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State/Territory Name: Texas

State Plan Amendment (SPA) #: 22-0006

This file contains the following documents in the order listed:

- 1) Approval Letter
- 2) CMS 179 Form/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

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,

Digitally signed by James G. Scott -S Date: 2022.05.09 15:39:51 -05'00'

James G. Scott, Director Division of Program Operations

DEPARTMENT OF HEALTH ANDHUMAN SERVICES CENTERS FOR MEDICARE & MEDICAID SERVICES	FORM APPROVED OMB No.0938-0193
TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL FOR: CENTERS FOR MEDICARE & MEDICAID SERVICES TO: CENTER DIRECTOR	1. TRANSMITTAL NUMBER 2. STATE 2 2 0 0 6 T X 3. PROGRAM IDENTIFICATION: TITLE XIX OF THE SOCIAL SECURITY ACT 4. PROPOSED EFFECTIVE DATE 2. STATE
CENTERS FOR MEDICAID & CHIP SERVICES DEPARTMENT OF HEALTH AND HUMAN SERVICES	01/01/2022
5. FEDERAL STATUTE/REGULATION CITATION 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	6. FEDERAL BUDGET IMPACT (Amounts in WHOLE dollars) 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 Attachment 3.1-B Page 11	N/A
The purpose of the amendment is 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 patient costs furnished in connection with participation in qualifying clinical trials. 10. GOVERNOR'S REVIEW (Check One) Image: GOVERNOR'S OFFICE REPORTED NO COMMENT Image: GOVERNOR'S OFFICE REPORTED NO COMMENT Image: GOVERNOR'S OFFICE REPORTED NO COMMENT Image: GOVERNOR'S OFFICE ENCLOSED Image: NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL	
Digitally signed by Stephanie Stephens Date: 2022.03.30 11:13:44 - 05'00' 12. TY PED NAME Stephanie Stephens 13. TITLE State Medicaid Director	S. RETURN TO Stephanie Stephens State Medicaid Director Post Office Box 13247, MC: H-100 Austin, Texas 78711
14. DATE SUBMITTED March 30, 2022	
FOR CM S USE ONLY 16. DATE RECEIVED Marsh 20, 2022 17. DATE APPROVED	
March 30, 2022 May 9, 2022	
18. EFFECTIVE DATE OF APPROVED MATERIAL 19 January 1, 2022 19	NSIGNA Digitally signed by James G. Scott -S Date: 2022.05.09 15:40:20 -05'00'
20. TY PED NAME OF APPROVING OFFICIAL 21 James G. Scott	. TITLE OF APPROVING OFFICIAL Director, Division of Program Operations
22. REMARKS	

State/Territory: <u>TX</u>

AMOUNT, DURATION AND SCOPE OF MEDICAL AND REMEDIAL CARE AND SERVICES PROVIDED TO THE CATEGORICALLY NEEDY

30. Coverage of Routine Patient Cost in Qualifying Clinical Trials

Provided: \checkmark

I. General Assurances:

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

 $\underline{\checkmark}$ 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)

 \checkmark A qualified clinical trial is a clinical trial that meets the definition at section 1905(gg)(2).

Coverage Determination – Section 1905(gg)(3)

 \checkmark 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> Supersedes TN: <u>New Page</u> Approval Date: 05-09-2022 Effective Date: 01-01-2022

State of Texas Attachment 3.1-B Page 11

State/Territory: <u>TX</u>

AMOUNT, DURATION AND SCOPE OF SERVICES PROVIDED

MEDICALLY NEEDY GROUP(S)

30. Coverage of Routine Patient Cost in Qualifying Clinical Trials

Provided: \checkmark

I. General Assurances:

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

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Qualifying Clinical Trial – Section 1905(gg)(2)

 \checkmark A qualified clinical trial is a clinical trial that meets the definition at section 1905(gg)(2).

Coverage Determination – Section 1905(gg)(3)

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