

California Health Benefits Review Program

Analysis of California Senate Bill 583 Clinical Trials

A Report to the 2019–2020 California State Legislature

April 21, 2019



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:

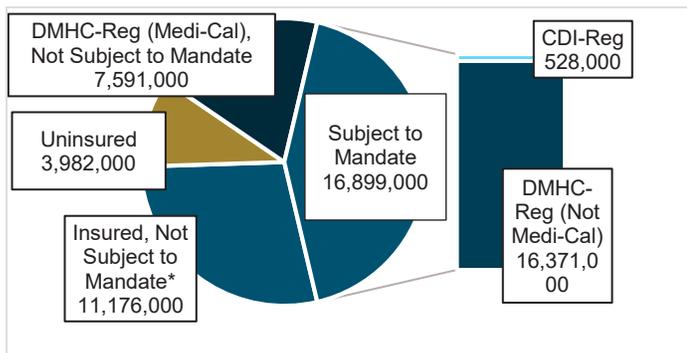
- Broaden the mandate to address participation in clinical trials related to any life-threatening diseases or conditions (not just cancer);
- Allow enrollee self-referral to access benefit coverage related to the clinical trial (referral by a provider would no longer be required); and

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.

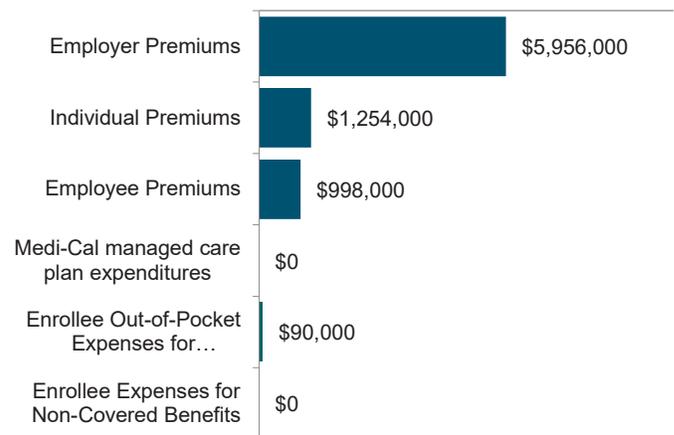
Currently, out of the 16.9 million commercial and CalPERS enrollees with coverage subject to SB 583, CHBRP estimates that 7,035 are enrolled in a clinical trial that is generating bills for the enrollee's plan or insurer. Postmandate, CHBRP estimates that the number of these enrollees participating in 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).

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California Health Benefits Review Program
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REVISION HISTORY

Date	Description of Revisions
May 15, 2019	This revised report makes clear that the current California mandate that SB 583 would alter – a mandate that addresses coverage for services related to cancer clinical trial participation – implicitly requires coverage of out-of-network providers when the relevant service is not available in-network. As projected impacts were related only to SB 583’s requirement that enrollees to be able to self-refer for related coverage, the projected cost impacts in this document are the same as presented in the initial version.



The California Health Benefits Review Program (CHBRP) was established in 2002. As per its authorizing statute, CHBRP provides the California Legislature with independent analysis of the medical, financial, and public health impacts of proposed health insurance benefit-related legislation. The state funds CHBRP through an annual assessment on health plans and insurers in California.

An analytic staff based at the University of California, Berkeley, supports a task force of faculty and research staff from multiple University of California campuses to complete each CHBRP analysis. A strict conflict-of-interest policy ensures that the analyses are undertaken without bias. A certified, independent actuary helps to estimate the financial impact. Content experts with comprehensive subject-matter expertise are consulted to provide essential background and input on the analytic approach for each report.

More detailed information on CHBRP's analysis methodology, authorizing statute, as well as all CHBRP reports and other publications are available at www.chbrp.org.

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Table 1. SB 583 Clinical Trials Impacts on Benefit Coverage, Utilization, and Cost, 2020

	Baseline	Postmandate	Increase/ Decrease	Percentage Change
Benefit coverage				
Total enrollees with health insurance subject to state benefit mandates (a)	24,490,000	24,490,000	0	0%
Total enrollees subject to mandate	16,899,000	16,899,000	0	0%
Total enrollees with health insurance subject to SB 583	69%	69%	0%	0%
Total percentage of enrollees with coverage for noncancer clinical trials	100%	100%	0%	0%
Total percentage of enrollees with ability to self-refer to clinical trials	7%	100%	93%	1339%
Utilization and unit cost				
Number of enrollees with coverage subject to SB 583 participating in clinical trials	7,035	7,372	337	5%
Clinical trial participants per 1,000 enrollees	0.416	0.436	0.020	5%
Utilization of routine health care services per person enrolled in clinical trials				
Inpatient days	0.713	0.713	0.000	0%
Outpatient visits	2.872	2.872	0.000	0%
Professional visits	0.458	0.458	0.000	0%
Professional procedures	1.731	1.731	0.000	0%
Average cost per person enrolled in clinical trials	\$20,548	\$20,548	\$0.00	0%
Expenditures				
<u>Premiums by payer</u>				
Private employers for group insurance	\$86,438,375,000	\$86,444,125,000	\$5,750,000	0.0067%
CalPERS HMO employer expenditures (c) (b)	\$3,098,551,000	\$3,098,757,000	\$206,000	0.0066%
Medi-Cal Managed Care Plan expenditures	\$28,492,273,000	\$28,492,273,000	\$0	0.0000%
Enrollees with individually purchased insurance	\$12,045,324,000	\$12,046,578,000	\$1,254,000	0.0104%
Enrollees with group insurance, CalPERS HMOs, Covered California, and Medi-Cal Managed Care (c)	\$14,476,394,000	\$14,477,392,000	\$998,000	0.0069%
<u>Enrollee expenses</u>				
For covered benefits (deductibles, copayments, etc.)	\$14,750,880,000	\$14,750,970,000	\$90,000	0.0006%
For noncovered benefits (d) (e)	---	---	---	---
Total expenditures	\$159,301,797,000	\$159,310,095,000	\$8,298,000	0.0052%

Source: California Health Benefits Review Program, 2019.

Notes: (a) Enrollees in plans and policies regulated by DMHC or CDI aged 0 to 64 years as well as enrollees 65 years or older in employer-sponsored health insurance. This group includes commercial enrollees (including those associated with Covered California or CalPERS) and Medi-Cal beneficiaries enrolled in DMHC-regulated plans.²

(b) Approximately 56.17% of CalPERS enrollees in DMHC-regulated plans are state retirees, state employees, or their dependents. About one in five (20.5%) of these enrollees has a pharmacy benefit not subject to DMHC.³ CHBRP has projected no impact for those enrollees. However, CalPERS could, postmandate, require equivalent coverage for all its members (which could increase the total impact on CalPERS).

(c) Enrollee premium expenditures include contributions by employees to employer-sponsored health insurance, health insurance purchased through Covered California, and contributions to Medi-Cal Managed Care.

(d) Includes only expenses paid directly by enrollees (or other sources) to providers for services related to the mandated benefit that are not currently covered by insurance. This only includes those expenses that would be newly covered postmandate. Other components of expenditures in this table include all health care services covered by insurance.

(e) Although enrollees with newly compliant benefit coverage may have paid for some health care services related to clinical trial participation before SB 583, CHBRP cannot estimate the frequency with which such situations may have occurred and therefore cannot estimate the related expense. Postmandate, such expenses would be eliminated, though enrollees with newly compliant benefit coverage might, postmandate, pay for some such services for which coverage is denied (through utilization management review), as some enrollees who always had compliant benefit coverage may have done and may continue to do, postmandate.

(f) CHBRP is unaware of a measurable number of Medi-Cal beneficiaries enrolled in DMHC-regulated plans that currently have SB 583-compliant self-referral options.

Key: CalPERS = California Public Employees' Retirement System; CDI = California Department of Insurance; DMHC = Department of Managed Health Care; HMO = Health Maintenance Organizations; --- = No mathematic calculation possible

² For more detail, see *Estimates of Sources of Health Insurance in California*, available at http://chbrp.com/analysis_methodology/cost_impact_analysis.php.

³ For more detail, see *Estimates of Pharmacy Benefit Coverage*, available at http://chbrp.com/analysis_methodology/cost_impact_analysis.php.

POLICY CONTEXT

The California Senate Committee on Health has requested that the California Health Benefits Review Program (CHBRP)⁴ conduct an evidence-based assessment of the medical, financial, and public health impacts of Senate Bill (SB) 583, Clinical Trials.

Bill Language Summary

SB 583 would be applicable to the benefit coverage of enrollees in health plans regulated by the California Department of Managed Care (DMHC) and to the benefit coverage of enrollees in health policies regulated by the California Department of Insurance (CDI).

SB 583 would alter a current benefit mandate (see Appendix A). The current mandate:

- Requires coverage for routine patient care costs related to a cancer clinical trial when the enrollee's treating physician recommends participation.
- Specifies that routine patient care related to a cancer clinical trial:
 - Includes, among other things, health care services:
 - Typically provided absent a clinical trial;
 - Required solely for the provision of the investigational drug, item, device, or service;
 - Required for the clinically appropriate monitoring of the investigational item or service;
 - Provided for the prevention of complications arising from the provision of the investigational drug, item, device, or service; and
 - Needed for the reasonable and necessary care arising from the provision of the investigational drug, item, device, or service.
 - Does not include:
 - Drugs or devices that have not been approved by the FDA and that are associated with the trial;
 - Services other than health care (such as housing or travel);
 - Any item or service that is provided solely to satisfy data collection and analysis (and is not used in clinical management of the patient);
 - Services otherwise excluded from coverage; or
 - Services customarily provided by the research sponsor free of charge for the patient.
- Requires coverage of out-of-network providers when the relevant service is not available in-network and requires payment to and cost sharing related to use of in-network and out-of-network providers be similar.

⁴ CHBRP's authorizing statute is available at <http://chbrp.org/faqs.php>.

SB 583 would:

- Expand the mandate to address clinical trials related to cancer and to other life-threatening diseases, defined as a disease or condition from which the likelihood of death is probable, unless the course of the disease or condition is interrupted;
- Allow enrollee-submitted medical and scientific information to substitute for the treating physician's recommendation/referral as a means of accessing coverage for health care services related to participation in a clinical trial; and

The full text of SB 583 can be found in Appendix A.

As noted in Table 2, several laws and policies address coverage for routine health care for participants in clinical trials. The laws and policies differ in terms of which groups of Californians have health insurance that must comply. The Center for Medicare and Medicaid (CMS) requirements⁵ are applicable to the benefit coverage of Medicare and Medicaid beneficiaries (including Medi-Cal beneficiaries enrolled in DMHC-regulated plans). The Affordable Care Act (ACA) requirements,⁶ which are based on the CMS policy, are applicable to the benefit coverage of commercial and CalPERS enrollees in nongrandfathered plans and policies regulated by DMHC or CDI. The current California mandate as well as SB 583 would be applicable to the benefit coverage of all commercial and CalPERS enrollees.

The laws and policies also differ as to the trials for which benefit coverage is required. The CMS requirements are applicable to trials related to all conditions and diseases covered by Medicare. The ACA requirements are applicable only to trials related to life-threatening diseases and conditions. The current California mandate is applicable only to trials related to cancer. SB 583 would be applicable only to trials related to life-threatening diseases (including cancer).

The laws and policies also differ as to the terms of required benefit coverage. The CMS policy does not address self-referral for access to benefit coverage or cost sharing and does not require coverage of out-of-network providers when the service is not available in-network. The ACA requires that self-referral be allowed, but does not address cost sharing and does not require coverage of out-of-network providers. SB 583 would require that self-referral be allowed, and, like the current California mandate, would require that cost sharing be at in-network rates, and would require coverage of out-of-network providers when the service is not available in-network.

For commercial and CalPERS enrollees, SB 583 would align with the ACA requirements regarding coverage for routine health care services for clinical trials related to life-threatening diseases and conditions. SB 583 would also align with the ACA's requirement that self-referral to access benefit coverage be allowed. Beyond the ACA's requirements, SB 583 would additionally require that all cost sharing be at in-network rates and that coverage for out-of-network providers be present when the service is not available in-network.

⁵ Clinical Trials Policy (NCD310.1), available at <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=1&fromdb=true>

⁶ See https://www.cms.gov/ccio/resources/fact-sheets-and-faqs/aca_implementation_faqs15.html

Table 2. Comparison of SB 583 and Current State and Federal Requirements

	CMS Policy	ACA	Current California Mandate	SB 583
Applicable to the benefit coverage of:	Medicare and Medi-Cal (a) beneficiaries	Commercial and CalPERS enrollees in nongrandfathered plans and policies	Commercial and CalPERS enrollees	Commercial and CalPERS enrollees
Requires coverage of routine health care services for participants in trials related to ...				
... cancer	Yes	Yes	Yes	Yes
... noncancer life-threatening diseases conditions	Yes	Yes	No	Yes
... non-life-threatening diseases/conditions	Yes	No (d)	No	No
Specifies that ...				
...self-referral to access benefit coverage is allowed (b)	No	Yes (c)	No	Yes
... coverage of out-of-network providers is required when in-network providers do not offer service	No	No	Yes	Yes
... all related cost sharing must be at in-network rates	No	No	No	Yes

Source: California Health Benefits Review Program, 2019.

