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State/Territory Name: The United States Virgin Islands

State Plan Amendment (SPA) #: 23-0002

This file contains the following documents in the order listed:

- 1) Approval Letter
- 2) 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

June 15, 2023

Gary Smith, Medicaid Director
Department of Human Services
Medical Assistance Program
1303 Hospital Ground
Knur Hansen Complex, Bldg. A
St. Thomas, Virgin Islands 00802

Re: U.S. Virgin Islands State Plan Amendment (SPA) 23-0002

Dear Medicaid Director Smith:

The Centers for Medicare & Medicaid Services (CMS) reviewed your Medicaid State Plan Amendment (SPA) submitted under transmittal number (TN) 23-0002. This amendment establishes compliance with the mandatory coverage and reimbursement of routine patient costs furnished concerning participation in qualifying clinical trials under Section 1905(gg) of the Social Security Act.

We reviewed your submittal according to statutory requirements in Title XIX of the Social Security Act and implementing regulations section 1905(a)(30) and 1905(gg) of the Act. This letter informs you that the U.S. Virgin Islands' SPA 23-0002 was approved on June 13, 2023, with an effective date of May 10, 2023.

If you have any questions, please contact Ivelisse Salce at 212-616-2411 or via email at Ivelisse.Salce@cms.hhs.gov.

Sincerely,

A large black rectangular redaction box covers the signature of James G. Scott.

James G. Scott, Director
Division of Program Operations

Enclosures
cc: Gary Smith

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

1. TRANSMITTAL NUMBER <u>2 3 — 0 0 0 2</u>	2. STATE <u>VI</u>
3. PROGRAM IDENTIFICATION TITLE OF THE SOCIAL SECURITY ACT <input checked="" type="radio"/> XIX <input type="radio"/> XXI	

TO: CENTER DIRECTOR CENTERS FOR MEDICAID & CHIP SERVICES DEPARTMENT OF HEALTH AND HUMAN SERVICES	4. PROPOSED EFFECTIVE DATE <p style="text-align: center;">May 10, 2023</p>
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5. FEDERAL STATUTE/REGULATION CITATION Section 1905(a)(30) of the Act	6. FEDERAL BUDGET IMPACT (Amounts in WHOLE dollars) a. FFY <u>2023</u> \$ <u>0</u> b. FFY <u>2024</u> \$ <u>0</u>
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7. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT Attachment 3.1.A Page, 1 Attachment 3.1.B Page, 1 Attachment 4.19B Page, 1	8. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (If Applicable) All New
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9. SUBJECT OF AMENDMENT
Coverage of routine patient costs in qualifying clinical trials.

10. GOVERNOR'S REVIEW (Check One)

GOVERNOR'S OFFICE REPORTED NO COMMENT OTHER, AS SPECIFIED:

COMMENTS TO GOVERNOR'S OFFICE ENCLOSED


NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL

11. SIGNATURE OF STATE AGENCY OFFICIAL 	15. RETURN TO Gary A. Smith Medicaid Director VI Department of Human Services 1303 Hospital Ground Knud Hansen Complex, Building A St. Thomas, USVI 00802
12. TYPED NAME Gary A. Smith	
13. TITLE Medicaid Director	
14. DATE SUBMITTED 04/11/2023	

FOR CMS USE ONLY

16. DATE RECEIVED 04/11/2023	17. DATE APPROVED 06/13/2023
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PLAN APPROVED - ONE COPY ATTACHED

18. EFFECTIVE DATE OF APPROVED MATERIAL 05/10/2023	19. SIGNATURE OF APPROVING OFFICIAL 
20. TYPED NAME OF APPROVING OFFICIAL James G. Scott	21. TITLE OF APPROVING OFFICIAL Director, Division of Program Operations

22. REMARKS

State/Territory the U.S. Virgin Islands

**AMOUNT, DURATION, AND SCOPE OF SERVICES PROVIDED
CATEGORICALLY NEEDY GROUP(S)**

30. Coverage of Routine Patient Cost in Qualifying Clinical Trials

Provided: X

I. General Assurances:

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

 X Coverage of routine patient costs 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 concerning coverage for an individual participating in a qualified clinical trial will be made per 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 the 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 only required to respond to, a collection of information if 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). The public burden for collecting 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.

State/Territory The U.S. Virgin Islands

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State/Territory USVI**4.19B Payment for Services****30. OTHER TYPES OF CARE**

Coverage of Routine Patient Costs Associated with Participation in Qualifying Clinical Trials Pursuant to Section 1905(a)(30) of the Social Security Act, Medicaid reimburses routine patient costs for items and services furnished in connection with participation in a qualifying clinical trial (pursuant to section 1905(a)(30) of the Social Security Act), according to the state plan reimbursement methodology for the item or service provided.

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 the 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 only required to respond to, a collection of information if 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). The public burden for collecting 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: VI-23-0002
Supersedes TN: New

Approval Date: 06/13/2023
Effective Date 05/10/2023