Table of Contents

State Name: Virginia

State Plan Amendment (SPA) #: 22-0009

This file contains the following documents in the order listed:

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

CENTERS FOR MEDICARE & MEDICAID SERVICES
CENTER FOR MEDICAID & CHIP SERVICES

Medicaid and CHIP Operations Group

April 8, 2022

Karen Kimsey, Director
Department of Medical Assistance Services
600 East Broad Street, Suite 1300
Richmond, VA 23219

Re: Virginia State Plan Amendment 22-0009

Dear Ms. Kimsey:

The Centers for Medicare & Medicaid Services (CMS) has reviewed your Medicaid State Plan Amendment (SPA) submitted under transmittal number (TN) 22-0009. This amendment proposes to add coverage for Virginia's Clinical Trials.

We conducted our review of your submittal according to statutory requirements in Title XIX of the Social Security Act and implementing regulations Title 42 of the Code of Federal Regulations §440. This letter is to inform you that Virginia Medicaid SPA 22-0009 was approved on April 7, 2022, with an effective date of January 1, 2022.

If you have any questions, please contact Margaret Kosherzenko at 215-861-4288 or via email at Margaret.Kosherzenko@cms.hhs.gov.

Sincerely,

Digitally signed by James G. Scott -S
Date: 2022.04.08 08:41:22 -05'00'

James G. Scott, Director
Division of Program Operations

cc: Emily McClellan

DEPARTMENT OF HEALTH AND HUMAN 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: 22 — 0009

2. STATE: VA

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
1/1/2022

5. FEDERAL STATUTE/REGULATION CITATION
42 CFR 440

6. FEDERAL BUDGET IMPACT (Amounts in WHOLE dollars)
a. FFY 2022 $ 0
b. FFY 2023 $ 0

7. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT
Attachment 3.1-A: new page 13
Attachment 3.1-B, new page 11

8. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT *(If Applicable)*
Same as box #7.

9. SUBJECT OF AMENDMENT
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: Secretary of Health and Human Resources

11. SIGNATURE OF STATE AGENCY OFFICIAL
Karen Kimsey

12. TYPED NAME
Karen Kimsey

13. TITLE
Director

14. DATE SUBMITTED
2/24/2022

15. RETURN TO
Department of Medical Assistance Services
600 East Broad Street, #1300
Richmond VA 23219

Attn: Policy, Regulations, and Manuals Supervisor

FOR CMS USE ONLY

16. DATE RECEIVED
03/28/2022

17. DATE APPROVED
4/7/2022

PLAN APPROVED - ONE COPY ATTACHED

18. EFFECTIVE DATE OF APPROVED MATERIAL
01/01/2022

19. SIGNATURE OF APPROVING OFFICIAL
Digitally signed by James G. Scott -S
Date: 2022.04.08 08:42:19 -05'00'

20. TYPED NAME OF APPROVING OFFICIAL
James G. Scott

21. TITLE OF APPROVING OFFICIAL
Director, Division of Program Operations

22. REMARKS

Instructions on Back

State/Territory: Virginia

AMOUNT, DURATION AND SCOPE OF SERVICES PROVIDED

CATEGORICALLY NEEDY GROUP(S)

30. Coverage of Routine Patient Cost in Qualifying Clinical Trials

*The state needs to check each assurance below.

Provided: _____

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 unlessit 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 SecurityBoulevard, Attn: Paperwork Reduction Act Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.

State/Territory: Virginia

AMOUNT, DURATION AND SCOPE OF SERVICES PROVIDED

MEDICALLY NEEDY GROUP(S)

30. Coverage of Routine Patient Cost in Qualifying Clinical Trials

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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 unlessit 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 SecurityBoulevard, Attn: Paperwork Reduction Act Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.