

**DEPARTMENT OF HEALTH CARE SERVICES**  
**NOTICE OF GENERAL PUBLIC INTEREST**  
**RELEASE DATE: 12/31/2021**

**PROPOSED STATE PLAN AMENDMENT TO ADD ROUTINE PATIENT COSTS  
ASSOCIATED WITH PARTICIPATION IN QUALIFYING CLINICAL TRIALS AS  
A MEDI-CAL BENEFIT**

This notice provides information of public interest about proposed State Plan Amendment (SPA) 22-0017 that the Department of Health Care Services (DHCS) plans to submit to the Centers for Medicare and Medicaid Services (CMS). SPA 22-0017 seeks to add routine patient costs associated with participation in qualifying clinical trials as a Medi-Cal benefit and seeks to clarify and make any necessary changes to the reimbursement methodology that will be used to pay for the new benefit, effective no sooner than January 1, 2022.

Division CC, Title II, Section 210 of the Consolidated Appropriations Act, 2021 (Public Law 116-260) (section 210) amended section 1905(a) of the Social Security Act (the Act), by adding to the definition of medical assistance a new benefit at section 1905(a)(30) for routine patient costs for items and services furnished in connection with participation by Medicaid beneficiaries in qualifying clinical trials, subject to further provisions in a new section 1905(gg). Section 210 also amends sections 1902(a)(10)(A) of the Act to make coverage of this new benefit mandatory under the state plan with respect to items and services furnished on or after January 1, 2022.

DHCS proposes to add as a benefit and reimburse routine patient costs, as required by section 1905(a)(30) and 1905(gg)(1) of the Act, that must be covered for a beneficiary participating in a 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 or the beneficiary would otherwise be covered outside the course of participation in the qualifying clinical trial under the State Plan or Waiver.

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 non-institutional services, 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.

DHCS estimates that these changes will result in an increase in annual aggregate expenditures by \$5,000,000 in total funds. To the extent that the expected changes are modified as a result of the SPA submission and resulting negotiations with CMS or additional guidance from CMS, DHCS will update the notice accordingly.

The effective date of the proposed SPA is January 1, 2022, or July 1, 2022, pending guidance and approval from CMS. All proposed SPAs are subject to approval by CMS.

## **PUBLIC REVIEW AND COMMENTS**

Upon submission to CMS, a copy of the proposed SPA #22-0017 will be published at the following internet address:

<https://www.dhcs.ca.gov/formsandpubs/laws/Pages/PendingStatePlanAmendments.aspx>.

If you would like to view the SPA in person once it becomes available, please visit your local county welfare department. You may also request a copy of proposed SPA #22-0017 using the mailing or email addresses listed below.

Written comments may be sent to the following address:

Department of Health Care Services  
Fee-For-Service Rate Development Division  
Attn: Provider Rates Section  
P.O. Box 997413, MS 4600  
Sacramento, California 95899-7417

Comments may also be emailed to [PublicInput@dhcs.ca.gov](mailto:PublicInput@dhcs.ca.gov). Please indicate SPA #22-0017 in the subject line or message.

A copy of submitted public comments to SPA #22-0017 may be requested in writing to the mailing or email addresses identified above.