Note: (a) Includes Medi-Cal beneficiaries enrolled in DMHC-regulated plans. (b) Provider referral is commonly required. (c) See definition of qualified individual, 42 US code 300gg-8 section (b). (d) See specification of life-threatening conditions, 42 US code 300gg-8 section (d).

Key: ACA = Affordable Care Act; CMS = Center for Medicare and Medicaid Services; DMHC = Department of Managed Health Care

Relevant Populations

If enacted, SB 583 would affect the health insurance of approximately 16.9 million enrollees (41% of all Californians). This figure represents 69% Californians who will have health insurance regulated by the state that may be subject to any state health benefit mandate law — health insurance regulated by the DMHC or the CDI. As SB 583 specifies applicability to “group and individual” health insurance, it would

not be applicable to the benefit coverage of the 7.6 million Medi-Cal beneficiaries enrolled in DMHC-regulated plans.⁷

Analytic Approach and Key Assumptions

SB 583 would eliminate the language in the current mandate that explicitly exempts nonmedical services (housing, travel, etc.) from coverage. Since the bill language does not create an explicit requirement for coverage for nonmedical services, for this analysis CHBRP has assumed that the plans and policies would not add coverage for nonmedical services.

As mentioned previously, CHBRP is asked to provide an evidence-based assessment of the medical, financial, and public health impacts of SB 583. This typically involves a systematic literature review on the benefit or treatment referenced in the legislation. In this case, that would be a review of the effectiveness of clinical trials. This would encompass all literature for all clinical trials for a wide range of conditions. It was not feasible to complete this task given the timeframe for this analysis. In addition, there is no overall consensus regarding if patients participating in clinical trials have better outcomes compared to those not participating in clinical trials (ACS CAN, 2018). For that reason, CHBRP has not included a medical effectiveness analysis of clinical trials in this report. In addition, without literature that describes the effectiveness of the proposed benefit or treatment, it is not possible to estimate a public health impact of the legislation.

Interaction With Existing Requirements

Health benefit mandates may interact and align with the following state and federal mandates or provisions.

California Policy Landscape

California law and regulations

As noted, SB 583 would alter a current benefit mandate (see Appendix A), that requires benefit coverage related to cancer clinical trials.

Similar requirements in other states

All 50 states have benefit mandates related to clinical trials (BCBSA), though CHBRP is unaware of any that allow self-referral to substitute for the treating physician's recommendation/referral, that require in-network cost sharing for all covered services, or that require coverage of out-of-network providers when a service is not available in-network.

Federal Policy Landscape

As previously mentioned, federal law and policy place requirements around benefit coverage related to both cancer and noncancer clinical trials that are similar in many ways to what SB 583 would require and

⁷ Enrollment in DMHC-regulated plans purchased by the California Department of Health Care Services (DHCS) for Medi-Cal beneficiaries is not considered to be enrollment in either group or individual health insurance, see Sec. 2791 of the federal Public Health Service Act, January 2014, which defines Medicaid as "not group."

are relevant to the benefit coverage of almost all enrollees in plans and policies regulated by DMHC or CDI.

Medicaid and Medicare

As per a Federal Clinical Trials Policy (NCD310.1),⁸ both Medicaid (Medi-Cal in California) and Medicare cover health care services related to participation in clinical trials. The policy does not require coverage for nonmedical services, does not address potential participant self-referral, and does not require coverage by an out-of-network provider when no in-network provider can provide the service. However, the policy is broader than SB 583 in terms of disease/condition, as it is not limited to life-threatening situations.

Affordable Care Act

A number of Affordable Care Act (ACA) provisions have the potential to or do interact with state benefit mandates. Below is an analysis of how SB 583 may interact with requirements of the ACA as presently exists in federal law, including the requirement for certain health insurance to cover essential health benefits (EHBs).⁹

Any changes at the federal level may impact the analysis or implementation of this bill, were it to pass into law. However, CHBRP analyzes bills in the current environment given current law and regulations.

Benefit coverage related to clinical trials

For nongrandfathered plans and policies, the ACA requires compliance¹⁰ with requirements based on the previously discussed Federal Clinical Trials Policy (NCD310.1).¹¹ For Medicare and Medicaid beneficiaries, the policy addresses coverage for health care services related participation in a clinical trials. The ACA makes the requirements applicable to commercial and CalPERS enrollees in nongrandfathered plans and policies regulated by DMHC and CDI. However, the ACA defines a more restricted scope, requiring benefit coverage only when the trial is related to a life-threatening disease or condition. The ACA also adds a requirement to allow self-referral to access benefit coverage for services related to clinical trial participation.

Essential Health Benefits

State health insurance marketplaces, such as Covered California, are responsible for certifying and selling qualified health plans (QHPs) in the small-group and individual markets. QHPs are required to meet a minimum standard of benefits as defined by the ACA as essential health benefits (EHBs). In California, EHBs are related to the benefit coverage available in the Kaiser Foundation Health Plan Small

⁸ Available at <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=1&fromdb=true>

⁹ The ACA requires nongrandfathered small-group and individual market health insurance — including but not limited to QHPs sold in Covered California — to cover 10 specified categories of EHBs. Resources on EHBs and other ACA impacts are available on the CHBRP website: http://www.chbrp.org/other_publications/index.php.

¹⁰ See https://www.cms.gov/ccii/resources/fact-sheets-and-faqs/aca_implementation_faqs15.html

¹¹ Available at <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=1&fromdb=true>

Group Health Maintenance Organization (HMO) 30 plan, the state's benchmark plan for federal EHBs.^{12,13}

States may require QHPs to offer benefits that exceed EHBs.¹⁴ However, a state that chooses to do so must make payments to defray the cost of those additionally mandated benefits, either by paying the purchaser directly or by paying the QHP.^{15,16} State rules related to provider types, cost sharing, or reimbursement methods would *not meet* the definition of state benefit mandates that could exceed EHBs.¹⁷

SB 583 would not require coverage for a new state benefit mandate but rather would alter a current benefit mandate and appears not to exceed the definition of EHBs in California.

¹² The U.S. Department of Health and Human Services (HHS) has allowed each state to define its own EHBs for 2014 and 2015 by selecting one of a set of specified benchmark plan options. CCIIO, Information on Essential Health Benefits Benchmark Plans. Available at: <https://www.cms.gov/ccio/resources/data-resources/ehb.html>.

¹³ H&SC Section 1367.005; IC Section 10112.27.

¹⁴ ACA Section 1311(d)(3).

¹⁵ State benefit mandates enacted on or before December 31, 2011, may be included in a state's EHBs, according to the U.S. Department of Health and Human Services (HHS). Patient Protection and Affordable Care Act: Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation. Final Rule. Federal Register, Vol. 78, No. 37. February 25, 2013. Available at: www.gpo.gov/fdsys/pkg/FR-2013-02-25/pdf2013-04084.pdf.

¹⁶ However, as laid out in the Final Rule on EHBs HHS released in February 2013, state benefit mandates enacted on or before December 31, 2011, would be included in the state's EHBs and there would be no requirement that the state defray the costs of those state mandated benefits. For state benefit mandates enacted after December 31, 2011, that are identified as exceeding EHBs, the state would be required to defray the cost.

¹⁷ Essential Health Benefits. Final Rule. A state's health insurance marketplace would be responsible for determining when a state benefit mandate exceeds EHBs, and QHP issuers would be responsible for calculating the cost that must be defrayed.

BACKGROUND ON CLINICAL TRIALS

This background section provides context for CHBRP’s analysis of SB 583 by defining and describing the various aspects and design of clinical trials, identifying the steps for protecting participants in clinical trials, identifying the availability of clinical trials in the United States and California, and describing disparities and social determinants of health related to participation in clinical trials. Other than clinical trial registry data that is available at ClinicalTrials.gov, there is very little literature that addresses clinical trials in a comprehensive way. Typically, the literature is limited to specific trials for specific diseases or conditions. The broadest literature is related to clinical trials for cancer treatments; therefore, much of this background section on clinical trials is informed by literature related to cancer clinical trials.

It is important to note that the universe of clinical trials discussed in this background section is much larger than the specific clinical trials that would be approved for benefit coverage under SB 583, as not all clinical trials would address “the prevention, detection, or treatment of cancer or another life-threatening condition” or have “meaningful potential to benefit the insured.” In addition, SB 583 would not require coverage for trials that test exclusively for toxicity and do not have a “therapeutic intent.”

Clinical Trials

Clinical trials are research studies that recruit human volunteers to participate in an intervention to determine the overall safety of a particular treatment/drug and its effects on health outcomes (ClinicalTrials.gov, 2019; NIH, 2017a). The objective of a clinical trial is to explore and investigate new manners and modes to prevent, detect, or treat an illness or disease (NIH, 2017a).

Types of Clinical Trials

Clinical trials can be categorized into six different types including (1) prevention trials, (2) screening trials, (3) diagnostic trials, (4) treatment trials, (5) behavioral trials, and (6) quality of life trials (NIH, 2017a). Prevention trials study new and/or improved modes (e.g., new medicines, vaccines, or lifestyle alterations) to prevent disease in individuals who have never had the disease or to prevent the disease from recurring in individuals (NIH, 2017a). Screening trials study new ways to detect for disease and health conditions in individuals whereas diagnostic trials study or compare tests/procedures for diagnosing particular diseases or health conditions in individuals (NIH, 2017a). Treatment trials study the effects of new treatments or new modalities in which to use existing treatments, new combination of drugs, new ways of conducting surgery, or new approaches to radiation therapy (NIH, 2017a). Behavioral trials evaluate or compare ways to alter behavior and attitudes to improve health and health outcomes. And quality of life trials (also referred to as supportive care trials) investigate interventions that improve the comfort and quality of life for individuals with acute or chronic conditions (NIH, 2017a).

Design of Clinical Trials

When developing and implementing a clinical trial, researchers must first review the current/available related topical research information and subsequently develop a strict plan (i.e., protocol) to follow throughout the clinical trial (NIH, 2017a). A protocol is designed to ensure the safety of the participants by balancing the potential benefits and risks in participation and to answer specific research questions (NIH, 2017a). As laid out by the NIH (2017a), a clinical trial protocol is comprised of the following items:

- The objective(s) and design of the study, such as the expected duration of the study and number of participants and eligibility criteria (i.e., participant selection criteria);

- Informed consent and protections against risks to participants;
- Research methodology, such as study details regarding the tests, procedures, and treatments to be administered and whether a control group will be included;
- Data collection and management; and
- Timeline for review and analysis of the data.

Phases of Clinical Trials

Clinical trials follow a sequential series of phases (i.e., Phase I-IV) ranging from early, small-scale studies (Phase I) to introduction to the public, post-drug/-treatment approval by the U.S. Food and Drug Administration (FDA) (Phase IV). More specifically, Phase I is the phase in which researchers test a drug or treatment among a small cohort of individuals — typically 20 to 80 individuals — for the first time to learn about the safety and potential side effects of the drug/treatment (NIH, 2017a). Phase II is the phase in which the new drug or treatment is distributed to a larger cohort of individuals — typically 100 to 300 individuals. The purpose of Phase II is to further study the treatment/drug's effectiveness and safety. During Phase III, the drug/treatment is distributed to approximately 1,000 to 3,000 individuals to validate its effectiveness, monitor side effects, compare it to a standard or similar treatment available in the market, and collect additional information (NIH, 2017a). Phase IV is the phase in which the drug/treatment has been approved by the FDA and is available for use among the general public. During Phase IV, researchers will continue to track the drug/treatment's safety and seek additional information regarding its benefits and optimal use (NIH, 2017a).

Clinical Trials in the United States and California

The Center for Information and Study on Clinical Research Participation (CISCRP) estimates that 2.33 million Americans participated in clinical trials in 2015 (CISCRP, 2015). Clinical trials participants report participating in clinical trials for a range of reasons, including helping to advance science and the treatment of the disease/condition (49%), to obtain better treatment (44%), to help others with the same disease/condition (39%), and to receive monetary compensation (29%) (CISCRP, 2017).

There are currently 21,361 clinical trials actively recruiting in the United States (ClinicalTrials.gov, 2019). Of these, nearly one-quarter (4,909) are located in California (ClinicalTrials.gov, 2019). As depicted in Table 3, approximately 16% of clinical trials actively recruiting in California are funded by the National Institutes of Health (NIH), 4% are funded by another U.S. federal agency, 55% are funded by industry, and 25% are funded by other sources (ClinicalTrials.gov, 2019). Clinical trials recruiting patients in California differ in composition from those in the U.S. overall in that the clinical trials currently recruiting patients in California are more likely to be funded by industry (58% vs. 33%). In addition, 20% of trials actively recruiting in California are in Phase I of development, 30% are in Phase II, 21% are in Phase III, 5% are in Phase IV, and 24% are trials without FDA-defined phases including trials of devices and behavioral interventions (Table 3) (ClinicalTrials.gov, 2019). Again, the trials actively recruiting in California differ from the U.S. as a whole in that they are more likely to be trials with FDA-defined phases (76% vs. 61%) and specifically more trials that are in phase III (21% vs. 9%) (ClinicalTrials.gov, 2019).

