



Abbreviated Analysis

California Senate Bill 1473: COVID- 19 Therapeutics

Summary to the 2021–2022
California State Legislature
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Prepared by
California Health Benefits Review Program
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SUMMARY

In addition to some other changes to existing law, SB 1473 would place new COVID-19 therapeutics coverage requirements on health plans and policies regulated by the Department of Managed Health Care (DMHC) and the California Department of Insurance (CDI). SB 1473 would require coverage of therapeutics approved or granted emergency use authorization (EUA) by the federal Food and Drug Administration (FDA) for COVID-19 – regardless of whether the provider is in-network (INN) or out-of-network (OON). For these therapeutics, SB 1473 would prohibit cost sharing and utilization management. There are currently five outpatient drugs with FDA authorization/EUA to which cost sharing and utilization management could be independently (not part of a hospitalization) applied.

If the key assumptions described in this report are correct for year 2023, and if benefit coverage remains compliant (the five outpatient drugs considered in this analysis continue to be generally covered without cost sharing or utilization management), SB 1473 could have no measurable impact on utilization or premiums in 2023.

As an informative example, CHBRP has modeled the impacts that could occur if, in 2023, all enrollees would have cost sharing for the four treatment drugs without the presence of the SB 1473 prohibition. Were this the case, increased use of the drugs and decreased COVID-19–related emergency department use and hospitalization could increase net annual expenditures by 0.003% (\$4,050,000) for commercial/CalPERS enrollees in DMHC-regulated plans and CDI-regulated policies. If, at baseline, any or all of these enrollees would not have cost sharing for any or all four treatment drugs, the possible postmandate impact would be less, potentially a less-than-measurable impact.

Drugs (and other therapeutics) used as part of a hospital stay are not generally subject to independent cost sharing or utilization management. Cost sharing and utilization management can be applied directly to the coverage of outpatient drugs.

There are currently five outpatient drugs with FDA approval/EUA for COVID-19.

One, tixagevimab/cilgavimab, is a pre-exposure prophylactic drug prescribed for persons who are immunocompromised and are not likely to respond to vaccination or cannot be immunized to decrease the likelihood of infection. An injectable drug generally administered by a clinician, it is generally covered under a medical benefit.

The other four are treatment drugs prescribed to persons for whom post-infection hospitalization seems likely in order to decrease hospitalization likelihood.

- Two, remdesivir and bebtelovimab, are injected or infused drugs, generally administered by a clinician and

generally covered under a medical benefit.

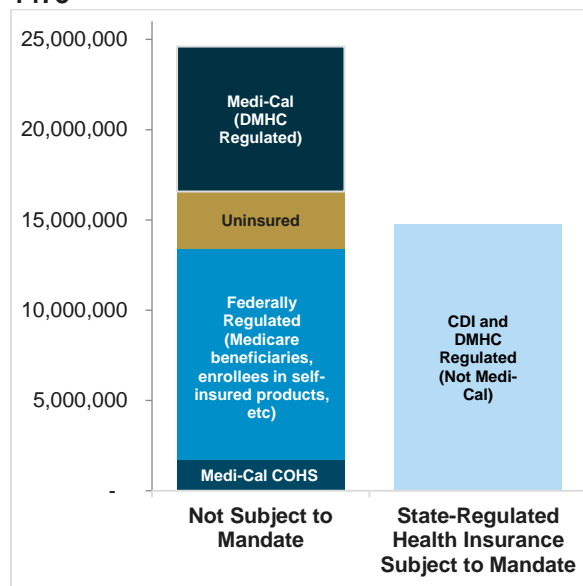
- The other two, nirmatrelvir/ritonavir (Paxlovid) and molnupiravir, are oral drugs generally available through a pharmacy and generally covered under a pharmacy benefit.

The standard treatment path calls for one of the four treatment drugs to be chosen and use begun within 5 to 7 days of symptom onset.

For this analysis, CHBRP has interpreted the SB 1473 requirements as applicable to:

- Pharmacy benefit coverage regulated by DMHC or CDI; and
- Medical benefit coverage of commercial enrollees and enrollees associated with the California Public Employees' Retirement System (CalPERS) in plans and policies regulated by DMHC or CDI.

Figure A. Health Insurance in CA and SB 1473



Source: California Health Benefits Review Program, 2022.

