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State/Territory Name: Hawaii

State Plan Amendment (SPA) #: 22-0004

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 6, 2022

Judy Mohr Peterson, PhD Med-QUEST Division Administrator Office of the Director Department of Human Services PO Box 339 Honolulu, HI 96809-0339

Re: Hawaii State Plan Amendment (SPA) 22-0004

Dear Dr. Mohr Peterson:

The Centers for Medicare & Medicaid Services (CMS) reviewed your Medicaid State Plan Amendment (SPA) submitted under transmittal number (TN) 22-0004. This amendment adds an assurance of coverage of routine patient services and costs associated with participation in qualifying clinical trials, as required by section 210 of the Consolidated Appropriations Act.

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 Hawaii Medicaid SPA 22-0004 was approved on May 6, 2022, with an effective date of January 1, 2022.

If you have any questions, please contact Brian Zolynas at 415-744-3601 or via email at Brian.Zolynas@cms.hhs.gov

Sincerely,

Digitally signed by James G. Scott -S Date: 2022.05.06 13:00:31 -05'00'

James G. Scott, Director Division of Program Operations

cc: Jodeen Enesa, Med-QUEST Cori Kekina, Med-QUEST Edie Mayeshiro, Med-QUEST

	1. TRANSMITTAL NUMBER 2. STATE			
TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL	$\underline{22} - \underline{0} 0 0 4 \underline{HI}$			
FOR: CENTERS FOR MEDICARE & MEDICAID SERVICES	3. PROGRAM IDENTIFICATION: TITLE OF THE SOCIAL SECURITY ACT O XIX O XXI			
TO: CENTER DIRECTOR CENTERS FOR MEDICAID & CHIP SERVICES DEPARTMENT OF HEALTH AND HUMAN SERVICES	4. PROPOSED EFFECTIVE DATE 01/01/2022			
5. FEDERAL STATUTE/REGULATION CITATION Section 210 of the Consolidated Appropriations Act (CAA)	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 Attachment 3.1-A pg. 13 Attachment 3.1-B pg. 12 Attachment 4.19-B pg. 1.2	8. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (<i>If Applicable</i>)			
9. SUBJECT OF AMENDMENT Consolidated Appropriations Act (CAA) adds a new mandatory ben participation in qualifying clinical trials. Routine Costs for Clinical Tria				
10. GOVERNOR'S REVIEW (Check One) O GOVERNOR'S OFFICE REPORTED NO COMMENT COMMENTS OF GOVERNOR'S OFFICE ENCLOSED NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL	OTHER, AS SPECIFIED:			
S	5. RETURN TO tate of Hawaii			
12. TYPED NAME O Judy Mohr Peterson, PhD P 13. TITLE H	partment of Human Services ïce of Director D Box 339 nolulu ,HI 96809-0339			
Med-QUEST Division Administrator 14. DATE SUBMITTED 03/30/2022				
FOR CMS US				
March 30, 2022	DATE APPROVED May 6, 2022			
PLAN APPROVED - ONE				
January 1, 2022	D. SIGNATURE OF ARROVING OFFICIAL Digitally signed by James G. Scott -S Date: 2022.05.06 13:01:06 -05'00'			
20. TYPED NAME OF APPROVING OFFICIAL 2" James G. Scott 2"	1. TITLE OF APPROVING OFFICIAL Director, Division of Program Operations			
22. REMARKS Box 9: State authorized pen and ink change on 05/04/2022.				

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State: Hawaii

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

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.

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State: Hawaii

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

29. Coverage of Routine Patient Cost in Qualifying Clinical Trials

*The state needs to check each assurance below.

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General Assurances:

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(j) Routine Patient Cost for Items and Services in connection with participation by Medicaid Beneficiaries in qualifying clinical trials under 1905(a)(30).

Hawaii Medicaid Fee Schedule is based on a combination of sixty percent of the 2006 to current Medicare Fee Schedule as applicable. Services not covered by Medicare in 2006 are paid at sixty percent of the Medicare Fee Schedule on the first year in which the code/service is covered by Medicare, whichever is later. The Medicaid Fee Schedule is located at https://medquest.hawaii.gov

Reimbursement rates, except as specified below and other parts of this Attachment, for providers of medical care who are individual practitioners and other providing non-institutional items and services shall not exceed the maximum permitted under federal laws and regulations and shall be the lower of the Medicare Fee Schedule as described above.

TN No.	22-0004				
Supersedes		Approval Date:	05/06/2022	Effective Date:	01/01/2022
TN No.	NEW	_		-	