There are no published estimates of the number of Californians participating in a clinical trial each year, but as 12% of the U.S. population lives in California (U.S. Census Bureau, 2018), CHBRP estimates that 12% of the 2.33 million American clinical trial participants — or nearly 280,000 Californians — participate in a clinical trial each year. The number of participants who would be eligible for the types of clinical trials covered under SB 583 would be much lower as only 41% of Californians are enrolled in plans or policies

that would be subject to SB 583, and approximately 41% of clinical trial participants are in observational studies (i.e. clinical trials where “patients are identified as belonging to study groups and are assessed for biomedical or health outcomes.”)¹⁸ Additionally clinical trial participation covered under SB 583 would be limited to life-threatening conditions. Furthermore, it is not clear to what extent that clinical trial administrators consistently bill insurance for services provided within the clinical trial either due to a lack of awareness of this option or due to a desire to maintain control of the data on study participants. Therefore, the number of participants in clinical trials subject to SB 583 as documented in claims databases will vary greatly from the estimate of the overall number of clinical trial participants in California.

Table 3. Actively Recruiting Clinical Trials in California Categorized by Funder Type and by Phase, As of February 23, 2019

Funder Type	% of Trials
NIH	16%
Other U.S. Federal Agency	4%
Industry	55%
Others	25%
Phase	% of Trials
Phase I	20%
Phase II	30%
Phase III	21%
Phase IV	5%
Trials without FDA-defined Phases	24%

Source: ClinicalTrials.gov, 2019.

Note: Data was downloaded from ClinicalTrials.gov on February 23, 2019. Percentages do not add to 100% due to rounding error.

The following table (Table 4) identifies the various types/categories of clinical trials that are actively recruiting in California as of February, 23, 2019. Clinical trials address a wide array of diseases and conditions, but the most common disease addressed through clinical trials actively recruiting in California in 2019 is cancer (32%), followed by mental health conditions (4%), cardiovascular disease (4%), diabetes (3%), and HIV/AIDS (2%). The other 56% of the trials fall into the “other category” which includes studies addressing a wide range of issues such as Alzheimer’s disease, Parkinson’s disease, obesity, sedentary lifestyles, pain management, and reproductive health.

Table 4. Clinical Trials Actively Recruiting in California, as of February 23, 2019

Condition	# of Trials	% of Total
Cancer	1,561	32.1%
Mental Health	201	4.1%
Cardiovascular Disease	193	4.0%

¹⁸ CHBRP analysis of clinical trial registry data located at ClinicalTrials.gov on April 7, 2019.

Condition	# of Trials	% of Total
Diabetes	121	2.5%
HIV/AIDS	81	1.7%
Pain Management	63	1.3%
Substance Abuse	58	1.2%
Eye Conditions	42	0.9%
Alzheimer's	40	0.8%
Asthma	38	0.8%
Obesity	36	0.7%
Parkinson's	25	0.5%
Other	2,401	49.4%

Source: California Health Benefits Review Program, 2019.

Note: Data was downloaded from ClinicalTrials.gov on February 23, 2019.

Participation in Clinical Trials

Many different types of individuals can be recruited to participate in a clinical trial ranging from healthy individuals to individuals with a specific illness or type of disease. Clinical trials involving “healthy volunteers” are typically designed to aid researchers in understanding and developing new knowledge around a treatment/drug, and not to provide direct benefit to the participants (NIH, 2017a). Healthy volunteers are recruited to help researchers in defining the range of “normalcy” for new devices, diagnostic, and screening tools (NIH, 2017a). Clinical trials may also recruit “patient volunteers,” who are identified as having a disease/illness in which researchers are interested in better understanding, diagnosing, and/or treating that particular disease/illness (NIH, 2017a). As indicated by the NIH (2017a), although clinical trials have the potential to provide direct benefit to patient volunteers, the main objective of a clinical trial is to develop the evidence-base regarding the effects and limitations of the experimental treatment/drug. Even for participants with life-threatening conditions, enrollment in a clinical trial does not mean that a patient will get access to a specific treatment, as they can be randomized into either a treatment or control group, which may include a placebo — a substance or treatment that looks like the experimental treatment but has no therapeutic effect — and/or the minimum standard of care for their condition.

When recruiting volunteers to participate in clinical trials, researchers must follow clinical trial guidelines (more commonly referred to as inclusion/exclusion criteria) (NIH, 2017a). Developed by researchers, inclusion criteria are comprised of the factors that make an individual eligible to participate in a specific clinical trial such as age, gender, type and stage of disease, treatment history, and medical history (NIH, 2017a). In contrast, exclusion criteria are comprised of the factors that exclude individuals from eligible participation in a specific Clinical Trial (NIH, 2017a). According to the American Cancer Society Cancer Action Network (ACS CAN), with respect to cancer clinical trials, patients are excluded at a rate of 24.3% and 15.7% within academic centers and community centers, respectively, due to a number of reasons (ACS CAN, 2018). For example, patients may be excluded from a cancer clinical trial due to the presence of comorbidities in patients such as heart failure, coronary artery disease, HIV, hepatitis, or hemoglobin-related criteria (ACS CAN, 2018; Mariotti et al., 2017).

Barriers to Participating in Clinical Trials

According to the ACS, despite patient interest and a willingness to enroll in clinical trials, few patients end up participating in cancer clinical trials due to a multitude of barriers (ACS CAN, 2018). In a recent executive summary on an analysis of barriers to patient participation in U.S.-based cancer clinical trials, ACS CAN cited the following findings: (1) 56% of patients will not have a local trial available for their cancer; (2) 17% will be identified as ineligible due to exclusion criteria; (3) many eligible patients are not asked/referred to participate in clinical trials by their provider; and (4) only 27% of cancer patients have the opportunity to participate in a local cancer clinical trial (ACS CAN, 2018). With respect to items 1 and 4, opportunities for participation in clinical trials will differ depending on the location where a patient receives care. For example, large research centers will often have more available clinical trials compared to smaller, non-research focused sites, as well as dedicated personnel and an electronic content management system (i.e., electronic medical records [EMR]) to prescreen patients for trial eligibility (ACS CAN, 2018). In contrast, in smaller, non-research focused sites patients may only become aware of a trial if they themselves ask or their provider asks due to a lack of research infrastructure.

Additionally, health care providers play an influential role in whether patients opt into participating in clinical trials (ACS CAN, 2018). According to the ACS CAN (2018), the majority of the public expects their providers to be cognizant of clinical trial opportunities, provide trusted guidance, and serve as their primary source of information with respect to clinical trials and eligibility criteria. In fact, most cancer patients who have participated in clinical trials (66%) initially learned of their trial through one of their providers or via the research staff compared to only 6% who learned of their trial through a patient advocacy group (ACS CAN, 2018). Furthermore, in a survey study of 360 women, researchers found that women advised by their provider to participate in breast cancer clinical trial were 13 times more likely to participate compared to those advised to not participate (ACS CAN, 2018; Kinney et al., 1998). While efforts have also been made to increase awareness of clinical trials via public awareness campaigns such as in Florida and California, both initiatives failed to increase overall clinical trial participation rates (ACS CAN, 2018; Moffitt et al., 2010; Umutyan et al., 2008).

Despite geographic barriers, patients presenting with a certain disease/illness have been known to travel out of state to participate in a clinical trial targeting their specific disease/illness. The reasons for participating in an out-of-state clinical trial vary by patient and may include (1) not having access to a particular treatment in state due to the patient having a rare disease/illness; (2) having previously been rejected from an in-state trial due to stringent inclusion and exclusion criteria (e.g., presence of comorbidities or participation in a previous clinical trial leading to ineligibility); and/or (3) having been matched with a specific clinical trial in another state given a set of specific conditions (per use of a clinical trial matching organization/website) (Kaiser Health News, 2016).

Participant Protection in Clinical Trials

To ensure participant protection prior to enrollment and throughout the duration of a clinical trial, researchers must (1) obtain Institutional Review Board (IRB) approval (i.e., obtain approval from an independent committee comprised of physicians, statisticians, and other stakeholders known as the IRB) prior to recruitment and initiation of the study, (2) obtain informed consent from the participant prior to enrollment, and (3) follow a set of ethical guidelines (NIH, 2017a). By seeking IRB approval prior to the start of a clinical trial, participants can rest assured that the study has been identified as both ethical and safe (NIH, 2017a). During the recruitment process, researchers must share and obtain a signed informed consent document from each participant, which highlights the key features of the study design, specific risks, and potential benefits for participating in a clinical trial (NIH, 2017a). To further ensure a participant's safety, a participant must be allowed to withdraw from a study at any point in time (NIH, 2017a).

Disparities¹⁹ and Social Determinants of Health²⁰ in Participation in Clinical Trials

Per statute, CHBRP includes discussion of disparities and social determinants of health (SDoH) as it relates to the participation in clinical trials. Disparities are differences between groups that are modifiable. CHBRP found literature identifying disparities in clinical trials by age, gender, and race/ethnicity.

Disparities

Race or ethnicity

Despite the release of the National Institute of Health's mandate on the inclusion of members of minority populations in clinical trials in 1993 (Freedman et al., 1995), disparities in racial and ethnic minority representation in clinical trials continue to persist (Hamel et al., 2016; Kwiatkowski et al., 2013). In a systematic review of 304 peer-reviewed publications focused on cancer clinical trials, between the study periods of 2001 and 2010, when race/ethnicity were reported in treatment studies, researchers found that 82.9% of participants were white, 6.2% were African American, 3.3% were Asian, 2.2% were Hispanic, and 0.1% were Native American (Kwiatkowski et al., 2013). Kwiatkowski et al. (2013) also reported on clinical trials participant demographics from 10 years prior (i.e., 1999 to 2000), and found that the proportion of participants who are white are decreasing over the two 10-year study periods, yet whites continue to overwhelmingly comprise the participant cohort in cancer clinical trials (Hamel et al., 2016; Kwiatkowski et al., 2016). Additionally, despite minor advances in the proportion of Asian and Hispanic participation from study period 1 (1999–2000) to 2 (2001–2010), the proportion of African American participants in cancer clinical trials saw reductions from study period 1 to 2 (Hamel et al., 2016; Kwiatkowski et al., 2013).

Gender

As detailed in a 1992 U.S. General Accounting Office (GAO) study,²¹ historically women have been underrepresented in clinical trials since the 1980s (Labots et al., 2018). However, in response to those findings, the U.S. Food and Drug Administration (FDA) published the *Guideline for the Study and Evaluation of Gender Differences in the Clinical Evaluation of Drugs* in 1993, which included a call for increased participation of females in clinical trials as well as increased analyses of gender-specific responses to drugs (Labots et al., 2018; U.S. FDA, 1993). Despite the continued perception of the underrepresentation of women in clinical trials in present day, recent studies and reports investigating gender-based disparities/gender-based subgroup differences in randomized clinical trials (RCTs) have found little evidence to support the underrepresentation of women in clinical studies (Labots et al., 2018; Wallach et al., 2016).

¹⁹ Several competing definitions of “health disparities” exist. CHBRP relies on the following definition: Health disparity is defined as the differences, whether unjust or not, in health status or outcomes within a population. Wyatt et al., 2016.

²⁰ CHBRP defines social determinants of health as conditions in which people are born, grow, live, work, learn, and age. These social determinants of health (economic factors, social factors, education, physical environment) are shaped by the distribution of money, power, and resources and impacted by policy (adapted from Healthy People 2020, 2015; CDC, 2014). See CHBRP's SDoH white paper for further information: http://chbrp.com/analysis_methodology/public_health_impact_analysis.php.

²¹ See: <http://archive.gao.gov/d35t11/147861.pdf>

Age

Across cancer clinical trials, studies have documented the underrepresentation of elderly participants (i.e., individuals identified as 65 years of age or older) due to a multitude of reasons, such as physicians' perceptions, treatment tolerability, protocol eligibility criteria (with restrictions on the presence of comorbidities such as hypertension, cardiac disease, pulmonary infection), functional status, and previous malignancies (Hutchins et al., 1999; Mahipal et al., 2015; Townsley et al., 2005). For example, in a study of 16,936 patients enrolled in cancer clinical trials between 1993 and 1996, the overall proportion of women and African American minorities enrolled in the trial (41% and 10%, respectively) were equal to or similar to the U.S. population of women and African American patients with cancer (43% and 10%, respectively); however, participants 65 years of age or older only represented 25% of enrollees when they comprise 63% of the U.S. population of patients with cancers (Hutchins et al., 1999). In a systematic review of barriers to recruitment of elderly patients with cancer onto clinical trials, Townsley et al. (2005) further noted that only 25% to 33% of potentially eligible older patients are recruited and enrolled into trials. In response to this persistent disparity, in December of 2017 the NIH released a policy mandating that researchers include plans in their protocol on the inclusion of patients across the lifespan, including children and the elderly (NIH, 2017b).

Social Determinants of Health (SDoH)

SDoH include factors outside of the traditional medical care system that influence health status and health outcomes (e.g., income, education, geography, etc.). CHBRP found literature related to barriers to participation in clinical trials influenced by geographic location, income, and insurance status.