Key: CDI = California Department of Insurance; COHS = County Organized Health System; DMHC = Department of Managed Health Care.

For this analysis, CHBRP has made a number of key assumptions for calendar year 2023:

- The COVID-19 virus will be unchanged or substantially similar to the omicron variant. More changes, like that from alpha to omicron, could alter infection rates and/or effectiveness of some or all the current drugs.
- Drugs with current FDA approval/EUA will be available. Production problems could limit availability and could result in short-term shortages.
- Use will be conservative. If prescribed/ordered conservatively by providers, as suggested by the EUAs, possible harms (drug–drug interactions, fertility issues, etc.) should be limited and short-term shortages should be less likely.
- There will not be new drugs that gain FDA approval/EUA that substantively alter use of the current set. The availability and use of new drugs could alter use of the current set of drugs.

Should any or all of these key assumptions not be correct for calendar year 2023, the impacts projected in this analysis could be larger – or smaller – by orders of magnitude.

Benefit Coverage

Currently, among enrollees for whom SB 1473 would make new benefit coverage requirements, coverage of all five outpatient drugs with FDA approval/EUA seems standard, and neither cost sharing nor utilization management seems common. Additionally, so long as providers remain conservative regarding the prescribing/ordering of these drugs, SB 1473 would not be expected to measurably change the current mix of INN and ONN provider use. Should these situations persist, there could be no measurable impact from implementation of SB 473 in 2023. In this scenario, baseline figures would look the same as the postmandate figures presented below.

Informative Example

The following estimates are intended as an informative example of impacts that could occur, but which CHBRP cannot project as expected.

Example – Benefit Coverage

These figures assume that, in 2023, cost sharing would become applicable for the four treatment drugs, were cost sharing not prohibited by SB 1473.

Cost sharing is common for treatment drugs, but not common for prevention drugs, and so CHBRP has not modeled any change for the pre-exposure prophylaxis drug tixagevimab/cilgavimab.

In 2023, should any or all enrollees not have cost sharing at baseline for any or all of the four treatment drugs, the postmandate impacts presented below would be less, potentially less-than-measurable impacts.

Example – Utilization

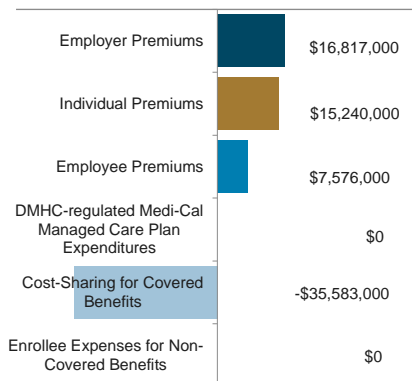
Use of the treatment drugs could increase postmandate: nirmatrelvir/ritonavir (Paxlovid) by 3% (426,100 to 438,900); molnupiravir by 2.68%

(22,400 to 23,000); remdesivir by 10.48% (12,400 to 13,700); bebtelovimab by 10.48% (12,400 to 13,700). COVID-19–related emergency department visits could decrease postmandate by 0.62% (42,000 to 41,740), and COVID-19–related hospitalization could decrease postmandate by 0.61% (86,630 to 86,100).

Example – Expenditures

Total net annual expenditures could increase by 0.003% (\$4,050,000) for commercial/CalPERS enrollees in DMHC-regulated plans and CDI-regulated policies. Premiums and enrollee cost sharing impacts are presented in Figure B.

Figure B. Informative Example Expenditure Impacts



Source: California Health Benefits Review Program, 2022.

Example – Uninsured

Because the change in average premiums does not exceed 1% for any market segment, CHBRP

would expect no measurable change in the number of uninsured persons.

Example – Medi-Cal

Because CHBRP interprets the language as not placing requirements on DMHC-regulated plans enrolling Medi-Cal beneficiaries, no impact would be expected for Medi-Cal.

Example – CalPERS

Aggregate employer premiums for CalPERS HMO enrollees could increase by 0.009% (\$52,000).

Example – Covered California

Aggregate premiums for all persons purchasing individual market plans and policies through Covered California could increase by 0.062% (\$10,911,000).

Essential Health Benefits and the Affordable Care Act

As SB 1473 would not require coverage for a new benefit, the bill appears not to exceed the definition of essential health benefits in California.

