

Key Findings:

Analysis of California Senate Bill 583 Clinical Trials

Summary to the 2019–2020 California State Legislature, April 21, 2019



AT A GLANCE

The version of California Senate Bill (SB) 583 analyzed by CHBRP would expand an existing benefit mandate to require coverage of health care services related to participation in clinical trials connected to any life-threatening disease.

1. CHBRP estimates that, in 2020, of the 23 million Californians enrolled in state-regulated health insurance, the 16.9 commercial and CalPERS enrollees will have insurance subject to SB 583.
2. **Benefit coverage.** 100% of enrollees have coverage for health care services related to clinical trial participation but 7% can access benefit coverage through self-referral. Postmandate, 100% could self-refer.
3. **Utilization.** 7,035 enrollees participate in clinical trials that bill the enrollee's plan or insurer. Postmandate, influenced by their ability to self-refer for benefit coverage, 7,372 would do so (a 5% increase).
4. **Expenditures.** SB 583 would increase net annual expenditures by \$8,298,000 (0.0052%).
5. **Long-term impacts.**
 - Over time, growing awareness of the mandate (and related federal mandates) may lead to greater use of benefit coverage (and so increased expenditures).
 - SB 583 would allow commercial and CalPERS enrollees to self-refer to access benefit coverage but would not do so for Medi-Cal beneficiaries enrolled in DMHC-regulated plans. Clinical trial participants are predominately white. By exempting coverage for the Medi-Cal population, which has a higher representation of blacks and Hispanics, SB 583 could worsen disparities by race/ethnicity.

BACKGROUND

SB 583 addresses health insurance benefit coverage related to an enrollee's participation in a clinical trial.

Clinical trials are a type of research study that recruits human volunteers to participate in an intervention to determine the overall safety of a particular treatment/drug and its effects on health outcomes. The objective of a clinical trial is to explore and investigate new manners and modes to prevent, detect, or treat an illness or disease. Common reasons for clinical trial participation include helping to advance science and the treatment of a disease/condition, obtaining better treatment, helping others with the same disease/condition, and receiving monetary compensation.

A number of barriers may prevent a person from participating in a clinical trial. The lack of health insurance that includes related benefit coverage (as a way to cover the costs of trial-related health care services) may be a barrier, as may be the lack of funds to cover nonmedical expenses (such as any needed travel, lodging, etc.). In addition to these potential participant financial barriers, a number of others exist. Limited investigational funding limits the total number of active clinical trials and each active trial's inclusion/exclusion criteria may make an interested person ineligible due to the presence of a complicating comorbidity, prior treatments that could confound results, or some other factor. Being unaware that a trial is occurring may also be a barrier, as may be the lack of a local trial site.

BILL SUMMARY

For commercial and CalPERS enrollees in plans and policies regulated by the California Department of Managed Health Care (DMHC) or the California Department of Insurance (CDI), SB 583 would address benefit coverage for health care services related to participation in a clinical trial. SB 583 would alter a current state-level benefit mandate.¹ The current mandate

¹ Refer to CHBRP's full report for full citations and references.

requires coverage of health care services related to participation in a cancer clinical trial. SB 583 would:

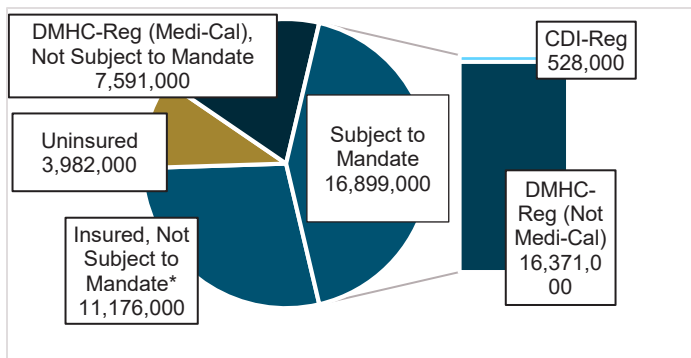
- Broaden the mandate to address participation in clinical trials related to any life-threatening diseases or conditions (not just cancer);
- Allow enrollee self-referral to access benefit coverage related to the clinical trial (referral by a provider would no longer be required); and

Additionally, SB 583 would expand the existing mandate’s requirement that in-network cost sharing to apply to noncancer trial related services.

SB 583 would exempt from compliance the health insurance of Medi-Cal beneficiaries enrolled in DMHC-regulated plans.

Figure A notes how many Californians have health insurance that would be subject to SB 583.

Figure A. Health Insurance in CA and SB 583



Source: California Health Benefits Review Program, 2019.
 Notes: *Medicare beneficiaries, enrollees in self-insured products, Medi-Cal beneficiaries in the fee-for-service program or in County Operated Health System managed care, etc.

POLICY CONTEXT

SB 583’s requirements regarding coverage of health care services related to clinical trial participation are very similar to current federal requirements that are generally applicable to the benefit coverage of enrollees in DMHC-regulated plans and CDI-regulated policies.

As per a Centers for Medicare and Medicaid Services (CMS) Clinical Trials Policy, both Medicaid (Medi-Cal in California) and Medicare cover health care services

related to participation in clinical trials. For nongrandfathered plans and policies, the Affordable Care Act (ACA) references this policy, making similar requirements applicable to almost all enrollees in plans and policies regulated by DMHC and CDI, though the ACA’s requirements indicate a more limited the scope of trials (only “life-threatening”) and require allowing self-referral to access benefit coverage. .