Geographic location

A number of U.S.-based studies have found geographic location to be a significant barrier to participation in clinical trials (Kanarek et al., 2010; Martin et al., 2013). Specifically, individuals who did not participate in clinical trials were more likely to live out of state or further away from the hospital catchment area such as in rural areas, thus, indicating travel distance as a barrier to participation in clinical trials (Kanarek et al., 2010; Martin et al., 2013). This finding, among other factors, was similarly echoed in a study located in West Virginia, in which researchers found an individual's length of commute as an influential factor for lack of participation in cancer clinical trials (Virani et al., 2011). To increase the rate of rural participation in clinical trials, researchers have suggested simple strategies to combat this barrier, including the provision of telehealth-delivered interventions or transportation alternatives such as reimbursement of transportation expenses by study investigators and/or free transportation (Young et al., 2015).

Income

Several U.S.-based studies have indicated an association between income and the likelihood of participation in clinical trials (Unger et al., 2013, Unger et al., 2016). Researchers found that lower income individuals were less likely to participate in clinical trials (Unger et al., 2013). This finding was reiterated in a subsequent 2015 prospective study, in which researchers further validated that cancer patients with an income below \$50,000 were 27% less likely to participate in clinical trials (Unger et al., 2016). Researchers hypothesized that lower income individuals may be more sensitive to discretionary expenses in comparison to higher income individuals (Unger et al., 2016).

In a 2018 policy brief disseminated by the American Society of Clinical Oncology (ASCO), Winkfield et al. (2018) further shed light on the financial barriers to participation in clinical trials. Researchers noted that the "financial toxicity" defined as "the negative patient-level impacts of the cost of cancer care" has played a pivotal role in reducing one's ability to enroll and/or continue to participate in cancer clinical trials

(Winkfield et al., 2018). The types of expenses associated with clinical trials are vast and include (1) investigational care expenses, (2) routine-care expenses, and (3) nonmedical expenses (e.g., lodging, meals, dependent care, and transportation required for participation). While benefit coverage from Medicare, Medicaid, and commercial health insurance typically includes the costs of routine care associated with clinical trials (as per the 2010 ACA²²), benefit coverage does not often cover nonmedical expenses (Winkfield et al., 2018). Thus, patients with lower income may find the nonmedical expenses associated with clinical trials such as travel, time off work, and dependent care, to be prohibitive (ACS CAN, 2018).

Insurance status

Several U.S. based studies also suggest that insurance status is positively associated with participation in clinical trials (Klamerus et al., 2010; Parsons et al., 2011; Ward et al., 2008). According to Klamerus et al. (2010) and Ward et al. (2008), a lack of health insurance serves as a barrier to the receipt of health care services related to the prevention, detection, and/or treatment of cancer as well as a barrier to participation in cancer clinical trials in the U.S. In one study focusing on adolescent and young adult patients with cancer (i.e., cancer patients between the ages of 15 and 39 years) who were registered in the *Surveillance, Epidemiology, and End Results* program, researchers found that uninsured (and older) patients were less likely to participate in clinical trials (3.2%) compared to patients with HMO or private insurance, equal to 7.3% and 13.9%, respectively (Parsons et al., 2011). This evidence suggests that insurance status plays an important role in the likelihood of participation in clinical trials.

²² See: https://www.cms.gov/ccio/resources/fact-sheets-and-faqs/aca_implementation_faqs15.html

BENEFIT COVERAGE, UTILIZATION, AND COST IMPACTS

As discussed in the *Policy Context* section, SB 583 would expand a currently existing mandate, and require that commercial and CalPERS enrollees in DMHC-regulated health plans and CDI-regulated policies have coverage for health care services related to participation in clinical trials focused on noncancer life-threatening diseases. SB 583 would exempt from compliance the benefit coverage of Med-Cal beneficiaries enrolled in DMHC-regulated plans. Additionally, SB 583 would allow enrollees to self-refer to access benefit coverage for health care services related to participation in a clinical trial by providing evidence from medical literature (eliminating the common current requirement for a physician direct referral).

SB 583 would also eliminate from the current mandate the specification that nonmedical expenses (travel, housing, etc.) related to a clinical trial need not be covered (see *Policy Context* section). As SB 583 would not actively require coverage for nonmedical expenses, CHBRP has not included any related change of benefit coverage in the analysis of the estimated impact of SB 583.

This section reports the potential incremental impacts of SB 583 on estimated baseline benefit coverage, utilization, and overall cost. CHBRP used the 2016 MarketScan[®] and Milliman's proprietary 2016 Consolidated Health Cost Guidelines[™] Sources Database (CHSD) commercial claims and enrollment data for the state of California to model participation in clinical trials that charge DMHC-regulated plans and CDI-regulated insurers for trial-related health care services. Based on consultation with a content expert, CHBRP understands that clinical trial administrators and health care providers can charge insurers and plans for all routine health care related to a clinical trial, from administration of the drug or service to mid-trial monitoring tests to follow-up care needed due to side effects — but that not all clinical trials administrators charge plans and insurers for those services.²³ Health care providers may use a general ICD-9 code identifier when the enrollee is participating in a clinical trial, which CHBRP was able to capture using Milliman's claims data analysis. This database relies on claims data, which does not include a separate code identifying the type of clinical trial (i.e., cancer vs. noncancer, or whether the disease is "life-threatening"). Furthermore, SB 583's definition of "life-threatening" is unclear. Therefore, CHBRP's estimates represent a maximum projection of the impact of SB 583, as CHBRP as the analysis assumes that the benefit coverage of every enrollee participating in a clinical trial that charges plans and insurers for related health care services would be subject to SB 583.

SB 583 would expand the existing mandate's requirement that out-of-network providers be covered if the relevant service is not available in-network and would similarly expand the existing mandate's requirement that in-network cost-sharing to apply to all benefit coverage for health care services related to participation in a clinical trial. SB 583 would make these requirements applicable to noncancer trials as well as cancer trials. According to the claims data available, the in-network cost sharing and out-of-network cost sharing for enrollees who participate in a clinical trial that charge plans and insurers is commonly equivalent. In some cases, the similarity may be due to the enrollees having already exceeded their annual out-of-pocket maximum due to extensive health care needs related to the disease or condition that has made them eligible for participation in the clinical trial. Because in-network and out-of-network cost sharing were found to be equivalent, CHBRP projects no measurable impacts of this provision.

For further details on the underlying data sources and methods used in this analysis, including a full set of billing codes used, please see Appendix B.

²³ Personal communication with G. Stepanyan, March 28, 2019.

Baseline and Postmandate Benefit Coverage

SB 583 would apply to the benefit coverage of commercial and CalPERS enrollees, 69% of enrollees in DMHC-regulated plans and CDI-regulated policies (see Table 1).

CHBRP estimates that 100% of enrollees with health insurance that would be subject to SB 583 have coverage for health care services related to any clinical trial (not just those for life-threatening diseases). However, only 7% of these enrollees have the ability to self-refer for related benefit coverage based on medical literature. Current benefit coverage was determined by a survey of the largest (by enrollment) providers of health insurance in California that can be subject to state mandates. Responses to this survey represent 74% of commercial and CalPERS enrollees with health insurance that can be subject to state mandates.

Postmandate, 100% of commercial and CalPERS enrollees in DMHC-regulated plans or CDI-regulated policies would have coverage for health care services related to clinical trials and would have the ability to access benefit coverage through self-referral based on medical literature (see Table 1).

Baseline and Postmandate Utilization

Currently, out of the 16.9 million enrollees with benefit coverage subject to SB 583, CHBRP estimates 7,035 are enrolled in a clinical trial that is generating chargers for the enrollee's plan or insurer. This estimate is based on analyses of MarketScan and the Milliman CHSD database (see Table 1). As a prevalence rate for the entire enrollee population, this translates to 0.416 per 1,000 enrollees.

Postmandate, CHBRP estimates that the number of these enrollees participating in clinical trials would increase to 7,372, a 5% increase (see Table 1). 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 becoming a participant in a clinical trial which is a precursor to exercising this option of self-referral to access coverage for trial-related health care services. For an enrollee to self-refer, the enrollee must first be aware of a relevant clinical trial, which itself is a barrier to entry (Friedman et al., 2015; Leiter et al., 2015) and be accepted into it. 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 (Leiter et al., 2015). There is a supply-side limitation, 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 (see *Background* section for a fuller discussion of barriers to clinical trial participation).

CHBRP used MarketScan and the Milliman CHSD database to determine utilization of routine health care services among enrollees who participate in clinical trials that charge plans and insurers (see Table 1). 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.

Baseline and Postmandate Per-Unit Cost

Currently, the average unit cost of routine care related to participation in a clinical trial for a commercial/CalPERS enrollee is \$20,548. These average unit costs per enrollee are not expected to change postmandate (see Table 1).

Baseline and Postmandate Expenditures

Table 6 and Table 7 present baseline and postmandate expenditures by market segment for DMHC-regulated plans and CDI-regulated policies. The tables present per member per month (PMPM) premiums, enrollee expenses for both covered and noncovered benefits, and total expenditures (premiums as well as enrollee expenses).

SB 583 would increase total net annual expenditures by \$8,298,000 or 0.0052% for 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 benefits. The additional costs for enrollee expenses are due to cost-sharing for routine health care services for new enrollees who participate in clinical trials, who gain access through self-referral.

Premiums

Changes in premiums as a result of SB 583 would vary by market segment. Note that such changes are related to the number of enrollees (see Table 6 and Table 7), with health insurance that would be subject to SB 583.

Premium increases in privately funded DMHC-regulated plans range from \$0.0394 for large-group plans to \$0.0473 PMPM for individual plans. Among CDI-regulated policies, premium increases range from \$0.0121 PMPM for individual policies to \$0.0342 PMPM for large-group policies.

Among publicly funded DMHC-regulated health plans, premium increases range from \$0.0391 PMPM for CalPERS plans to \$0.000 PMPM for Medi-Cal managed care plans, as the benefit coverage of Medi-Cal enrollees is not subject to SB 583.

Enrollee Expenses

SB 583-related changes in enrollee expenses for covered benefits (deductibles, copays, etc.) and enrollee expenses for noncovered benefits would vary by market segment. Note that such changes are related to the number of enrollees (see Table 6 and Table 7) with health insurance that would be subject to SB 583 expected to enroll in clinical trials during the year after enactment.

CHBRP assumes no unit cost change, but does project an increase in utilization of routine health care services related to participating in a clinical trial charges plans and insurers due to an increased number of enrollees who would participate in clinical trials, and therefore an increase in the total amount of enrollee cost sharing.

Enrollee expenses for all enrollees with coverage subject to SB 583 would increase by a low of \$0.0001 PMPM for enrollees in CDI-regulated individual policies, to a high of \$0.0005 PMPM for enrollees in DMHC-regulated individual plans.

Out-of-Pocket Spending for Covered and Noncovered Expenses

When possible, CHBRP estimates the marginal impact of the bill on out-of-pocket spending for covered and noncovered expenses, defined as uncovered medical expenses paid by the enrollee as well as out-of-pocket expenses (e.g., deductibles, copayments, and coinsurance). Due to new coverage, CHBRP estimates that total out-of-pocket expenses for enrollees with existing coverage baseline and those newly covered who participate in clinical trials would increase by a total of \$91,000 for all enrollees who participate in clinical trials under the new mandate.

Table 5. Cost-Sharing Impact of SB 583

	Large Group	Small Group	Individual	CaIPERS HMO	Medi-Cal HMO
Number of people with cost-sharing impact from the mandate	4,536	1,337	944	218	-
Avg annual cost-sharing impact of cost-sharing impacted members (a)	\$12.17	\$12.01	\$13.41	\$12.13	\$ -
Avg annual cost-sharing of cost-sharing impacted members (b)	\$1,144.01	\$3,942.63	\$6,681.56	\$1,708.42	\$ -
% Avg annual cost-sharing impact of cost-sharing impacted members	1.1%	0.3%	0.2%	0.7%	0.0%

Source: California Health Benefits Review Program, 2019

Notes: (a) Not including impacts on premiums; (b) Includes member premium and cost sharing from deductibles, copayments, and coinsurance.

Potential Cost Offsets or Savings in the First 12 Months After Enactment

CHBRP is unable to quantify any cost offsets or savings in health care that would result in the first 12 months after enactment because of the provisions in SB 583, although there is potential for an increase in both negative health outcomes due to side effects or adverse effects from the clinical trial itself, and positive health outcomes due to successful testing of a new pharmaceutical or treatment.

Postmandate Administrative Expenses and Other Expenses

CHBRP estimates that the increase in administrative costs of DMHC-regulated plans and/or CDI-regulated policies will remain proportional to the increase in premiums. CHBRP assumes that if health care costs increase as a result of increased utilization or changes in unit costs, there is a corresponding proportional increase in administrative costs. CHBRP assumes that the administrative cost portion of

premiums is unchanged. All health plans and insurers include a component for administration and profit in their premiums.

Other Considerations for Policymakers

In addition to the impacts a bill may have on benefit coverage, utilization, and cost, related considerations for policymakers are discussed below.

Postmandate Changes in the Number of Uninsured Persons²⁴

Because the change in average premiums does not exceed 1% for any market segment (see Table 1, Table 6, and Table 7), CHBRP would expect no measurable change in the number of uninsured persons due to the enactment of SB 583.

Changes in Public Program Enrollment

CHBRP estimates that the mandate would produce no measurable impact on enrollment in publicly funded insurance programs due to the enactment of SB 583.