POLICY CONTEXT

The California Assembly Committee on Health has requested that the California Health Benefits Review Program (CHBRP)¹ conduct an abbreviated analysis of SB 1473, COVID-19 Therapeutics.

In addition to some other changes to existing law, SB 1473 would place new requirements on health plans and policies regulated by the Department of Managed Health Care (DMHC) and the California Department of Insurance (CDI). SB 1473 would require coverage of drugs (and any other therapeutics) approved or granted emergency use authorization (EUA) by the federal Food and Drug Administration (FDA) for COVID-19 – and do so regardless of whether the provider is in-network (INN) or out-of-network (OON).

- For plans and insurers
 - Provider rates would be as negotiated or would be based on negotiated rates in the region.
 - Cost sharing would be prohibited – though plans/insurers would pay the provider any cost sharing to which the provider would otherwise have been entitled.
 - For OON providers, the cost-sharing prohibition would expire 12 months after the federal public health emergency ends.
 - Utilization management would be prohibited.
- For providers
 - Balance billing would be prohibited.
 - Reporting adverse information to a consumer credit reporting agency would be prohibited.
 - Commencing civil action against the enrollee would be prohibited.

The full text of SB 1473 can be found in Appendix A.

Descriptions of cost sharing and utilization management are included in Appendix B

Analytic Approach and Key Interpretations

Because cost sharing and utilization management can be specifically applicable to outpatient drugs (not part of a broader service, such as inpatient hospitalization), CHBRP has focused on the five outpatient COVID-19 drugs with current FDA approval or EUA (see Table 1). Two of the five are available as oral drugs distributable through pharmacies and so are generally covered under an enrollee's pharmacy benefit. The other three are injection or infusion drugs, generally administered by a clinician, with clinician/facility time as well as the drug covered under an enrollee's medical benefit. SB 1473 would place requirements on both medical and pharmacy benefits.

Changes to the Health & Safety Code are not always applicable to the benefit coverage of Medi-Cal beneficiaries enrolled in DMHC-regulated plans. For this analysis, CHBRP has interpreted the SB 1473 language as not affecting the pharmacy benefit or medical benefit of these beneficiaries.

Medical benefit coverage is standard for all enrollees in plans and policies regulated by DMHC and CDI, but there is some variation for pharmacy benefit coverage.² Almost all commercial enrollees have a pharmacy benefit that covers brand name and generic drugs. However, a limited number of commercial enrollees have no pharmacy benefit or have a "generics only" pharmacy benefit. Additionally, a limited number of commercial enrollees as well as about half of the DMHC-regulated plan enrollees associated

¹ CHBRP's authorizing statute is available at www.chbrp.org/about_chbrp/faqs/index.php.

² See CHBRP's resource, *Pharmacy Benefit Coverage in State-Regulated Health Insurance*, available at https://chbrp.org/other_publications/index.php.

with the California Public Employees' Retirement System (CalPERS) have a pharmacy benefit separate from their plan/policy and so are not subject to regulation by DMHC or CDI. For this analysis, CHBRP has interpreted the SB 1473 language as requiring compliance from brand name and generic drug pharmacy benefits regulated by DMHC or CDI. However, CHBRP has interpreted the language as not requiring the addition of brand name drug coverage to “generics only” pharmacy benefits and not requiring compliance for oral drugs that can be accessed through a pharmacy from plans/policies without a pharmacy benefit regulated by DMHC or CDI.

Relevant Populations

Given the interpretations discussed above, if enacted, SB 1473 would apply to the health insurance of approximately 14.8 million enrollees (37% of all Californians). This represents 65% of the 22.8 million Californians who will have health insurance regulated by the state that may be subject to any state health benefit mandate law, which includes health insurance regulated by the DMHC or CDI. If enacted, the law would apply to the health insurance of enrollees in plans and policies regulated by DMHC or CDI, CDI-regulated policies. It would not apply to the benefit coverage of Medi-Cal beneficiaries. In addition, it would not apply the oral drug coverage of enrollees without a pharmacy benefit regulated by DMHC or CDI – an exemption relevant for a limited number of commercial enrollees and about half of the CalPERS enrollees in DMHC-regulated plans.³

Interaction With Existing State and Federal Requirements

As noted below, SB 1473 may interact with and/or align with state and federal health insurance mandates or provisions.

