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

May 9, 2022

Ms. Stephanie Stephens State Medicaid Director Texas Health and Human Services Commission Mail Code: H100 Post Office Box 13247 Austin, Texas 78711

Re: Texas State Plan Amendment (SPA) 22-0006

Dear Ms. Stephens:

The Centers for Medicare & Medicaid Services (CMS) reviewed your Medicaid State Plan Amendment (SPA) submitted under transmittal number (TN) TX SPA 22-0006. This amendment proposes to conform the state plan to Section 210 of the Consolidated Appropriations Act, 2021 (Public Law 116-260) related to mandatory Medicaid coverage of routine patients costs furnished in connection with participation in qualifying clinical trials.

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 TX Medicaid SPA 22-0006 was approved on May 9, 2022, with an effective date of January 1, 2022."

If you have any questions, please contact Ford Blunt at 214-767-6381 or via email at Ford.Blunt@cms.hhs.gov.

Sincerely,

James G. Scott, Director Division of Program Operations

	1. TRANSMITTAL NUMBER 2. STATE
TRANSMITTAL AND NOTICE OF APPROVAL OF	F 2 2 0 0 0 6 T X
STATE PLAN MATERIAL	
FOR: CENTERS FOR MEDICARE & MEDICAID SERVICES	3. PROGRAM IDENTIFICATION: TITLE XIX OF THE SOCIAL SECURITY ACT
TO: CENTER DIRECTOR	4. PROPOSED EFFECTIVE DATE
CENTERS FOR MEDICAID & CHIP SERVICES DEPARTMENT OF HEALTH AND HUMAN SERVICES	01/01/2022
5. FEDERAL STATUTE/REGULATION CITATION	6. FEDERAL BUDGET IMPACT (Amounts in WHOLE dollars)
Section 210 amended section 1905(a) of the Social Security Act (the Act) adding to 1905(a)(30) and adding a new section 1905(gg). Also amends sections 1902(a)(10)(A) and 1937(b)(5) of the Act	a. FFY <u>2022</u> \$ <u>0</u> b. FFY <u>2023</u> \$ <u>0</u>
7. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT	8. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (If Applicable)
Attachment 3.1-A Page 12	(PP - 11 - 3)
Attachment 3.1-B Page 11	N/A
9. SUBJECT OF AMENDMENT The purpose of the amendment is to conform the state plan to See	tion 240 of the Concelidated Appropriations Act 2024 (Bublic Low
The purpose of the amendment is to conform the state plan to Sec 116-260) related to mandatory Medicaid coverage of routine patien clinical trials.	
10. GOVERNOR'S REVIEW (Check One)	
GOVERNOR'S OFFICE REPORTED NO COMMENT	OTHER, AS SPECIFIED: Sent to Governor's Officethis
COMMENTS OF GOVERNOR'S OFFICE ENCLOSED	date. Comments, if any, will be forwarded upon receipt.
NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL	
11. SIGNATURE OF STATE AGENCY OFFICIAL	15. RETURN TO
Stephanie Digitally signed by Stephanie Stephens	
Stephens Date: 2022.03.30 11:13:44 - 05:00	Stephanie Stephens
12. TYPED NAME	State Medicaid Director
Stephanie Stephens	Post Office Box 13247, MC: H-100 Austin, Texas 78711
13. TITLE State Medicaid Director	
14. DATE SUBMITTED	
March 30, 2022 FOR CMS U	ISE ONLY
16 DATE DECEMED	17. DATE APPROVED
March 30, 2022	May 9, 2022
PLAN APPROVED - O	·
18. EFFECTIVE DATE OF APPROVED MATERIAL January 1, 2022	19. SIGNATURE OF APPROVING OFFICIAL
20. TYPED NAME OF APPROVING OFFICIAL	21. TITLE OF APPROVING OFFICIAL
James G. Scott	Director, Division of Program Operations
22. REMARKS	
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AMOUNT, DURATION AND SCOPE OF MEDICAL AND REMEI	DIAL
CARE AND SERVICES PROVIDED TO THE CATEGORICALLY	NEEDY

State/Territory: ___TX

30. Coverage of Routine Patient Cost in Qualifying Clinical Trials
Provided:
I. General Assurances:
Routine Patient Cost – Section 1905(gg)(1)
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)
✓ A qualified clinical trial is a clinical trial that meets the definition at section 1905(gg)(2).
Coverage Determination – Section 1905(gg)(3)
✓ 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>22-0006</u> Approval Date: <u>05-09-2022</u> Supersedes TN: <u>New Page</u> Effective Date: <u>01-01-2022</u>

AMOUNT, DURATION AND SCOPE OF SERVICES PRO	VIDED
MEDICALLY NEEDY GROUP(S)	

TX

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