How Lack of Benefit Coverage Results in Cost Shifts to Other Payers

Public payers, including the Veteran's Administration, Medicare, and Medicaid, do provide coverage for routine health care services related to clinical trials for beneficiaries of those programs. Benefit coverage from Medicare and Medicaid is discussed in the *Policy Context* section. The Veteran's Administration administers their own clinical trials directly, and coverage is provided through the VA system (U.S. Veteran's Administration, 2019). These public payers do not generally cover the commercial and CalPERS enrollees in the DMHC-regulated plans or CDI-regulated policies that are subject to SB 583. However, the administrators of clinical trials often cover all related health care expenses for enrollees directly through their research funding.

²⁴ See also CHBRP's [Uninsured: Criteria and Methods for Estimating the Impact of Mandates on the Number of Individuals Who Become Uninsured in Response to Premium Increases \(December 2015\)](http://chbrp.com/analysis_methodology/cost_impact_analysis.php), available at http://chbrp.com/analysis_methodology/cost_impact_analysis.php.

Table 6. Baseline Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2020

	DMHC-Regulated						CDI-Regulated			Total
	Privately Funded Plans (by Market) (a)			Publicly Funded Plans			Privately Funded Plans (by Market) (a)			
	Large Group	Small Group	Individual	CalPERS HMOs (b)	MCMC (Under 65) (c)	MCMC (65+) (c)	Large Group	Small Group	Individual	
Enrollee counts										
Total enrollees in plans/policies subject to state mandates (d)	10,565,000	3,099,000	2,184,000	523,000	6,796,000	795,000	318,000	108,000	102,000	24,490,000
Total enrollees in plans/policies subject to SB 583	10,565,000	3,099,000	2,184,000	523,000	6,796,000	795,000	318,000	108,000	102,000	24,490,000
Premiums										
Average portion of premium paid by employer	\$555.35	\$341.99	\$0.00	\$493.71	\$268.13	\$694.55	\$710.92	\$462.84	\$0.00	\$118,029,198,000
Average portion of premium paid by employee	\$39.66	\$205.44	\$437.39	\$94.04	\$0.00	\$0.00	\$250.37	\$202.64	\$475.67	\$26,521,718,000
Total premium	\$595.01	\$547.43	\$437.39	\$587.76	\$268.13	\$694.55	\$961.29	\$665.48	\$475.67	\$144,550,916,000
Enrollee expenses										
For covered benefits (deductibles, copays, etc.)	\$46.18	\$121.03	\$115.38	\$48.33	\$0.00	\$0.00	\$162.44	\$186.84	\$168.51	\$14,750,880,000
For noncovered benefits (e)	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0
Total expenditures	\$641.19	\$668.46	\$552.77	\$636.08	\$268.13	\$694.55	\$1,123.73	\$852.31	\$644.18	\$159,301,796,000

Source: California Health Benefits Review Program, 2019.

Notes: (a) Includes enrollees with grandfathered and nongrandfathered health insurance acquired outside or through Covered California (the state's health insurance marketplace).

(b) Approximately 56.17% of CalPERS enrollees in DMHC-regulated plans are state retirees, state employees, or their dependents.

(c) Medi-Cal Managed Care Plan expenditures for members over 65 include those who are also Medicare beneficiaries. This population does not include enrollees in COHS.

(d) Enrollees in plans and policies regulated by DMHC or CDI aged 0 to 64 years as well as enrollees 65 years or older in employer-sponsored health insurance. This group includes commercial enrollees (including those associated with Covered California or CalPERS) and Medi-Cal beneficiaries enrolled in DMHC-regulated plans.²⁵

(e) Includes only those expenses that are paid directly by enrollees or other sources to providers for services related to the mandated benefit that are not currently covered by insurance. This only includes those expenses that would be newly covered postmandate. Other components of expenditures in this table include all health care services covered by insurance.

Key: CalPERS HMOs = California Public Employees' Retirement System Health Maintenance Organizations; CDI = California Department of Insurance; COHS = County Organized Health Systems; DMHC = Department of Managed Health Care; MCMC = Medi-Cal Managed Care.

²⁵ For more detail, see *Estimates of Sources of Health Insurance in California*, available at http://chbrp.com/analysis_methodology/cost_impact_analysis.php.

Table 7. Postmandate Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2020

	DMHC-Regulated						CDI-Regulated			Total
	Privately Funded Plans (by Market) (a)			Publicly Funded Plans			Privately Funded Plans (by Market) (a)			
	Large Group	Small Group	Individual	CalPERS HMOs (b)	MCMC (Under 65) (c)	MCMC (65+) (c)	Large Group	Small Group	Individual	
Enrollee counts										
Total enrollees in plans/policies subject to state mandates (d)	10,565,000	3,099,000	2,184,000	523,000	6,796,000	795,000	318,000	108,000	102,000	24,490,000
Total enrollees in plans/policies subject to SB 583	10,565,000	3,099,000	2,184,000	523,000	0	0	318,000	108,000	102,000	16,899,000
Premiums										
Average portion of premium paid by employer	\$0.0368	\$0.0260	\$0.0000	\$0.0329	\$0.0000	\$0.0000	\$0.0253	\$0.0183	\$0.0000	\$5,957,000
Average portion of premium paid by employee	\$0.0026	\$0.0156	\$0.0473	\$0.0063	\$0.0000	\$0.0000	\$0.0089	\$0.0080	\$0.0121	\$2,253,000
Total premium	\$0.0394	\$0.0416	\$0.0473	\$0.0391	\$0.0000	\$0.0000	\$0.0342	\$0.0262	\$0.0121	\$8,210,000
Enrollee expenses										
For covered benefits (deductibles, copays, etc.)	\$0.0004	\$0.0004	\$0.0005	\$0.0004	\$0.0000	\$0.0000	\$0.0004	\$0.0003	\$0.0001	\$91,000
For noncovered benefits (e)	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0
Total expenditures	\$0.0399	\$0.0421	\$0.0478	\$0.0396	\$0.0000	\$0.0000	\$0.0346	\$0.0265	\$0.0122	\$8,300,000
Percent change										
Premiums	0.0066%	0.0076%	0.0108%	0.0067%	0.0000%	0.0000%	0.0036%	0.0039%	0.0025%	0.0057%
Total expenditures	0.0062%	0.0063%	0.0087%	0.0062%	0.0000%	0.0000%	0.0031%	0.0031%	0.0019%	0.0052%

Source: California Health Benefits Review Program, 2019.

Notes: (a) Includes enrollees with grandfathered and nongrandfathered health insurance acquired outside or through Covered California (the state's health insurance marketplace).

(b) Approximately 56.17% of CalPERS enrollees in DMHC-regulated plans are state retirees, state employees, or their dependents.

(c) Medi-Cal Managed Care Plan expenditures for members over 65 include those who are also Medicare beneficiaries. This population does not include enrollees in COHS.

(d) Enrollees in plans and policies regulated by DMHC or CDI aged 0 to 64 years as well as enrollees 65 years or older in employer-sponsored health insurance. This group includes commercial enrollees (including those associated with Covered California or CalPERS) and Medi-Cal beneficiaries enrolled in DMHC-regulated plans.²⁶

(e) Includes only those expenses that are paid directly by enrollees or other sources to providers for services related to the mandated benefit that are not currently covered by insurance. This only includes those expenses that would be newly covered postmandate. Other components of expenditures in this table include all health care services covered by insurance.

Key: CalPERS HMOs = California Public Employees' Retirement System Health Maintenance Organizations; CDI = California Department of Insurance; COHS = County Organized Health Systems; DMHC = Department of Managed Health Care; MCMC = Medi-Cal Managed Care.

²⁶ For more detail, see *Estimates of Sources of Health Insurance in California*, available at http://chbrp.com/analysis_methodology/cost_impact_analysis.php.

LONG-TERM IMPACTS

In this section, CHBRP estimates the long-term impact²⁷ of SB 583, which CHBRP defines as impacts occurring beyond the first 12 months after implementation. These estimates are qualitative and based on the existing evidence available in the literature. CHBRP does not provide quantitative estimates of long-term impacts because of unknown improvements in clinical care, changes in prices, implementation of other complementary or conflicting policies, and other unexpected factors.

Long-Term Utilization and Cost Impacts

Utilization Impacts

Participation in clinical trials does have a supply-side cap, in that there are only so many spots in trials available. Additionally, enrollees have to meet the inclusion criteria to participate in a clinical trial. However, the provision of the ACA that requires insurers to cover routine health care related to participation in clinical trials and to allow self-referral (see further discussion in the *Policy Context* section), which went into effect in January 2014, may not yet be well known among administrators of clinical trials. This lack of knowledge likely contributed to the limited number of commercial and CalPERS enrollees whose current participation in a clinical trial generates charges for their plans and insurers.

The passage of SB 583 may increase the awareness of both the state mandate and the federal mandate, which may cause administrators of clinical trials to charge insurers for routine health care services more frequently in the future. 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 past the one- or two-year timeframe estimated in Table 1.

Cost Impacts

With potential increases in charges to plans and insurers for routine health care services for enrollees who participate in clinical trials, CHBRP estimates that the associated costs would also correspondingly increase, although CHBRP cannot quantify those potential future costs.

Long-Term Public Health Impacts

SB 583 would impact benefit coverage for commercial and CalPERS enrollees but would exempt the benefit coverage of Medi-Cal beneficiaries enrolled in DMHC-regulated plans. This means that commercial enrollees could self-refer for access to benefit coverage related to clinical trials whereas Medi-Cal enrollees would not. As presented in the *Background* section, 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.

²⁷ See also CHBRP's *Criteria and Guidelines for the Analysis of Long-Term Impacts on Healthcare Costs and Public Health*, available at http://www.chbrp.org/analysis_methodology/cost_impact_analysis.php.

APPENDIX A TEXT OF BILL ANALYZED

On February 22, 2019, the California Senate Committee on Health requested that CHBRP analyze SB 583.

SENATE BILL

No. 583

Introduced by Senator Jackson

February 22, 2019

An act to repeal and add Section 1370.6 of the Health and Safety Code, and to repeal and add Section 10145.4 of the Insurance Code, relating to clinical trials.

LEGISLATIVE COUNSEL'S DIGEST

SB 583, as introduced, Jackson. Clinical trials.

Existing law, the Knox-Keene Health Care Service Plan Act of 1975, provides for the licensure and regulation of health care service plans by the Department of Managed Health Care, and makes a willful violation of the act a crime. Existing law provides for the regulation of health insurers by the Department of Insurance. Existing law requires a health care service plan or health insurer to provide coverage for routine patient care costs related to a clinical trial for cancer, including, among other things, health care services required for the clinically appropriate monitoring of the investigational item or service. Existing law requires the clinical trial to either be exempt from a federal new drug application or be approved by a specified federal agency.

This bill would expand required coverage for clinical trials under a plan contract or insurance policy to include a clinical trial relating to the prevention, detection, or treatment of a life-threatening disease or condition, as defined, and include a trial funded by, among others, a qualified nongovernmental research entity. The bill would prohibit a plan contract or insurance policy from, among other things, discriminating against an enrollee or insured for participating in an approved clinical trial. The bill would authorize a plan or insurer to require a qualified enrollee or insured to participate in a clinical trial, as specified, and to restrict coverage to an approved clinical trial in this state, unless the clinical trial is not offered or available through a provider in this state. Because a willful violation of the bill's requirements relative to health care service plans would be a crime, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

DIGEST KEY

Vote: majority Appropriation: no Fiscal Committee: yes Local Program: yes

BILL TEXT

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. Section 1370.6 of the Health and Safety Code is repealed.

