

**Department of Health Care Services  
Proposed Trailer Bill Legislation**

**Conform Coverage of Clinical Trials in the Medi-Cal Program to Federal Law**

**FACT SHEET**

**Issue Title: Conform Coverage of Clinical Trials in the Medi-Cal Program to Federal Law.** The Department of Health Care Services (DHCS) proposes to conform the coverage and reimbursement of routine patient costs associated with participation in qualifying clinical trials in the Medi-Cal program with federal law, effective July 1, 2022.

**Background:** Pursuant to Welfare and Institutions Code Section 14132.98, Medi-Cal currently pays for all routine patient care costs related to clinical trials for a beneficiary diagnosed with cancer and accepted into a phase I-IV clinical trial for cancer when the patient's treating physician believes participation has meaningful potential to benefit the beneficiary.

**Justification for the Change:** Per recently enacted federal law, Medi-Cal is now required to reimburse costs associated with clinical trials for other conditions. Specifically, routine patient costs for items and services furnished in connection with participation by Medicaid beneficiaries in a "qualifying clinical trial" are a new mandatory benefit. A qualifying clinical trial is a clinical trial in any phase of development that is conducted in relation to the prevention, detection, or treatment of any serious or life-threatening disease or condition that has been approved, conducted, or supported by any of the organizations listed in federal law (Section 1905(gg)(2) of the Social Security Act). Therefore, federal law defines clinical trials more broadly than current state law defines them for Medi-Cal. DHCS must update state law to come into compliance with this new federal requirement. Routine patient costs do not include any item or service that is not otherwise covered outside of the clinical trial under the state plan, waiver, or demonstration project.

According to [State Medicaid Directors letter 21-005](#), dated December 7, 2021, the Centers for Medicare and Medicaid Services (CMS) requires states to cover routine patient costs as defined in federal law starting January 1, 2022 (Social Security Act Section 1905(gg)). However, CMS will consider an extension to the required start date "if the only reason the state cannot come into compliance by January 1, 2022 is due to lack of state legislation that is needed to meet the requirement." DHCS submitted a request for extension, based on the legislative calendar. CMS notified DHCS on March 7, 2022 that it granted DHCS' request, which requires DHCS to come into compliance with federal law by no later than January 1, 2023.

**Summary of Argument in Support:** This change is required by federal law. Additionally, Medi-Cal beneficiaries would be eligible to obtain coverage for routine costs associated with participation in qualifying clinical trials as a Medi-Cal benefit and would no longer be responsible for covering the patient routine costs, thus eliminating a potential barrier in access to care.

**Estimate # and Title: PC 281: Routine Costs for Clinical Trials**