

## COMMONWEALTH of VIRGINIA

## Office of the Governor

John E. Littel Secretary of Health and Human Resources

March 8, 2022

Francis McCullough, Associate Regional Administrator Centers for Medicare & Medicaid Services 801 Market Street, Suite 9400 Philadelphia, PA 19107-3134

Dear Mr. McCullough:

Attached for your review and approval is amendment 22-009, entitled "Clinical Trials" to the Plan for Medical Assistance for the Commonwealth. I request that your office approve this change as quickly as possible.

Sincerely,

John E. Littel

Attachment

cc: Karen Kimsey, Director, Department of Medical Assistance Services

#### SPA 22-009

#### I. IDENTIFICATION INFORMATION

Title of Amendment: Clinical Trials

#### II. SYNOPSIS

<u>Basis and Authority</u>: The <u>Code of Virginia</u> (1950) as amended, § 32.1-325, grants to the Board of Medical Assistance Services the authority to administer and amend the Plan for Medical Assistance. The <u>Code of Virginia</u> (1950) as amended, § 32.1-324, authorizes the Director of the Department of Medical Assistance Services (DMAS) to administer and amend the Plan for Medical Assistance according to the Board's requirements.

<u>Purpose</u>: The state plan is being revised to include reimbursement for coverage for routine patient costs furnished in connection with a member's participation in a qualifying clinical trial in accordance with Section 210 of the Consolidated Appropriations Act of 2021 and the Centers for Medicare and Medicaid Services (CMS) State Medicaid Director (SMD) letter #21-005. Per the SMD letter, DMAS will cover any item or service provided to the individual under the qualifying clinical trial, including any item or service provided to prevent, diagnose, monitor, or treat complications resulting from participation in the qualifying clinical trial, to the extent that the provision of such items or services to the beneficiary would otherwise be covered outside the course of participation in the qualifying clinical trial under the state plan or waiver, including a demonstration project under section 1115 of the Social Security Act. Such routine services and costs also include any item or service required to administer the investigational item or service.

<u>Substance and Analysis</u>: The sections of the State Plan for Medical Assistance that are affected by this action are "Amount, Duration and Scope of Services Provided-Categorically Needy Group(s)" and "Amount, Duration and Scope of Services Provided-Medically Needy Group(s)."

<u>Impact</u>: There will be negligible impact given the services covered and the payment methodologies will remain the same as the underlying services. The SPA will clarify that DMAS will pay for those items in the context of a clinical trial.

Tribal Notice: Please see Attachments A-1 and A-2.

Prior Public Notice: Please see Attachment B-1.

Public Comments and Agency Analysis: N/A.

## Commonwealth of 'irginia

#### Attachment A-1

Lee, Meredith < meredith.lee@dmas.virginia.gov>

#### Tribal Notice-Clinical Trials

1 message

Lee, Meredith <meredith.lee@dmas.virginia.gov>

Thu, Feb 24, 2022 at 2:58 PM

To: TribalOffice@monacannation.com, chiefannerich@aol.com, jerry.stewart@cit-ed.org, Pamelathompson4@yahoo.com, rappahannocktrib@aol.com, regstew007@gmail.com, Robert Gray <robert.gray@pamunkey.org>, tribaladmin@monacannation.com, Sam Bass <samflyingeagle48@yahoo.com>, chiefstephenadkins@gmail.com, WFrankAdams@verizon.net, bradbybrown@gmail.com, heather.hendrix@ihs.gov, tabitha.garrett@ihs.gov, Kara.Kearns@ihs.gov

Cc: Emily Mcclellan <emily.mcclellan@dmas.virginia.gov>

Dear Tribal Leaders and Indian Health Programs:

Attached is a Tribal Notice letter from Virginia Medicaid Director Karen Kimsey indicating that the Dept. of Medical Assistance Services (DMAS) plans to submit a State Plan Amendment (SPA) to the federal Centers for Medicare and Medicaid Services. This SPA will provide coverage for routine patient costs furnished in connection with a member's participation in a qualifying clinical trial.