~~1370.6. (a) For an enrollee diagnosed with cancer and accepted into a phase I, phase II, phase III, or phase IV clinical trial for cancer, every health care service plan contract, except a specialized health care service plan contract, that is issued, amended, delivered, or renewed in this state, shall provide coverage for all routine patient care costs related to the clinical trial if the enrollee's treating physician, who is providing covered health care services to the enrollee under the enrollee's health benefit plan contract, recommends participation in the clinical trial after determining that participation in the clinical trial has a meaningful potential to benefit the enrollee. For purposes of this section, a clinical trial's endpoints shall not be defined exclusively to test toxicity, but shall have a therapeutic intent.~~

~~(b) (1) "Routine patient care costs" means the costs associated with the provision of health care services, including drugs, items, devices, and services that would otherwise be covered under the plan or contract if those drugs, items, devices, and services were not provided in connection with an approved clinical trial program, including:~~

~~(A) Health care services typically provided absent a clinical trial.~~

~~(B) Health care services required solely for the provision of the investigational drug, item, device, or service.~~

~~(C) Health care services required for the clinically appropriate monitoring of the investigational item or service.~~

~~(D) Health care services provided for the prevention of complications arising from the provision of the investigational drug, item, device, or service.~~

~~(E) Health care services needed for the reasonable and necessary care arising from the provision of the investigational drug, item, device, or service, including the diagnosis or treatment of the complications.~~

~~(2) For purposes of this section, “routine patient care costs” does not include the costs associated with the provision of any of the following:~~

~~(A) Drugs or devices that have not been approved by the federal Food and Drug Administration and that are associated with the clinical trial.~~

~~(B) Services other than health care services, such as travel, housing, companion expenses, and other nonclinical expenses, that an enrollee may require as a result of the treatment being provided for purposes of the clinical trial.~~

~~(C) Any item or service that is provided solely to satisfy data collection and analysis needs and that is not used in the clinical management of the patient.~~

~~(D) Health care services that, except for the fact that they are being provided in a clinical trial, are otherwise specifically excluded from coverage under the enrollee’s health plan.~~

~~(E) Health care services customarily provided by the research sponsors free of charge for any enrollee in the trial.~~

~~(3) Nothing in this section shall require a health care service plan contracting with the State Department of Health Services for the purpose of providing Medi-Cal benefits to enrolled beneficiaries or contracting with the Managed Risk Medical Insurance Board for the purposes of providing benefits under the Healthy Families Program, the Access for Infants and Mothers Program, or the California Major Risk Medical Insurance Program, to be responsible for reimbursement of services excluded from their contract because another entity is responsible by statute or otherwise for reimbursement of the service provider.~~

~~(c) The treatment shall be provided in a clinical trial that either:~~

~~(1) Involves a drug that is exempt under federal regulations from a new drug application.~~

~~(2) Is approved by one of the following:~~

~~(A) One of the National Institutes of Health.~~

~~(B) The federal Food and Drug Administration, in the form of an investigational new drug application.~~

~~(C) The United States Department of Defense.~~

~~(D) The United States Veterans’ Administration.~~

~~(d) In the case of health care services provided by a participating provider, the payment rate shall be at the agreed-upon rate. In the case of a nonparticipating provider, the payment shall be at the negotiated rate the plan would otherwise pay to a participating provider for the same services, less any applicable copayments and deductibles.~~

~~(e) Nothing in this section shall be construed to prohibit a health care service plan from restricting coverage for clinical trials to participating hospitals and physicians in California unless the protocol for the clinical trial is not provided for at a California hospital or by a California physician.~~

~~(f) The provision of services when required by this section shall not, in itself, give rise to liability on the part of the health care service plan.~~

~~(g) Nothing in this section shall be construed to limit, prohibit, or modify an enrollee's rights to the independent review process available under Section 1370.4 or to the Independent Medical Review System available under Article 5.55 (commencing with Section 1374.30).~~

~~(h) Nothing in this section shall be construed to otherwise limit or modify any existing requirements under the provisions of this chapter or to prevent application of copayment or deductible provisions in a plan.~~

~~(i) Copayments and deductibles applied to services delivered in a clinical trial shall be the same as those applied to the same services if not delivered in a clinical trial.~~

SEC. 2. Section 1370.6 is added to the Health and Safety Code, to read:

1370.6. (a) An individual or group health care service plan contract that is issued, amended, or renewed on or after January 1, 2020, shall not:

(1) Deny a qualified enrollee's participation in an approved clinical trial.

(2) Deny, limit, or impose additional conditions on the coverage of routine patient care costs for items and services furnished in connection with a qualified enrollee's participation in an approved clinical trial.

(3) Discriminate against an enrollee based on the qualified enrollee's participation in an approved clinical trial.

(b) (1) Subdivision (a) applies to:

(A) A qualified enrollee participating in an approved clinical trial conducted by a participating provider.

(B) A qualified enrollee participating in an approved clinical trial conducted by a nonparticipating provider, including a nonparticipating provider located outside this state, if the clinical trial is not offered or available through a participating provider.

(2) If one or more participating providers is conducting an approved clinical trial, a health care service plan may require a qualified enrollee to participate in the clinical trial through a participating provider if the participating provider accepts the enrollee as a clinical trial participant.

(3) A health care service plan may restrict coverage to an approved clinical trial in this state, unless the clinical trial is not offered or available through a provider in this state.

(c) (1) The payment rate for routine patient care costs provided by a participating provider under a contract that is issued, amended, or renewed on or after January 1, 2020, shall be the negotiated rate the health care service plan would otherwise pay a participating provider for the same services, less applicable cost sharing.

(2) Cost sharing for routine patient care costs shall be the same as that applied to the same services not delivered in a clinical trial, except that the in-network cost sharing and out-of-pocket maximum shall apply if the clinical trial is not offered or available through a participating provider.

(3) This section does not limit or modify any existing requirements under this chapter or prevent application of cost-sharing provisions in a contract, except as provided in paragraph (2).

(d) For purposes of this section:

(1) “Approved clinical trial” means a phase I, phase II, phase III, or phase IV clinical trial conducted in relation to the prevention, detection, or treatment of cancer or another life-threatening disease or condition that meets at least one of the following:

(A) The study or investigation is approved or funded, which may include funding through in-kind donations, by one or more of the following:

(i) The National Institutes of Health.

(ii) The federal Centers for Disease Control and Prevention.

(iii) The Agency for Healthcare Research and Quality.

(iv) The Centers for Medicare and Medicaid Services.

(v) A cooperative group or center of any of the entities described in clauses (i) to (iv), inclusive, the Department of Defense, or the United States Department of Veterans Affairs.

(vi) A qualified nongovernmental research entity identified in the guidelines issued by the National Institutes of Health for center support grants.

(vii) One of the following departments, if the study or investigation has been reviewed and approved through a system of peer review that the Secretary of the United States Department of Health and Human Services determines is comparable to the system of peer review used by the National Institutes of Health and assures unbiased review of the highest scientific standards by qualified individuals who have no interest in the outcome of the review:

(I) The United States Department of Veterans Affairs.

(II) The United States Department of Defense.

(III) The United States Department of Energy.

(B) The study or investigation is conducted under an investigational new drug application reviewed by the United States Food and Drug Administration.

(C) The study or investigation is a drug trial that is exempt from an investigational new drug application reviewed by the United States Food and Drug Administration.

(2) “Life-threatening disease or condition” means a disease or condition from which the likelihood of death is probable, unless the course of the disease or condition is interrupted.

(3) “Qualified enrollee” means an enrollee who meets both of the following conditions:

(A) The enrollee is eligible to participate in an approved clinical trial, according to the clinical trial protocol, for the treatment of cancer or another life-threatening disease or condition.

(B) Either of the following applies:

(i) The referring health care professional is a participating provider and has concluded that the enrollee’s participation in the clinical trial would be appropriate because the enrollee meets the conditions of subparagraph (A).

(ii) The enrollee provides medical and scientific information establishing that the enrollee’s participation in the trial would be appropriate because the enrollee meets the conditions of subparagraph (A).

(4) “Routine patient care costs” include drugs, items, devices, and services provided consistent with coverage under the contract for an enrollee who is not enrolled in an approved clinical trial, including the following:

(A) Drugs, items, devices, and services typically covered absent a clinical trial.

(B) Drugs, items, devices, and services required solely for the provision of an investigational drug, item, device, or service.

(C) Drugs, items, devices, and services required for the clinically appropriate monitoring of the investigational drug, item, device, or service.

(D) Drugs, items, devices, and services provided for the prevention of complications arising from the provision of the investigational drug, item, device, or service.

(E) Drugs, items, devices, and services needed for the reasonable and necessary care arising from the provision of the investigational drug, item, device, or service, including diagnosis and treatment of complications.

(5) “Routine patient care costs” does not include the following:

(A) The investigational drug, item, device, or service itself.

(B) Drugs, items, devices, and services provided solely to satisfy data collection and analysis needs that are not used in the direct clinical management of the enrollee.

(C) Drugs, items, devices, and services specifically excluded from coverage in the contract, except for drugs, items, devices, and services required to be covered pursuant to this section or other applicable law.

(D) Drugs, items, devices, and services customarily provided free of charge to a clinical trial participant by the research sponsor.

(e) This section shall not be construed to limit coverage provided by a health care service plan with respect to clinical trials.

(f) The provision of services required by this section shall not, in itself, give rise to liability on the part of the health care service plan.

(g) This section does not apply to vision-only, dental-only, accident-only, specified disease, hospital indemnity, Medicare supplement, CHAMPUS supplement, long-term care, or disability income plan contracts, except that for specified disease and hospital indemnity plan contracts, coverage for benefits under this section shall apply, but only to the extent that the benefits are covered under the general terms and conditions that apply to all other benefits under the contract. This section shall not be construed as imposing a new benefit mandate on specified disease or hospital indemnity plans.

(h) This section does not limit, prohibit, or modify an enrollee's rights to the independent review process available under Section 1370.4 or to the Independent Medical Review System available under Article 5.55 (commencing with Section 1374.30).

SEC. 3. Section 10145.4 of the Insurance Code is repealed.

~~10145.4. (a) For an insured diagnosed with cancer and accepted into a phase I, phase II, phase III, or phase IV clinical trial for cancer, every policy of disability insurance that provides hospital, medical, or surgical coverage in this state shall provide coverage for all routine patient care costs related to the clinical trial if the insured's treating physician, who is providing covered health care services to the insured under the insured's health benefit plan contract, recommends participation in the clinical trial after determining that participation in the clinical trial has a meaningful potential to benefit the insured. For purposes of this section, a clinical trial's endpoints shall not be defined exclusively to test toxicity, but shall have a therapeutic intent.~~

~~(b)(1) "Routine patient care costs" means the costs associated with the provision of health care services, including drugs, items, devices, and services that would otherwise be covered under the plan or contract if those drugs, items, devices, and services were not provided in connection with an approved clinical trial program, including the following:~~

~~(A) Health care services typically provided absent a clinical trial.~~

~~(B) Health care services required solely for the provision of the investigational drug, item, device, or service.~~

~~(C) Health care services required for the clinically appropriate monitoring of the investigational item or service.~~

~~(D) Health care services provided for the prevention of complications arising from the provision of the investigational drug, item, device, or service.~~

~~(E) Health care services needed for the reasonable and necessary care arising from the provision of the investigational drug, item, device, or service, including the diagnosis or treatment of the complications.~~

~~(2) For purposes of this section, "routine patient care costs" does not include the costs associated with the provision of any of the following:~~

~~(A) Drugs or devices that have not been approved by the federal Food and Drug Administration and that are associated with the clinical trial.~~

~~(B) Services other than health care services, such as travel, housing, companion expenses, and other nonclinical expenses, that an insured may require as a result of the treatment being provided for purposes of the clinical trial.~~

~~(C) Any item or service that is provided solely to satisfy data collection and analysis needs and that is not used in the clinical management of the patient.~~

~~(D)Health care services which, except for the fact that they are not being provided in a clinical trial, are otherwise specifically excluded from coverage under the insured's health plan.~~

~~(E)Health care services customarily provided by the research sponsors free of charge for any enrollee in the trial.~~

~~(c)The treatment shall be provided in a clinical trial that either (1) involves a drug that is exempt under federal regulations from a new drug application or (2) that is approved by one of the following:~~

~~(A)One of the National Institutes of Health.~~

~~(B)The federal Food and Drug Administration, in the form of an investigational new drug application.~~

~~(C)The United States Department of Defense.~~

~~(D)The United States Veterans' Administration.~~

~~(d)In the case of health care services provided by a contracting provider, the payment rate shall be at the agreed upon rate. In the case of a noncontracting provider, the payment shall be at the negotiated rate the insurer would otherwise pay to a contracting provider for the same services, less applicable copayments and deductibles. Nothing in this section shall be construed to prohibit a disability insurer from restricting coverage for clinical trials to hospitals and physicians in California unless the protocol for the clinical trial is not provided for at a California hospital or by a California physician.~~

~~(e)The provision of services when required by this section shall not, in itself, give rise to liability on the part of the insurer.~~

~~(f)This section shall not apply to vision only, dental only, accident only, specified disease, hospital indemnity, Medicare supplement, CHAMPUS supplement, long-term care, or disability income insurance, except that for specified disease and hospital indemnity insurance, coverage for benefits under this section shall apply, but only to the extent that the benefits are covered under the general terms and conditions that apply to all other benefits under the policy. Nothing in this section shall be construed as imposing a new benefit mandate on specified disease or hospital indemnity insurance.~~

~~(g)Nothing in this section shall be construed to prohibit, limit, or modify an insured's rights to the independent review process available under Section 10145.3 or to the Independent Medical Review System available under Article 3.5 (commencing with Section 10169).~~

~~(h)Nothing in this section shall be construed to otherwise limit or modify any existing requirements under the provisions of this chapter or to prevent application of deductible or copayment provisions contained in the policy.~~

~~(i) Copayments and deductibles applied to services delivered in a clinical trial shall be the same as those applied to the same services if not delivered in a clinical trial.~~

SEC. 4. Section 10145.4 is added to the Insurance Code, to read:

10145.4. (a) An individual or group health insurance policy that is issued, amended, or renewed on or after January 1, 2020, shall not:

- (1) Deny a qualified insured's participation in an approved clinical trial.
- (2) Deny, limit, or impose additional conditions on the coverage of routine patient care costs for items and services furnished in connection with a qualified insured's participation in an approved clinical trial.
- (3) Discriminate against an insured based on the qualified insured's participation in an approved clinical trial.

(b) (1) Subdivision (a) applies to:

(A) A qualified insured participating in an approved clinical trial conducted by a participating provider.

(B) A qualified insured participating in an approved clinical trial conducted by a nonparticipating provider, including a nonparticipating provider located outside this state, if the clinical trial is not offered or available through a participating provider.

(2) If one or more participating providers is conducting an approved clinical trial, a health insurer may require a qualified insured to participate in the clinical trial through a participating provider if the participating provider accepts the insured as a clinical trial participant.

(3) A health insurer may restrict coverage to an approved clinical trial in this state, unless the clinical trial is not offered or available through a provider in this state.

