THE STATE of ALASKA
GOVERNOR MIKE DUNLEAVY

Department of Health and Social Services

OFFICE OF THE COMMISSIONER

Anchorage
3601 C Street, Suite 902
Anchorage, Alaska 99503-5923
Main: 907.269.7800
Fax: 907.269.0060

Juneau
350 Main Street, Suite 404
Juneau, Alaska 99801
Main: 907.465.3030
Fax: 907.465.3068

December 27, 2022

Dear Tribal Health Leaders,

On behalf of the Department of Health and Social Services (the department) and in keeping with the responsibility to conduct tribal consultation, I am writing to inform you of a proposed Medicaid state plan amendment (SPA) and a proposed revision to the Alternative Benefit Package (ABP), intended to comply with federal requirements as described below.

Purpose and content of the proposed amendment:

The department proposes to submit a Title XIX SPA and a corresponding ABP revision to comply with the Consolidated Appropriations Act, 2021, Division CC, Title II, Section 210 (Section 210).

Section 210 amended section 1905(a) of the Social Security Act (the Act), adding a new benefit at section 1905(a)(30) for routine patient costs for items and services furnished in connection with the participation by Medicaid beneficiaries in qualifying clinical trials. 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 the ABP concerning items and services furnished on or after January 1, 2022.

Under section 1905(a)(30) and 1905(gg)(1) of the Act, the routine patient costs that must be covered for a beneficiary participating in a qualifying clinical trial include any item or service provided to the individual under the qualifying clinical trial, including any item or service provided to prevent, diagnose, monitor, or treat complications resulting from participation in the qualifying clinical trial, to the extent that the provision of such items or services to the beneficiary would otherwise be covered outside the course of participation in the qualifying clinical trial under the state plan or waiver, including a demonstration project under section 1115 of the Act. Such routine services and costs also include any item or service required solely for the provision of the investigational item or service that is the subject of the qualifying clinical trial, including the administration of the investigational item or service.

As described under section 1905(gg) of the Act, routine patient costs within the meaning of section 1905(a)(30) of the Act do not include any investigational item or service that is the subject of the qualifying clinical trial and is not otherwise covered outside of the clinical trial under the state plan, waiver, or demonstration project.

Section 1905(gg)(2) of the Act defines the term “qualifying clinical trial,” for purposes of section 1905(a)(30) of the Act, as a clinical trial in any clinical phase of development conducted concerning the prevention, detection, or treatment of any serious or life-threatening disease or condition (described in any of clauses (i)-(iii) of section 1905(gg)(2)(A) of the Act).

Per section 1905(gg)(3) of the Act, a determination concerning coverage under section 1905(a)(30) of the Act for a beneficiary participating in a qualifying clinical trial must be expedited and completed within 72 hours. Additionally, the Medicaid agency or its designee must determine qualifying status without regard to the geographic location or network affiliation of the health care provider treating the beneficiary or the principal investigator of the qualifying

clinical trial.

Anticipated impact on Medicaid-eligible Alaska Native/American Indian beneficiaries:

The department anticipates that the proposed revisions will increase the viability of clinical trial participation for Medicaid-eligible tribal beneficiaries.

Anticipated impact on tribal health programs and the Indian Health Service:

The department anticipates that the proposed revisions will provide an avenue of reimbursement for the described routine costs when Medicaid-eligible tribal health beneficiaries participate in qualifying clinical trials.

Mechanism and timeline for comment:

Written comments or questions regarding the proposed amendment are due no later than January 26, 2022, by 5:00 PM. If seeking an in-person meeting to discuss the proposed changes, please provide a written request within 15-days of the date of this letter. Please direct all written correspondence to Courtney O'Byrne King, Alaska Department of Health and Social Services, 3601 C Street, Suite 902, Anchorage, AK 99503, or courtney.king@alaska.gov.

Sincerely,

/s/

Courtney O'Byrne King, MS
Medicaid State Plan Coordinator