



MICHELLE BAASS
DIRECTOR

State of California—Health and Human Services Agency
Department of Health Care Services



GAVIN NEWSOM
GOVERNOR

May 18, 2022

To: Tribal Chairpersons, Designees of Indian Health Programs,
and Urban Indian Organizations

Subject: Notice of Proposed Change to the Medi-Cal Program

The purpose of this letter is to provide information regarding a proposed change to the Department of Health Care Services' (DHCS) Medi-Cal Program that will be submitted to the Centers for Medicare and Medicaid Services (CMS). DHCS is forwarding this information for your review and comment.

DHCS is required to seek advice from designees of Indian Health Programs and Urban Indian Organizations on Medi-Cal matters having a direct effect on Indians, Indian Health Programs or Urban Indian Organizations per the American Recovery and Reinvestment Act of 2009 (ARRA). DHCS must solicit the advice of designees prior to submission to CMS of any State Plan Amendment (SPA), waiver requests or modifications, or proposals for demonstration projects in the Medi-Cal program.

Please see the enclosed summary for a detailed description of this DHCS proposal.

QUESTIONS AND COMMENTS

Indian Health Programs and Urban Indian Organizations may also submit written comments or questions concerning this proposal within 30 days from the receipt of notice. Comments may be sent by email to Angeli.Lee@dhcs.ca.gov or by mail to the address below:

Contact Information

Department of Health Care Services
Director's Office
ATTN: Angeli Lee
MS 0000
P.O. Box 997413
Sacramento, CA 95899-7413

Tribal Chairpersons, Designees of Indian Health Programs,
and Urban Indian Organizations

Page 2

May 18, 2022

In addition to this notice, DHCS plans to cover this SPA in the next quarterly Medi-Cal Indian Health webinar. Please note that Indian Health Programs and Urban Indian Organizations may request a consultation on this proposal at any time as needed.

Sincerely,

Original Signed by

Andrea Zubiate, Acting Chief
Office of Tribal Affairs
Department of Health Care Services

Enclosure



Department of Health Care Services Tribal and Designees of Indian Health Programs Notice

PURPOSE

To seek the necessary federal approvals to add routine patient costs associated with participation in qualifying clinical trials as a Medi-Cal benefit, effective July 1, 2022.

BACKGROUND

DHCS proposes to add as a benefit routine patient costs associated with participation in a qualifying clinical trial, which is required by federal law.¹ This would include any item or service provided under the State Plan or a waiver to prevent, diagnose, monitor, or treat complications resulting from participation in a qualifying clinical trial. Prior to adding this benefit, Medi-Cal only covered routine patient costs associated with being part of a clinical trial for cancer. Clinical trials covered under this new benefit are defined in federal law.²

DHCS proposes to provide reimbursement for routine patient costs associated with participation in qualifying clinical trials in accordance with the current methodologies described in State Plan Attachment 4.19-B for outpatient services and prescribed drugs, as applicable, including the methodologies for clinical laboratory services, radiology services, and durable medical equipment. Changes to the proposed reimbursement methodology may be required to meet federal requirements or to obtain federal approval.

SUMMARY OF PROPOSED CHANGES

DHCS is seeking to add routine patient costs associated with participation in a wider range of qualifying clinical trials than what is currently covered by Medi-Cal. Additional clinical trials would include an investigational drug exemption or an exemption for a biological product and a study or investigation that is approved, conducted, and supported by various organizations, as defined in federal law,² including the Centers for Disease Control and Prevention and the National Institutes of Health. These services would be available under both the fee-for-service (FFS) and managed care delivery systems.

The proposed effective date for SPA 22-0017 is July 1, 2022. SPA 22-0017 is subject to approval by CMS.

IMPACT TO TRIBAL HEALTH PROGRAMS

To the extent that Tribal Health Programs provide services for Medi-Cal beneficiaries who are participating in a clinical trial, those beneficiaries may access services more frequently.

IMPACT TO FEDERALLY QUALIFIED HEALTH CENTERS (FQHCs)

To the extent that FQHCs provide services for Medi-Cal beneficiaries who are participating in a clinical trial, those beneficiaries may access services more frequently.

IMPACT TO INDIAN MEDI-CAL BENEFICIARIES

Medi-Cal beneficiaries may have increased access to these benefits, which is expected to improve health outcomes.

¹ [Sections 1905\(a\)\(30\) and 1905\(gg\) of the Social Security Act.](#)

² [Section 1905\(gg\)\(2\) of the Social Security Act.](#)

RESPONSE DATE

Indian Health Programs and Urban Indian Organizations may submit written comments or questions concerning this proposal within 30 days from the receipt of notice.

Comments may be sent by email to Angeli.Lee@dhcs.ca.gov or by mail to the address below:

CONTACT INFORMATION

Department of Health Care Services

Director's Office

ATTN: Angeli Lee

MS 0000

P.O. Box 997413

Sacramento, CA 95899-7413