(c) (1) The payment rate for routine patient care costs provided by a participating provider under a contract that is issued, amended, or renewed on or after January 1, 2020, shall be the negotiated rate the health insurer would otherwise pay a participating provider for the same services, less applicable cost sharing.

(2) Cost sharing for routine patient care costs shall be the same as that applied to the same services not delivered in a clinical trial, except that the in-network cost sharing and out-of-pocket maximum shall apply if the clinical trial is not offered or available through a participating provider.

(3) This section does not limit or modify any existing requirements under this chapter or prevent application of cost-sharing provisions in a contract, except as provided in paragraph (2).

(d) For purposes of this section:

(1) “Approved clinical trial” means a phase I, phase II, phase III, or phase IV clinical trial conducted in relation to the prevention, detection, or treatment of cancer or another life-threatening disease or condition that meets at least one of the following:

(A) The study or investigation is approved or funded, which may include funding through in-kind donations, by one or more of the following:

(i) The National Institutes of Health.

(ii) The federal Centers for Disease Control and Prevention.

(iii) The Agency for Healthcare Research and Quality.

(iv) The Centers for Medicare and Medicaid Services.

(v) A cooperative group or center of any of the entities described in clauses (i) to (iv), inclusive, the Department of Defense, or the United States Department of Veterans Affairs.

(vi) A qualified nongovernmental research entity identified in the guidelines issued by the National Institutes of Health for center support grants.

(vii) One of the following departments, if the study or investigation has been reviewed and approved through a system of peer review that the Secretary of the United States Department of Health and Human Services determines is comparable to the system of peer review used by the National Institutes of Health and assures unbiased review of the highest scientific standards by qualified individuals who have no interest in the outcome of the review:

(I) The United States Department of Veterans Affairs.

(II) The United States Department of Defense.

(III) The United States Department of Energy.

(B) The study or investigation is conducted under an investigational new drug application reviewed by the United States Food and Drug Administration.

(C) The study or investigation is a drug trial that is exempt from an investigational new drug application reviewed by the United States Food and Drug Administration.

(2) “Life-threatening disease or condition” means a disease or condition from which the likelihood of death is probable, unless the course of the disease or condition is interrupted.

(3) “Qualified insured” means an insured who meets both of the following conditions:

(A) The insured is eligible to participate in an approved clinical trial, according to the clinical trial protocol, for the treatment of cancer or another life-threatening disease or condition.

(B) Either of the following applies:

(i) The referring health care professional is a participating provider and has concluded that the insured’s participation in the clinical trial would be appropriate because the insured meets the conditions of subparagraph (A).

(ii) The insured provides medical and scientific information establishing that the insured’s participation in the trial would be appropriate because the insured meets the conditions of subparagraph (A).

(4) “Routine patient care costs” include drugs, items, devices, and services provided consistent with coverage under the contract for an insured who is not enrolled in an approved clinical trial, including the following:

(A) Drugs, items, devices, and services typically covered absent a clinical trial.

(B) Drugs, items, devices, and services required solely for the provision of an investigational drug, item, device, or service.

(C) Drugs, items, devices, and services required for the clinically appropriate monitoring of the investigational drug, item, device, or service.

(D) Drugs, items, devices, and services provided for the prevention of complications arising from the provision of the investigational drug, item, device, or service.

(E) Drugs, items, devices, and services needed for the reasonable and necessary care arising from the provision of the investigational drug, item, device, or service, including diagnosis and treatment of complications.

(5) “Routine patient care costs” does not include the following:

(A) The investigational drug, item, device, or service itself.

(B) Drugs, items, devices, and services provided solely to satisfy data collection and analysis needs that are not used in the direct clinical management of the insured.

(C) Drugs, items, devices, and services specifically excluded from coverage in the contract, except for drugs, items, devices, and services required to be covered pursuant to this section or other applicable law.

(D) Drugs, items, devices, and services customarily provided free of charge to a clinical trial participant by the research sponsor.

(e) This section shall not be construed to limit coverage provided by a health insurer with respect to clinical trials.

(f) The provision of services required by this section shall not, in itself, give rise to liability on the part of the health insurer.

(g) This section does not apply to vision-only, dental-only, accident-only, specified disease, hospital indemnity, Medicare supplement, CHAMPUS supplement, long-term care, or disability income insurance policies, except that for specified disease and hospital indemnity insurance, coverage for benefits under this section shall apply, but only to the extent that the benefits are covered under the general terms and conditions that apply to all other benefits under the policy. This section shall not be construed as imposing a new benefit mandate on specified disease or hospital indemnity insurance.

(h) This section does not limit, prohibit, or modify an insured's rights to the independent review process available under Section 10145.3 or to the Independent Medical Review System available under Article 3.5 (commencing with Section 10169).

SEC. 5. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

APPENDIX B COST IMPACT ANALYSIS: DATA SOURCES, CAVEATS, AND ASSUMPTIONS

The cost analysis in this report was prepared by the members of the cost team, which consists of CHBRP task force members and contributors from the University of California, Los Angeles, and the University of California, Davis, as well as the contracted actuarial firm, Milliman, Inc. (Milliman).²⁸

Information on the generally used data sources and estimation methods, as well as caveats and assumptions generally applicable to CHBRP's cost impacts analyses are available at CHBRP's website.²⁹

This appendix describes analysis-specific data sources, estimation methods, caveats and assumptions used in preparing this cost impact analysis.

Analysis-Specific Caveats and Assumptions

This subsection discusses the caveats and assumptions relevant specifically to an analysis of SB 583. The population subject to the mandated offering includes enrollees in DMHC-regulated plans and CDI-regulated policies for large-group, small-group, and individual marketplace plans, and CalPERS plans.

Baseline commercial clinical trial-related services and associated utilization were based on 2016 MarketScan® and Milliman's proprietary 2016 Consolidated Health Cost Guidelines™ Source Database (CHSD) commercial claims and enrollment data for the state of California. Baseline Medi-Cal clinical trial-related services and associated utilization were based on Milliman's CHSD Medi-Cal claims and enrollment data for the state of California.

- CHBRP expects that the cost per service remains the same between premandate and postmandate.
- CHBRP assumes that the mandate would not impact any forms of member cost sharing, such as deductibles, copays, and coinsurance.

The following table lists the diagnosis and procedure codes used to identify clinical trial-related services. Most codes do not distinguish between cancer and noncancer clinical trials. Additionally, CHBRP could not distinguish between clinical trials for life-threatening and clinical trials for non-life-threatening conditions. Therefore, the utilization CHBRP captured reflects all clinical trial-related services.

Clinical trial-related services use Healthcare Common Procedure Coding System (HCPCS) and Current Procedural Terminology (CPT) codes identified with carrier coverage guidelines and reviewed by a content expert.

²⁸ CHBRP's authorizing statute, available at http://chbrp.com/CHBRP%20authorizing%20statute_2018_FINAL.pdf, requires that CHBRP use a certified actuary or "other person with relevant knowledge and expertise" to determine financial impact.

²⁹ See method documents posted here, http://chbrp.com/analysis_methodology/cost_impact_analysis.php; in particular, see *2019 Cost Analyses: Data Sources, Caveats, and Assumptions*.

Table 8. Diagnosis Codes for Clinical Trial–Related Services

Diagnosis Codes (ICD-10)	Description
Z00.6	Encounter for examination for normal comparison and control in clinical research program

Table 9. CPT/HCPCS Codes for Clinical Trial–Related Services

CPT/HCPCS Codes	Description
G0276	Blinded procedure for lumbar stenosis, percutaneous image-guided lumbar decompression (PILD) or placebo-control, performed in an approved coverage with evidence development (CED) clinical trial
G0293	Noncovered surgical procedure(s) using conscious sedation, regional, general or spinal anesthesia in a Medicare-qualifying clinical trial, per day
G0294	Noncovered procedure(s) using either no anesthesia or local anesthesia only, in a Medicare-qualifying clinical trial, per day
G8928	Adjuvant chemotherapy not prescribed or previously received, for documented reasons
G9057	Oncology; practice guidelines; management differs from guidelines as a result of patient enrollment in an institutional review board–approved clinical trial (for use in a Medicare-approved demonstration project)
G9196	Documentation of medical reason(s) for not ordering a first- or second-generation cephalosporin for antimicrobial prophylaxis (e.g., patients enrolled in clinical trials, patients with documented infection prior to surgical procedure of interest, patients who were receiving antibiotics more than 24 hours prior to surgery [except colon surgery patients taking oral prophylactic antibiotics], patients who were receiving antibiotics within 24 hours prior to arrival [except colon surgery patients taking oral prophylactic antibiotics], other medical reason(s))
G9361	Medical indication for induction (documentation of reason(s) for elective delivery [c-section] or early induction [e.g., hemorrhage and placental complications, hypertension, preeclampsia and eclampsia, rupture of membranes-premature or prolonged, maternal conditions complicating pregnancy/delivery, fetal conditions complicating pregnancy/delivery, late pregnancy, prior uterine surgery, or participation in clinical trial])
G9537	Documentation of system reason(s) for ordering an advanced brain imaging study (i.e., needed as part of a clinical trial; other clinician ordered the study)
G9927	Documentation of system reason(s) for not prescribing warfarin or another FDA-approved anticoagulation due to patient being currently enrolled in a clinical trial related to AF/atrial flutter treatment
S9988	Services provided as part of a Phase I clinical
S9990	Services provided as part of a Phase II clinical
S9991	Services provided as part of a Phase III clinical

CPT/HCPCS Codes	Description
S9992	Transportation costs to and from trial location and local transportation costs (e.g., fares for taxicab or bus) for clinical trial participant and one caregiver/companion
S9994	Lodging costs (e.g., hotel charges) for clinical trial participant and one caregiver/companion
S9996	Meals for clinical trial participant and one caregiver/companion

Table 10. CPT/HCPCS Modifiers for Clinical Trial–Related Services

CPT/HCPCS Codes	Description
Q0	Investigational clinical service provided in a clinical research study that is in an approved clinical research study
Q01	Routine clinical service provided in a clinical research study that is in an approved clinical research study

Baseline unit costs were trended at an annual rate of 2.0% per year from 2016 to 2020 based on the 2018 medical component of CPI. The analysis assumes that the unit cost per service does not change postmandate.

The analysis assumed that utilization rates per 1,000 enrollees change postmandate only due to increased coverage. Baseline utilization rates per 1,000 were developed based on MarketScan and CHSD data for commercial enrollees and CHSD for Medi-Cal enrollees.

Carrier surveys were administered to estimate the percentage of enrollees who had coverage for noncancer clinical trial–related services. Results from the surveys for commercial health plans and insurers indicate 100% coverage for clinical trial–related services. The carrier surveys indicated that 7% of enrollees have the ability to self-refer based on medical literature which would increase to 100% postmandate.

Determining Public Demand for the Proposed Mandate

This subsection discusses public demand for the benefits SB 583 would mandate. Considering the criteria specified by CHBRP’s authorizing statute, CHBRP reviews public demand for benefits relevant to a proposed mandate in two ways. CHBRP:

- Considers the bargaining history of organized labor; and
- Compares the benefits provided by self-insured health plans or policies (which are not regulated by DMHC or CDI and therefore not subject to state-level mandates) with the benefits that are provided by plans or policies that would be subject to the mandate.

On the basis of conversations with the largest collective bargaining agents in California, CHBRP concluded that unions currently do not include cost-sharing arrangements for coverage for routine health

care services related to participation in a clinical trial. In general, unions negotiate for broader contract provisions such as coverage for dependents, premiums, deductibles, and broad coinsurance levels.

Among publicly funded self-insured health insurance policies, the preferred provider organization (PPO) plans offered by CalPERS currently have the largest number of enrollees. The CalPERS PPOs currently provide benefit coverage similar to what is available through group health insurance plans and policies that would be subject to the mandate.

To further investigate public demand, CHBRP used the bill-specific coverage survey to ask carriers who act as third-party administrators for (non-CalPERS) self-insured group health insurance programs whether the relevant benefit coverage differed from what is offered in group market plans or policies that would be subject to the mandate. The responses indicated that there were no substantive differences.

Second Year Impacts on Benefit Coverage, Utilization, and Cost

In order to develop Table 11, CHBRP has considered whether continued implementation during the second year of the benefit coverage requirements of SB 583 would have a substantially different impact on utilization of either the tests, treatments, or services for which coverage was directly addressed, the utilization of any indirectly affected utilization, or both. To generate this table, CHBRP reviewed the literature and consulted content experts about the possibility of varied second year impacts and applied what was learned to a projection of a second year of implementation.

As displayed in Table 11, the second year's impacts of SB 583 would be substantially the same as the impacts in the first year (see Table 1).

