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State/Territory Name: Alabama

State Plan Amendment (SPA) #: 22-0001

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

April 13, 2022

Ms. Stephanie McGee Azar, Commissioner
Alabama Medicaid Agency
501 Dexter Avenue
Post Office Box 5624
Montgomery, AL 36103-5624

Re: Alabama State Plan Amendment (SPA) 22-0001 - Correction

Dear Commissioner Azar:

The Centers for Medicare & Medicaid Services (CMS) reviewed your Medicaid State Plan Amendment (SPA) submitted under transmittal number (TN) 22-0001. This amendment is regarding clinical trials and is in compliance with SMD #21-005, as it relates to the Consolidated Appropriations Act, 2021 (Public Law 116-260).

During a quality review being conducted by CMS, it was discovered that the original approval package sent to Alabama had an incorrect page number on an approved SPA page. The only update made to the approval package was to add the correct page number, Page 16. AL 22-0001 was approved on April 7, 2022. The enclosed corrected package contains the original signed letter, CMS-179, and SPA page.

If you have any questions, please contact Rita Nimmons at (404) 562-7415 or via email at Rita.Nimmons@cms.hhs.gov.

Sincerely,

A solid black rectangular box redacting the signature of Ruth A. Hughes.

Ruth A. Hughes, Acting Director,
Division of Program Operations

Enclosures

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

April 11, 2022

Ms. Stephanie McGee Azar, Commissioner
Alabama Medicaid Agency
501 Dexter Avenue
Post Office Box 5624
Montgomery, AL 36103-5624

Re: Alabama State Plan Amendment (SPA) 22-0001

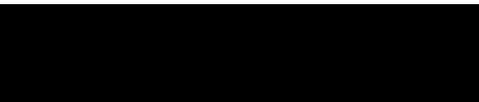
Dear Commissioner Azar:

The Centers for Medicare & Medicaid Services (CMS) reviewed your Medicaid State Plan Amendment (SPA) submitted under transmittal number (TN) AL 22-0001. This amendment is regarding clinical trials and is in compliance with SMD # 21-005, as it relates to the Consolidated Appropriations Act, 2021 (Public Law 116-260).

We conducted our review of your submittal according to statutory requirements in Title XIX of the Social Security Act and implementing regulations. This letter is to inform you that AL 22-0001 was approved on April 7, 2022, with an effective date of January 1, 2022.

If you have any questions, please contact Rita Nimmons at 404-562-7415 or via email at Rita.Nimmons@cms.hhs.gov.

Sincerely,



Ruth A. Hughes, Acting Director
Division of Program Operations

cc: Stephanie Lindsay

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

1. TRANSMITTAL NUMBER <u>2 2 0 0 0 1</u>	2. STATE <u>AL</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
January 1, 2022

5. FEDERAL STATUTE/REGULATION CITATION
Consolidated Appropriations Act, 2021 (Public Law 116-260)

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
State Plan 3.1-A page ~~5.2a~~ 16

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

9. SUBJECT OF AMENDMENT
This amendment is regarding clinical trials and is in compliance with SMD # 21-005, as it relates to the Consolidated Appropriations Act, 2021 (Public Law 116-260).

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: Governor's designee on file via letter with CMS

11. SIGNATURE OF STATE AGENCY OFFICIAL

12. TYPED NAME
Stephanie McGee Azar

13. TITLE
Commissioner

14. DATE SUBMITTED
March 3, 2022

15. RETURN TO
Stephanie McGee Azar
Commissioner
Alabama Medicaid Agency
501 Dexter Avenue
Post Office Box 5624
Montgomery, Alabama 36103-5624

FOR CMS USE ONLY

16. DATE RECEIVED <u>March 3, 2022</u>	17. DATE APPROVED <u>April 7, 2022</u>
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PLAN APPROVED - ONE COPY ATTACHED

18. EFFECTIVE DATE OF APPROVED MATERIAL
January 1, 2022



20. TYPED NAME OF APPROVING OFFICIAL
Ruth A. Hughes

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

22. REMARKS
Pen and ink change made to Box 7 with approval of the state on April 12, 2022.

State/Territory: Alabama
AMOUNT, DURATION AND SCOPE OF SERVICES PROVIDED
CATEGORICALLY NEEDY GROUP(S)

29. 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. AL-22-0001

Supersedes

TN No. NEW

Approval Date: 04/07/2022

Effective Date: 01/01/2022