California Policy Landscape

California law and regulations

Although CHBRP is unaware of a similar law or regulation for COVID-19 therapeutics, SB 1473 would amend (and make some alterations to) any existing California law that requires coverage (and prohibits cost sharing and utilization management) for COVID-19 testing and immunization.

California law prohibits some providers in some instances from balance billing (or “surprise billing”) enrollees.⁴

Similar requirements in other states

CHBRP is aware of three states that have issued emergency regulations prohibiting cost sharing for COVID-19 treatment and one state that also prohibits prior authorization for COVID-19 treatment. It is unclear whether “treatments” would include preventatives, such as pre-exposure prophylaxis drugs.

Massachusetts prohibits prior authorization requirements and cost sharing for medically necessary COVID-19 treatment provided by an in-network provider during the public health emergency – and by out-of-network emergency departments during the COVID-19 public health emergency (Mass.gov, 2022).

Vermont prohibits cost-sharing requirements for COVID-19 treatment (Vermont, 2020).

New Mexico prohibits cost sharing for health care services for COVID-19 (New Mexico, 2020).

³ See CHBRP's resource, *Pharmacy Benefit Coverage in State-Regulated Health Insurance*, available at https://chbrp.org/other_publications/index.php.

⁴ See CHBRP's issue brief *Balance Billing Prohibitions and the No Surprises Act*, available at https://chbrp.org/other_publications/index.php.

Federal Policy Landscape

Three of the four treatment drugs included in this analysis, bebtelovimab, nirmatrelvir/ritonavir (Paxlovid), and molnupiravir (but not remdesivir), are currently covered under EUA. The federal government secured inventory of the treatments approved under EUA for all individuals regardless of insurance status and is making them available at no charge (Tolbert et al., 2022).

Federal law generally prohibits providers (except ground ambulance services) from balance billing (or “surprise billing”) enrollees.⁵

For California’s commercial enrollees in small-group and individual market plans and policies that are required to cover essential health benefits (EHBs), federal guidance indicates that treatment for COVID-19 is an EHB and that cost sharing, as well as prior authorization, is permitted (CMS, 2020a,b). It is unclear whether “treatments” would include preventatives, such as pre-exposure prophylaxis drugs.

For Medicaid beneficiaries (as well as Medicare beneficiaries) cost sharing is prohibited for certain COVID-19 therapeutics (monoclonal antibody treatments) when used as authorized or approved by the FDA (CMS, 2021a,b).

Affordable Care Act and Essential Health Benefits

In California, nongrandfathered⁶ individual and small-group health insurance is generally required to cover EHBs.⁷ In 2023, approximately 12.1% of all Californians will be enrolled in a plan or policy that must cover EHBs.⁸ States may require state-regulated health insurance to offer benefits that exceed EHBs.^{9,10,11} However, state benefit mandates specifying provider types, cost sharing, or other details of existing benefit coverage would not meet the definition of state benefit mandates that could exceed EHBs.¹²

Federal guidance indicates that treatment for COVID-19 is an EHB (CMS, 2020b). Treatments may include therapeutics, including outpatient drugs. If so, SB 1473 would not exceed EHBs.

⁵ See CHBRP’s issue brief *Balance Billing Prohibitions and the No Surprises Act*, available at https://chbrp.org/other_publications/index.php.

⁶ A grandfathered health plan is “a group health plan that was created – or an individual health insurance policy that was purchased – on or before March 23, 2010. Plans or policies may lose their ‘grandfathered’ status if they make certain significant changes that reduce benefits or increase costs to consumers” (Healthcare.gov, 2022).

⁷ For more detail, see CHBRP’s issue brief, *California State Benefit Mandates and the Affordable Care Act’s Essential Health Benefits*, available at https://chbrp.org/other_publications/index.php.

⁸ See CHBRP’s resource, *Sources of Health Insurance in California* and CHBRP’s issue brief *California State Benefit Mandates and the Affordable Care Act’s Essential Health Benefits: An Update and Overview of New Federal Regulations*, both available at https://chbrp.org/other_publications/index.php.

⁹ ACA Section 1311(d)(3).

¹⁰ 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, 78(37):12834-12872. February 25, 2013.

¹¹ 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.

¹² 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.