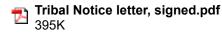
If you would like a copy of the SPA documents or proposed text changes, or if you have any questions, please let us know.

Thank you!

#### Meredith Lee

Meredith Lee Policy, Regulations, and Manuals Supervisor Division of Policy, Regulation, and Member Engagement Department of Medical Assistance Services 600 East Broad Street Richmond, VA 23219 meredith.lee@dmas.virginia.gov (804) 371-0552







## COMMONWEALTH of VIRGINIA

KAREN KIMSEY DIRECTOR Department of Medical Assistance Services

SUITE 1300 600 EAST BROAD STREET RICHMOND, VA 23219 804/786-7933 800/343-0634 (TDD) www.dmas.virginia.gov

February 24, 2022

SUBJECT: Notice of Opportunity for Tribal Comment – State Plan Amendment related to Clinical Trials.

Dear Tribal Leader and Indian Health Programs:

This letter is to notify you that the Department of Medical Assistance Services (DMAS) is planning to amend the Virginia State Plan for Medical Assistance with the Centers for Medicare and Medicaid Services (CMS). Specifically, DMAS is providing you notice about a State Plan Amendment (SPA) that the Agency will file with CMS in order to include reimbursement for coverage for routine patient costs furnished in connection with a member's participation in a qualifying clinical trial. In accordance with Section 210 of the Consolidated Appropriations Act of 2021, and the CMS State Medicaid Director (SMD) letter #21-005, DMAS will cover any item or service provided to the individual under the qualifying clinical trial, including any item or service provided to prevent, diagnose, monitor, or treat complications resulting from participation in the qualifying clinical trial, to the extent that the provision of such items or services to the beneficiary would otherwise be covered outside the course of participation in the qualifying clinical trial under the state plan or waiver, including a demonstration project under section 1115 of the Social Security Act. Such routine services and costs also include any item or service required to administer the investigational item or service.

The tribal comment period for this SPA is open through March 26, 2022. You may submityour comments directly to Meredith Lee, DMAS Policy, Regulation, and Member Engagement Division, by phone (804) 371-0552, or via email:

<u>Meredith.Lee@dmas.virginia.gov</u>. Finally, if you prefer regular mail you may send your comments or questions to:

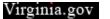
Virginia Department of Medical Assistance Services Attn: Meredith Lee 600 East Broad Street Richmond, VA 23219

Please forward this information to any interested party.

Sincerely,

Karen Kimsey

#### Attachment B-1



Agencies | Governor



Agency

**Department of Medical Assistance Services** 

Board

**Board of Medical Assistance Services** 

Edit Notice

### **General Notice**

#### **Public Notice - Intent to Amend State Plan - Clinical Trials**

Date Posted: 12/9/2021

Expiration Date: 4/30/2022

Submitted to Registrar for publication: YES

No comment forum defined for this notice.

#### LEGAL NOTICE

#### **COMMONWEALTH OF VIRGINIA**

#### DEPARTMENT OF MEDICAL ASSISTANCE SERVICES

#### NOTICE OF INTENT TO AMEND

(Pursuant to  $\S1902(a)(13)$  of the *Act* (*U.S.C.* 1396a(a)(13))

THE VIRGINIA STATE PLAN FOR MEDICAL ASSISTANCE

#### This Notice was posted on December 9, 2021

The Virginia Department of Medical Assistance Services (DMAS) hereby affords the public notice of its intention to amend the Virginia State Plan for Medical Assistance to provide for changes to the *Methods and Standards for Establishing Payment Rates*— Other Types of Care (12 VAC 30-80).