SB 583 would align with the ACA requirements and would additionally require, for participants in noncancer trials, coverage of out-of-network providers when a related service is not available in-network and require that all cost-sharing be at in-network rates.

IMPACTS

Benefit Coverage, Utilization, and Cost

SB 583 would require coverage for health care services related to an enrollee’s participation in a life-threatening disease clinical trial. Routine health care services may include administration of the drug or service under study, mid-trial monitoring tests, and follow-up care needed due to side effects.

Benefit Coverage

CHBRP estimates that 100% of commercial and CalPERS enrollees have coverage for health care services related to clinical trials, while 7% can access benefit coverage through self-referral based on medical literature. Postmandate, 100% of commercial and CalPERS enrollees could self-refer for benefit coverage.

Utilization

Not all participation in a clinical trial generates a charge for an enrollee’s health plan or policy. Approximately 41% of participants are in observational studies, which are unlikely to do so at all. Furthermore, it is not clear to what extent the administrators of clinical trials that could generate charges do so. Not generating such charges may indicate a lack of awareness of the existing benefit coverage mandates (some of which are relatively recent) or a desire to maintain control of data related to the study participants.

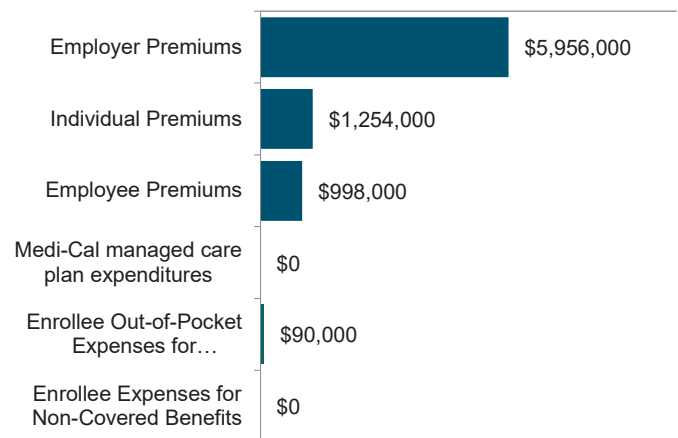
Currently, out of the 16.9 million commercial and CalPERS enrollees with coverage subject to SB 583, CHBRP estimates that 7,035 are enrolled in a clinical trial that is generating bills for the enrollee's plan or insurer. Postmandate, CHBRP estimates that the number of these enrollees participating in clinical trials would increase to 7,372, a 5% increase. This increase would be due to the new ability of enrollees to self-refer for related benefit coverage. CHBRP assumed a 5% increase due to the difficulty of exercising this option. For an enrollee to self-refer, the enrollee must first be aware of a relevant clinical trial, which itself is a barrier to entry. Then the enrollee must have, for submission to the plan or insurer, access to medical literature, which is often difficult, although not impossible, for the public at large to access. Access to the internet or to research institutions with library assistance can facilitate both of these. There is a supply-side limitation as well, in that there are a limited number of spaces open in actively recruiting clinical trials. Finally, the enrollee must meet the inclusion criteria to participate in the clinical trial.

CHBRP determined utilization of plan- or insurer-covered routine health care services used by enrollees who participate in clinical trials. An average of 0.713 inpatient days, 2.872 outpatient visits, 0.458 professional visits, and 1.731 professional procedures are used annually per enrollee, among enrollees who participate in clinical trials. CHBRP assumes these utilization rates per enrollee would not change postmandate, as the utilization of health care services is determined by the administration of the clinical trial. However, with more participants in clinical trials, the total number of routine health care services would increase.

Expenditures

SB 583 would increase total net annual expenditures by \$8,298,000 or 0.0052% for commercial and CalPERS enrollees in DMHC-regulated plans and CDI-regulated policies. This is due to an \$8,208,000 increase in total health insurance premiums paid by employers and enrollees for newly covered benefits, adjusted by a \$90,000 increase in enrollee expenses for covered and benefits. The additional costs for enrollee expenses are due to cost sharing for routine health care services used by enrollees who have newly gained access to benefit coverage through self-referral.

Figure B. Expenditure Impacts of SB 583



Source: California Health Benefits Review Program, 2019.

Medi-Cal

As the bill exempts the benefit coverage of Medi-Cal beneficiaries enrolled in DMHC-regulated plans, no impact is projected for Medi-Cal.

CalPERS

An increase in premiums of \$206,000 (0.007%) would be expected for CalPERS.

Number of Uninsured in California

No impact on the number of uninsured is projected.

Long-Term Impacts

The passage of SB 583 may increase the awareness of both the state mandate and the federal mandate for coverage of health care services related to clinical trial participation, which may, in the future, cause administrators of clinical trials to more frequently charge insurers for routine health care services. Therefore, while the number of overall enrollees who participate in clinical trials may remain the same, the number of clinical trials charging plans and insurers may increase by some unknown amount. An increase in such charges would be expected to cause a related increase in expenditures (premiums and enrollee expenses).

SB 583 would allow commercial and CalPERS enrollees to self-refer for access to benefit coverage related to clinical trials but would not do so for Medi-Cal beneficiaries enrolled in DMHC-regulated plans. Participation in clinical trials is predominantly comprised of whites, whereas other racial/ethnic groups such as blacks and Hispanics are underrepresented. Due to the Medi-Cal population distribution having a higher representation of blacks and Hispanics, it is possible that over time, SB 583

could lead to a worsening in disparities of participation in clinical trials by race/ethnicity.

Essential Health Benefits and the Affordable Care Act

As SB 583 would not require new benefit coverage, it would not exceed essential health benefits (EHBs).