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State/Territory Name: **Delaware**

State Plan Amendment (SPA) #: **22-0018**

This file contains the following documents in the order listed:

- 1) Approval Letter
- 2) CMS 179 Form/Summary Form (with 179-like data)
- 3) Approved SPA Pages

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
601 E. 12th St., Room 355
Kansas City, Missouri 64106



Medicaid and CHIP Operations Group

January 23, 2023

Mr. Theodore G. Mermigos, Jr.
Acting Division Director
Division of Medicaid Medical Assistance
P.O. Box 906
New Castle, DE, 19720

Re: Delaware (DE) State Plan Amendment (SPA) 22-0018

Dear Mr. Mermigos:

The Centers for Medicare & Medicaid Services (CMS) reviewed your Medicaid State Plan Amendment (SPA) submitted under transmittal number (TN) 22-0018. This amendment amends Delaware State Plan to assure coverage of routine patient costs associated with participation in qualifying clinical trials.

We conducted our review of your submittal according to statutory requirements in Title XIX of the Social Security Act. This letter is to inform you that Delaware Medicaid SPA 22-0018 was approved on January 20, 2023, with an effective date of October 1, 2022.

If you have any questions, please contact Talbatha Myatt at (215) 861-4259 or via email at Talbatha.Myatt@cms.hhs.gov.

Sincerely,



James G. Scott, Director
Division of Program Operations

**TRANSMITTAL AND NOTICE OF APPROVAL OF
STATE PLAN MATERIAL
FOR: CENTERS FOR MEDICARE & MEDICAID SERVICES**

1. TRANSMITTAL NUMBER

2 2 — 0 0 1 8

2. STATE

DE

3. PROGRAM IDENTIFICATION: TITLE OF THE SOCIAL SECURITY ACT



XIX



XXI

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

4. PROPOSED EFFECTIVE DATE

10/1/22

5. FEDERAL STATUTE/REGULATION CITATION

1905(a)(30) and 1905(gg)(1) of the SSA

6. FEDERAL BUDGET IMPACT (Amounts in WHOLE dollars)

a. FFY 2023 \$ 0
b. FFY 2024 \$ 0

7. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT

Attachment 3.1A Page 11b

8. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (If Applicable)

NEW

9. SUBJECT OF AMENDMENT

Qualifying Clinical Trials

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



OTHER, AS SPECIFIED:

11. SIGNATURE OF STATE AGENCY OFFICIAL

[Redacted Signature]

12. TYPED NAME

Stephen M. Groff

13. TITLE

Director

14. DATE SUBMITTED 12/16/2022 10:43 AM EST

15. RETURN TO

Stephen M. Groff, Director, DMMA, P.O. Box 906 New Castle, DE19720

FOR CMS USE ONLY

16. DATE RECEIVED 12/22/2023

17. DATE APPROVED 01/20/2023

PLAN APPROVED - ONE COPY ATTACHED

18. EFFECTIVE DATE OF APPROVED MATERIAL

10/01/2022

19. SIGNATURE OF APPROVING OFFICIAL

[Redacted Signature]

20. TYPED NAME OF APPROVING OFFICIAL

James G. Scott

21. TITLE OF APPROVING OFFICIAL

Director, Division of Program Operations

22. REMARKS

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACTSTATE/TERRITORY: DELAWAREAMOUNT, DURATION AND SCOPE OF SERVICES PROVIDED
CATEGORICALLY NEEDY GROUP(S)

27. Coverage of Routine Patient Cost in Qualifying Clinical Trials

*The state needs to check each assurance below.

Provided: X

I. General Assurances:

Routine Patient Cost – Section 1905(gg)(1)

X Coverage of routine patient cost for items and services as defined in section 1905(gg)(1) that are furnished in connection with participation in a qualified clinical trial.

Qualifying Clinical Trial – Section 1905(gg)(2)

X A qualified clinical trial is a clinical trial that meets the definition at section 1905(gg)(2).

Coverage Determination – Section 1905(gg)(3)

X A determination with respect to coverage for an individual participating in a qualified clinical trial will be made in accordance with section 1905(gg)(3).

PRA Disclosure Statement - This information is being collected to assist the Centers for Medicare & Medicaid Services in implementing Section 210 of the Consolidated Appropriations Act of 2021 amending section 1905(a) of the Social Security Act (the Act), by adding a new mandatory benefit at section 1905(a)(30). Section 210 mandates coverage of routine patient services and costs furnished in connection with participation by Medicaid beneficiaries in qualifying clinical trials effective January 1, 2022. Section 210 also amended sections 1902(a)(10)(A) and 1937(b)(5) of the Act to make coverage of this new benefit mandatory under the state plan and any benchmark or benchmark equivalent coverage (also referred to as alternative benefit plans, or ABPs). Under the Privacy Act of 1974 any personally identifying information obtained will be kept private to the extent of the law. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. The OMB control number for this project is 0938-1148 (CMS-10398 #74). Public burden for all of the collection of information requirements under this control number is estimated to take about 56 hours per response. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to CMS, 7500 Security Boulevard, Attn: Paperwork Reduction Act Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.

TN No. SPA 22-0018

Supersedes

TN No. SPA NEW

Approval Date: 01/20/2023

Effective Date: 10/01/2022