This notice is intended to satisfy the requirements of 42 C.F.R. § 447.205 and of § 1902(a)(13) of the *Social Security Act*, 42 U.S.C. § 1396a(a)(13). A copy of this notice is available for public review from Emily McClellan, DMAS, 600 Broad Street, Suite 1300, Richmond, VA 23219, or via e-mail at: Emily.McClellan@dmas.virginia.gov

This notice is available for public review on the Regulatory Town Hall on the General Notices page, found at: <a href="https://townhall.virginia.gov/L/generalnotice.cfm">https://townhall.virginia.gov/L/generalnotice.cfm</a>

#### Methods & Standards for Establishing Payment Rates-Other Types of Care (12 VAC 30-80)

The state plan is being revised to include reimbursement for coverage for routine patient costs furnished in connection with a member's participation in a qualifying clinical trial in accordance with the Centers for Medicare and Medicaid Services (CMS) State Medicaid Director (SMD) letter #21-005. Per the SMD letter, DMAS will cover any item or service provided to the individual under the qualifying clinical trial, including any item or service provided to prevent, diagnose, monitor, or treat complications resulting from participation in the qualifying clinical trial, to the extent that the provision of such items or services to the beneficiary would otherwise be covered outside the course of participation in the qualifying clinical trial under the state plan or waiver, including a demonstration project under section 1115 of the Social Security Act. Such routine services and costs also include any item or service required to administer the investigational item or service.

Costs for these changes are indeterminate at this time. However, DMAS does not anticipate a change in total annual expenditures.

## **Contact Information**

Name / Title:	Emily McClellan / Regulatory Manager
Address:	Division of Policy and Research 600 E. Broad St., Suite 1300 Richmond, 23219
Email Address:	Emily.McClellan@dmas.virginia.gov
Telephone:	(804)371-4300 FAX: (804)786-1680 TDD: (800)343-0634

This general notice was created by Emily McClellan on 12/09/2021 at 3:26pm

Approval Date: \_\_\_\_\_

Effective Date 1/1/2022

State/Territory: <u>Virginia</u>
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)
$\underline{X}$ 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)
$\underline{X}$ A qualified clinical trial is a clinical trial that meets the definition at section 1905(gg)(2).
Coverage Determination – Section 1905(gg)(3)
$\underline{X}$ 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.

TN: <u>22-000</u>9

Supersedes TN: New Page

Approval Date: \_\_\_\_\_

Effective Date 1/1/2022

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MEDICALLY NEEDY GROUP(S)

Virginia

State/Territory:

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TN:\_22-0009

Supersedes TN: New Page

	1. TRANSMITTAL NUMBER	2. STATE		
TRANSMITTAL AND NOTICE OF APPROVAL OF				
STATE PLAN MATERIAL				
FOR: CENTERS FOR MEDICARE & MEDICAID SERVICES	3. PROGRAM IDENTIFICATION: TITLE OF SECURITY ACT	· THE SOCIAL		
	XIX	XXI		
TO: CENTER DIRECTOR	4. PROPOSED EFFECTIVE DATE			
CENTERS FOR MEDICAID & CHIP SERVICES				
DEPARTMENT OF HEALTH AND HUMAN SERVICES				
5. FEDERAL STATUTE/REGULATION CITATION	6. FEDERAL BUDGET IMPACT (Amour a. FFY \$	nts in WHOLE dollars)		
	b. FFY \$			
7. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT	8. PAGE NUMBER OF THE SUPERSED	DED PLAN SECTION		
	OR ATTACHMENT (If Applicable)			
9. SUBJECT OF AMENDMENT				
10. GOVERNOR'S REVIEW (Check One)				
GOVERNOR'S OFFICE REPORTED NO COMMENT	OTHER, AS SPECIFIED:			
COMMENTS OF GOVERNOR'S OFFICE ENCLOSED		Secretary of Health and Human Resources		
NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL				
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22. REMARKS				

State/Territory: <u>Virginia</u>
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TN: 22-0009 Approval Date: Supersedes TN: New Page Effective Date 1/1/2022

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# AMOUNT, DURATION AND SCOPE OF SERVICES PROVIDED MEDICALLY NEEDY CROUP(S)

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