribal President, Keweenaw Bay Indian Community
Ms. Deanna Foucault, 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. Phyllis Davis, Tribal Council Member, Match-E-Be-Nash-She-Wish Potawatomi
Ms. Mariah Austin, Tribal Council Member, 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
Ms. Rebecca Richards, Tribal Chairwoman, Pokagon Band of Potawatomi Indians
Ms. Priscilla Gatties, Interim Health Director, Pokagon Potawatomi Health Services
Ms. Theresa Peters-Jackson, Tribal Chief, Saginaw Chippewa Indian Tribe
Mrs. Karmen Fox, Executive Health Director, Nimkee Memorial Wellness Center
Mr. Austin Lowes, Tribal Chairperson, Sault Ste. Marie Tribe of Chippewa Indians
Mr. Leonid Chugunov, Health Director, Sault Ste. Marie Tribe of Chippewa Indians - Health Center

CC: Keri Toback, CMS
Nancy Grano, CMS
Chasity Dial, CEO, American Indian Health and Family Services of Southeastern Michigan
Daniel Frye, Director, Indian Health Service - Bemidji Area Office
Lorna Elliott-Egan, MDHHS