

March 14, 2022

Brian Zolynas  
Division of Medicaid and Children's Health Operations  
U.S. Department of Health & Human Services  
Centers for Medicare & Medicaid Services  
90 Seventh Street, Suite 5-300 (5W)  
San Francisco, CA 94103-6707

**RE: Arizona SPA #22-0002 Qualified Clinical Trials**

Dear Mr. Zolynas:

Enclosed is State Plan Amendment (SPA) #22-0002, Clinical Trial Routine Patient Costs. This SPA updates the State Plan to attest to the state's compliance with Division CC, Title II, Section 210 of the Consolidated Appropriations Act (2020), which requires mandatory Medicaid coverage of routine patient costs furnished in connection with participation in qualifying clinical trials.

Tribal Consultation on this SPA occurred on February 10, 2022. The presentation materials are posted on the following webpage:

[https://www.azahcccs.gov/AmericanIndians/Downloads/Consultations/Meetings/2022/02102022\\_QuarterlyTC.pdf](https://www.azahcccs.gov/AmericanIndians/Downloads/Consultations/Meetings/2022/02102022_QuarterlyTC.pdf)

Public Notice for this SPA was posted on the following webpage:

<https://www.azahcccs.gov/AHCCCS/PublicNotices/ClinicalTrialRoutinePatientCosts.html>

If there are any questions about the enclosed SPA, please contact Ruben Soliz at [ruben.soliz@azahcccs.gov](mailto:ruben.soliz@azahcccs.gov) or 602-417-4355.

Sincerely,



Dana Flannery  
Assistant Director  
Arizona Health Care Cost Containment System (AHCCCS)

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

1. TRANSMITTAL NUMBER <u>22 - 0 0 0 2</u>	2. STATE <u>AZ</u>
3. PROGRAM IDENTIFICATION: TITLE <u>19</u> OF THE SOCIAL SECURITY ACT	

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

4. PROPOSED EFFECTIVE DATE  
**January 1, 2022**

5. FEDERAL STATUTE/REGULATION CITATION  
Division CC, Title II, Section 210 of the Consolidated Appropriations Act (2020)

6. FEDERAL BUDGET IMPACT (Amounts in WHOLE dollars)  
a. FFY 22 \$0  
b. FFY: 23 \$0

7. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT  
  
ATTACHMENT 3.1-A  
Page 14  
  
ATTACHMENT 3.1-B  
Page 10

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 PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (If Applicable)  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

9. SUBJECT OF AMENDMENT  
Attests to the state's compliance with Division CC, Title II, Section 210 of the Consolidated Appropriations Act (2020), which requires mandatory Medicaid coverage of routine patient costs furnished in connection with participation in qualifying clinical trials.

10. GOVERNOR'S REVIEW (Check One)

GOVERNOR'S OFFICE REPORTED NO COMMENT       OTHER, AS SPECIFIED:  
 COMMENTS OF GOVERNOR'S OFFICE ENCLOSED  
 NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL

11. SIGNATURE OF STATE AGENCY OFFICIAL  
  


15. RETURN TO  
  
Dana Flannery  
801 E. Jefferson, MD#4200  
Phoenix, AZ 85034

12. TYPED NAME  
Dana Flannery

13. TITLE  
Assistant Directory

14. DATE SUBMITTED: 3/14/2022

**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/Territory:

ARIZONA**AMOUNT, DURATION AND SCOPE OF SERVICES PROVIDED****CATEGORICALLY NEEDY GROUP(S)****Coverage of Routine Patient Cost in Qualifying Clinical Trials**

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: 22-0002  
Supersedes: NEW

Approval Date: \_\_\_\_\_  
Effective Date: January 1, 2022

**State/Territory:**  
**Arizona**

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

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