Table 11. Impacts of SB 583 Impacts on Benefit Coverage, Utilization, and Cost, 2021

	Baseline	Postmandate	Increase/ Decrease	Percentage Change
Benefit coverage				
Total enrollees with health insurance subject to state benefit mandates (a)	24,395,000	24,395,000	0	0%
Total enrollees subject to SB 583	16,894,000	16,894,000	0	0%
Total percentage of enrollees with health insurance subject to SB 583	69%	69%	0%	0%
Total percentage of enrollees with coverage for clinical trials	100%	100%	0%	0%
Total percentage of enrollees with ability to self-refer to clinical trials	7%	100%	93%	1339%
Utilization and unit cost				
Number of enrollees participating in clinical trials	7,034	7,370	337	5%
Clinical trial participants per 1,000 enrollees	0.416	0.436	0.020	5%
Utilization per person enrolled in clinical trials				
Inpatient days	0.713	0.713	0.000	0%
Outpatient visits	2.872	2.872	0.000	0%
Professional visits	0.458	0.458	0.000	0%
Professional procedures	1.731	1.731	0.000	0%
Average cost per person enrolled in clinical trials	\$20,959	\$20,959	\$0.00	0%
Expenditures				
<u>Premiums by payer</u>				
Private employers for group insurance	\$90,700,422,000	\$90,706,294,000	\$5,872,000	0.0065%
CalPERS HMO employer expenditures (c) (b)	\$3,234,903,000	\$3,235,114,000	\$211,000	0.0065%
Medi-Cal Managed Care Plan expenditures	\$29,186,401,000	\$29,186,401,000	\$0	0.0000%
Enrollees with individually purchased insurance	\$13,111,153,000	\$13,112,412,000	\$1,259,000	0.0096%
Enrollees with group insurance, CalPERS HMOs, Covered California, and Medi-Cal Managed Care (c)	\$15,255,718,000	\$15,256,737,000	\$1,019,000	0.0067%
<u>Enrollee expenses</u>				
For covered benefits (deductibles, copayments, etc.)	\$15,636,259,000	\$15,636,351,000	\$92,000	0.0006%
For noncovered benefits (d) (e)	---	---	---	---
Total expenditures	\$167,124,856,000	\$167,133,309,000	\$8,453,000	0.0051%

Source: California Health Benefits Review Program, 2019.

Notes: (a) Enrollees in plans and policies regulated by DMHC or CDI aged 0 to 64 years as well as enrollees 65 years or older in employer-sponsored health insurance. This group includes commercial enrollees (including those associated with Covered California or CalPERS) and Medi-Cal beneficiaries enrolled in DMHC-regulated plans.³⁰

(b) Approximately 56.17% of CalPERS enrollees in DMHC-regulated plans are state retirees, state employees, or their dependents.

(c) Enrollee premium expenditures include contributions by employees to employer-sponsored health insurance, health insurance purchased through Covered California, and contributions to Medi-Cal Managed Care.

(d) Includes only expenses paid directly by enrollees (or other sources) to providers for services related to the mandated benefit that are not currently covered by insurance. This only includes those expenses that would be newly covered postmandate. Other components of expenditures in this table include all health care services covered by insurance.

(e) Although enrollees with newly compliant benefit coverage may have paid for some health care services related to clinical trial participation before SB 583, CHBRP cannot estimate the frequency with which such situations may have occurred and therefore cannot estimate the related expense. Postmandate, such expenses would be eliminated, though enrollees with newly compliant benefit coverage might, postmandate, pay for some such services for which coverage is denied (through utilization management review), as some enrollees who always had compliant benefit coverage may have done and may continue to do, postmandate.

Key: CalPERS = California Public Employees' Retirement System; CDI = California Department of Insurance; DMHC = Department of Managed Health Care; HMO = Health Maintenance Organizations

³⁰ For more detail, see *Estimates of Sources of Health Insurance in California*, available at http://chbrp.com/analysis_methodology/cost_impact_analysis.php.

REFERENCES

- American Cancer Society Cancer Action Network (ACS CAN). *Barriers to Patient Enrollment in Therapeutic Clinical Trials for Cancer: A Landscape Report*. Washington DC: American Cancer Society Cancer Action Network; 2018.
- Blue Cross and Blue Shield Association (BCBSA). *State Legislative Health Care and Insurance Issues: 2015 Survey of Plans*. Washington, DC: The Blue Cross and Blue Shield Association, Office of Policy and Representation; 2016
- Center for Information and Study on Clinical Research Participation (CISCRP). *Estimated total number of volunteers completing clinical trials in 2015* [Powerpoint slide]. 2015. Available at: <https://www.ciscrp.org/wp-content/uploads/2018/05/Total-Volunteers.jpg>. Accessed March 25, 2019.
- Center for Information and Study on Clinical Research Participation (CISCRP). *Top participation reasons similar to prior years* [Powerpoint slide]. 2017. Available at: <https://www.ciscrp.org/wp-content/uploads/2018/05/Top-Participation-Reasons-1280x720.jpg>. Accessed March 25, 2019.
- Centers for Disease Control and Prevention (CDC). NCHHSTP Social Determinants of Health. Frequently Asked Questions. Page last reviewed: March 10, 2014. Available at: <http://www.cdc.gov/nchhstp/socialdeterminants/faq.html>. Accessed August 27, 2015.
- ClinicalTrials.gov. ClinicalTrials.gov Database. February 2019. Available at: <https://clinicaltrials.gov/>. Accessed February 23, 2019; March 25, 2019.
- Freedman LS, Simon R, Foulkes MA, et al. Inclusion of women and minorities in clinical trials and the NIH Revitalization Act of 1993—the perspective of NIH clinical trialists. *Controlled Clinical Trials*. 1995;16(5):277-285; discussion 286-279, 293-309.
- Friedman DB, Foster C, Bergeron CD, Tanner A, Kim SH. A qualitative study of recruitment barriers, motivators, and community-based strategies for increasing clinical trials participation among rural and urban populations. *American Journal of Health Promotion*. 2015; 29(5): 332-338.
- Hamel LM, Penner LA, Albrecht TL, Heath E, Gwede CK, Eggly S. Barriers to clinical trial enrollment in racial and ethnic minority patients with cancer. *Cancer Control*. 2016;23(4):327-337.
- Hutchins LF, Unger JM, Crowley JJ, Coltman CA, Jr., Albain KS. Underrepresentation of patients 65 years of age or older in cancer-treatment trials. *New England Journal of Medicine*. 1999;341(27):2061-2067.
- Kaiser Health News. *Want Into a Clinical Trial? Read This First*. January 2016. Available at: <https://khn.org/news/want-into-a-clinical-trial-read-this-first/>. Accessed April 1, 2019.
- Kanarek NF, Tsai HL, Metzger-Gaud S, et al. Geographic proximity and racial disparities in cancer clinical trial participation. *Journal of the National Comprehensive Cancer Network: JNCCN*. 2010;8(12):1343-1351.
- Kinney AY, Richards C, Vernon SW, Vogel VG. The effect of physician recommendation on enrollment in the Breast Cancer Chemoprevention Trial. *Preventive Medicine*. 1998;27(5 Pt 1):713-719.

- Klamerus JF, Bruinooge SS, Ye X, et al. The impact of insurance on access to cancer clinical trials at a comprehensive cancer center. *Clinical Cancer Research: An Official Journal of the American Association for Cancer Research*. 2010;16(24):5997-6003.
- Kwiatkowski K, Coe K, Bailar JC, Swanson GM. Inclusion of minorities and women in cancer clinical trials, a decade later: Have we improved? *Cancer*. 2013;119(16):2956-2963.
- Labots G, Jones A, de Visser SJ, Rissmann R, Burggraaf J. Gender differences in clinical registration trials: is there a real problem? *British Journal of Clinical Pharmacology*. 2018;84(4):700-707.
- Leiter A, Diefenbach MA, Doucette J, Oh WK, Galsky MD. Clinical trial awareness: Changes over time and sociodemographic disparities. *Clinical Trials*. 2015;12(3): 215-223.
- Mahipal A, Denson AC, Djulbegovic B, et al. Effect of Age on Clinical Outcomes in Phase 1 Trial Participants. *Cancer Control*. 2015;22(2):235-241.
- Mariotti V, Gonzalez Velez M, Duma N, et al. Early phase clinical trials conducted in North America are more likely to exclude breast cancer patients based on organ function and comorbidities compared to other countries: Analysis of 484 studies. *European Journal of Cancer*. 2017;72:S25.
- Martin SS, Ou FS, Newby LK, et al. Patient- and trial-specific barriers to participation in cardiovascular randomized clinical trials. *Journal of the American College of Cardiology*. 2013;61(7):762-769.
- Moffitt K, Brogan F, Brown C, et al. Statewide cancer clinical trial navigation service. *Journal of Oncology Practice*. 2010;6(3):127-132.
- National Institutes of Health (NIH). *NIH Clinical Research Trials and You: The Basics*. October 2017a. Available at: <https://www.nih.gov/health-information/nih-clinical-research-trials-you/basics>. Accessed March 14, 2019.
- National Institutes of Health (NIH). Revision: *NIH Policy and Guidelines on the Inclusion of Individuals Across the Lifespan as Participants in Research Involving Human Subjects*. December 2017b. Available at: <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-116.html>. Accessed April 1, 2019.
- Office of Disease Prevention and Health Promotion. Healthy People 2020: Social Determinants of Health. Available at: <http://www.healthypeople.gov/2020/topics-objectives/topic/socialdeterminantshealth/addressing-determinants>. Accessed February 16, 2016.
- Parsons HM, Harlan LC, Seibel NL, Stevens JL, Keegan TH. Clinical trial participation and time to treatment among adolescents and young adults with cancer: does age at diagnosis or insurance make a difference? *Journal of Clinical Oncology: Official Journal of the American Society of Clinical Oncology*. 2011;29(30):4045-4053.
- Townsley CA, Selby R, Siu LL. Systematic review of barriers to the recruitment of older patients with cancer onto clinical trials. *Journal of Clinical Oncology: Official Journal of the American Society of Clinical Oncology*. 2005;23(13):3112-3124.
- Umutyan A, Chiechi C, Beckett LA, et al. Overcoming barriers to cancer clinical trial accrual: impact of a mass media campaign. *Cancer*. 2008;112(1):212-219.

Unger JM, Gralow JR, Albain KS, Ramsey SD, Hershman DL. Patient Income Level and Cancer Clinical Trial Participation: A Prospective Survey Study. *JAMA Oncology*. 2016;2(1):137-139.

Unger JM, Hershman DL, Albain KS, et al. Patient income level and cancer clinical trial participation. *Journal of Clinical Oncology: Official Journal of the American Society of Clinical Oncology*. 2013;31(5):536-542.

U.S. Census Bureau. United States 2018 Population Estimates. July 1, 2018. Available at: <https://www.census.gov/search-results.html?q=population&page=1&stateGeo=none&searchtype=web&cssp=SERP& charset = UTF-8>. Accessed March 25, 2019.

U.S. Food and Drug Administration. Guideline for the study and evaluation of gender differences in the clinical evaluation of drugs; notice. *Fed. Regis*. 1993;58(139):39406-39416.

U.S. Veteran's Administration. Office of Research Oversight. Updated February 8, 2019. Available at: <https://www.va.gov/ORO/index.asp>.

Virani S, Burke L, Remick SC, Abraham J. Barriers to recruitment of rural patients in cancer clinical trials. *Journal of Oncology Practice*. 2011;7(3):172-177.

Wallach JD, Sullivan PG, Trepanowski JF, Steyerberg EW, Ioannidis JP. Sex based subgroup differences in randomized controlled trials: empirical evidence from Cochrane meta-analyses. *BMJ (Clinical research ed.)*. 2016;355:i5826.

Ward E, Halpern M, Schrag N, et al. Association of insurance with cancer care utilization and outcomes. *CA: A Cancer Journal for Clinicians*. 2008;58(1):9-31.

Winkfield KM, Phillips JK, Joffe S, Halpern MT, Wollins DS, Moy B. Addressing Financial Barriers to Patient Participation in Clinical Trials: ASCO Policy Statement. *Journal of Clinical Oncology: Official Journal of the American Society of Clinical Oncology*. 2018:Jco1801132.

Wyatt R, Laderman M, Botwinick L, Mate K, Whittington J. *Achieving Health Equity: A Guide for Health Care Organizations*. IHI White Paper. Cambridge, Massachusetts: Institute for Healthcare Improvement; 2016. (Available at ihi.org)

Young L, Barnason S, Do V. Review Strategies to Recruit and Retain Rural Patient Participating Self-management Behavioral Trials. *Online Journal of Rural Research and Policy*. 2015;10(2):1-12.

CALIFORNIA HEALTH BENEFITS REVIEW PROGRAM COMMITTEES AND STAFF

A group of faculty, researchers, and staff complete the analysis that informs California Health Benefits Review Program (CHBRP) reports. The CHBRP **Faculty Task Force** comprises rotating senior faculty from University of California (UC) campuses. In addition to these representatives, there are other ongoing researchers and analysts who are **Task Force Contributors** to CHBRP from UC that conduct much of the analysis. The **CHBRP staff** coordinates the efforts of the Faculty Task Force, works with Task Force members in preparing parts of the analysis, and manages all external communications, including those with the California Legislature. As required by CHBRP's authorizing legislation, UC contracts with a certified actuary, **Milliman**, to assist in assessing the financial impact of each legislative proposal mandating or repealing a health insurance benefit.

The **National Advisory Council** provides expert reviews of draft analyses and offers general guidance on the program to CHBRP staff and the Faculty Task Force. CHBRP is grateful for the valuable assistance of its National Advisory Council. CHBRP assumes full responsibility for the report and the accuracy of its contents.

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CHBRP assumes full responsibility for the report and the accuracy of its contents. All CHBRP bill analyses and other publications are available at www.chbrp.org.

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