

**STATE OF HAWAII
DEPARTMENT OF HUMAN SERVICES
MED-QUEST DIVISION**

PUBLIC NOTICE

Pursuant to 42 C.F.R. §447.205, the Department of Human Services (DHS), Med-QUEST Division (MQD) hereby notifies the public that the MQD intends to submit a State Plan Amendment (SPA) to the Centers for Medicare and Medicaid Services (CMS).

On December 7, 2021, the Centers for Medicare and Medicaid Services (CMS) outlined new Medicaid State Plan requirements for assuring coverage of routine patient costs associated with participation in qualifying clinical trials. In the past, states have had the flexibility to limit or exclude coverage for routine costs associated with clinical trials but amendments to Section 210 of the Consolidated Appropriations Act (CAA) 2021 (Public Law 116-260) added a new benefit for routine patient costs for items and services furnished in connection with participation by Medicaid beneficiaries in qualifying clinical trials.

To assist states with this new requirement, CMS developed templates for the regular Medicaid State Plan that create a new section “Coverage of Routine Patient Cost in Qualifying Clinical Trials”. Hawaii has created new pages (Attachment 3.1-A pg. 13 and Attachment 3.1-B pg. 12) to Section 3 “Services General Provisions” of the Hawaii Medicaid State Plan to include CMS recommendations. In addition, states are required to describe the payment methodology that will be used to pay service providers. Hawaii has created a new page to Attachment 4.19-B (pg. 1.2). These new pages will be submitted to CMS under SPA 22-0004 “Consolidated Appropriations Act (CAA) in connection to Qualifying Clinical Trials”.

Hawaii will also need to submit an Alternative Benefit Plan (ABP) (SPA 22-0005) to ensure that the state is appropriately covering and paying for these services to the low income adult group or to adults who are covered via the Medicaid expansion with an ABP. ABP5 pg. 24 of 51 mirrors the new regular Hawaii Medicaid State Plan language on Attachment 3.1-A pg. 13 and Attachment 3.1-B pg. 12 mentioned above. Hawaii will also attach Attachment 4.19-B pg. 1.2 to ABP11 payment methodology template.

Under Provisions of federal law, the state is required to issue public notice of proposed changes in statewide methods and standards for setting Medicaid payment rates.

SPA 22-0005 is expected to have minimal effect on the annual aggregate expenditures. The proposed change will be submitted for review to the federal government as a Medicaid SPA.

SPA 22-0005 is in compliance with §440.345 related to full access to Early and Periodic Screening, Diagnosis and Treatment (EPSDT) services, and complies with the provisions of section 5006(e) of the American Recovery and Reinvestment Act of 2009 in which states must seek advice from designees of Indian health programs and urban Indian organizations.

A printed copy of the proposed changes and special accommodations (i.e., interpreter, large print or taped materials) can be arranged if requested by contacting the Policy and Program Development Office at (808) 692-8058 no later than seven (7) working days before the comment period ends.

Comments should be received **within 30 days** from the time this notice is posted. Individuals may submit written comments using the following methods:

By email: PPDO@dhs.hawaii.gov (Please identify in the subject line: State Plan Amendment 22-0005)

By mail:

Department of Human Services
Med-QUEST Division
Attention: Policy and Program Development Office
P.O Box 700190
Kapolei, Hawaii 96709

DEPARTMENT OF HUMAN SERVICES, MED-QUEST DIVISION
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MED-QUEST DIVISION ADMINISTRATOR