IMPACTS

This section reports the potential incremental impacts of SB 1473 on estimated baseline benefit coverage, utilization, and overall cost.

Analytic Approach and Key Assumptions

The COVID-19 landscape is evolving. The virus is changing in transmissibility and seriousness of induced disease. Vaccine and drug effectiveness may also be affected. Future rates of infection and hospitalization might be changed as a result. The estimates rely on several key assumptions which are subject to extreme uncertainty. These assumptions include the overall reported infection rate for the state of California, assumed infection rates by age, gender and vaccination status, vaccination rates, vaccine effectiveness, hospitalization rates, treatment availability and effectiveness and projected costs by severity. The information relied on for this analysis may not be reflective of the COVID-19 environment in 2023. Due to the limited information available, any analysis is subject to a substantially greater than usual level of uncertainty. Differences between the estimates and actual amounts depend on the extent to which future experience conforms to the assumptions. It is almost certain that actual experience will not conform exactly to the assumptions. Actual amounts will differ from projected amounts to the extent that actual experience is better or worse than assumed.

CHBRP assumed that there will be 6.3 million COVID-19 cases in California in 2023. The infection rate is the reported California infection rate for the 12-month period ending May 2022, encompassing the Delta variant summer surge of 2021, the Omicron BA.1 variant winter surge of January 2022, and Omicron BA.2 surge in May 2022. The actual infection rate is greater than the reported infection rate due to home testing results that are not captured by public health reporting. The reported infection rate was increased by 5% to reflect more cases reported because treatments are available. As new variants arise, the frequency and severity of COVID-19 infections changes. The assumed infection rate may not be reflective of the COVID-19 frequency that we will face in 2023. The directionality and magnitude of the variance between the assumed infection rate and the 2023 rate are unknown.

COVID-19 vaccination effectiveness also varies by variant, and the effectiveness wanes over time, requiring multiple booster vaccination doses. Some enrollees may not stay current in their COVID-19 immunizations. This analysis assumes historical vaccine effectiveness and projects 2023 vaccination rates using California's vaccination rate as of June 1, 2022, projected to 2023 by applying recently observed monthly vaccination trends by age. The observed 2023 infection and hospitalization rates will vary from the assumed 2023 infection and hospitalization rates to the extent that the vaccines become less effective or the vaccination rate changes. The directionality and magnitude of the variance between the assumed infection and hospitalization rates and the 2023 rates are unknown.

CHBRP assumed the drugs currently available to treat or prevent COVID-19 will be the only drugs available in 2023 and that there will not be new drugs with current FDA approval/EUA that substantively alter use of the current set. It is possible that there may be other drugs that are already FDA approved for other indications that could be used for COVID-19 in the future. It is also possible that new monoclonal antibodies may emerge as their effectiveness is susceptible to variants. New drugs that either are proven to be or are hoped to be more effective could alter the impacts projected in this analysis.

CHBRP assumed drugs will be available for infected enrollees. There are several reasons why the drugs may not be available. Once these drugs are FDA-approved, there may not be criteria on who is eligible to use these drugs for treatment and use can be off-label. Prohibitions on utilization management may result in patients asking to have the drug on hand "just in case," which limits availability of the drug for infected enrollees. Alternatively, there may be COVID-19 surges or production issues that could result in short-term shortages. Drug availability may alter the impact of this analysis.

CHBRP assumed drugs with current FDA approval/EUA will be prescribed/ordered within guidance outlined by the package insert/EUA. Utilization management guidance included in the EUAs, if used conservatively by providers, should limit the potential for harms that can be associated with the oral drugs. If not used conservatively (so as to avoid undesirable drug-on-drug interaction, fertility complications, etc.), utilization could be greater than projected in ways that could result in measurable harms (and associated use of other health services).

The drugs with FDA approval/EUA for COVID-19 currently include four treatment drugs, nirmatrelvir/ritonavir (Paxlovid), molnupiravir, remdesivir, and bebtelovimab, as well as a pre-exposure prophylactic drug, tixagevimab/cilgavimab.

CHBRP surveyed California's eight largest (by enrollment) health plans and insurers about current coverage, enrollee cost sharing, and utilization management for each of the five drugs. Respondents representing 71% of commercial enrollees indicated that the drugs are currently covered, cost sharing is \$0 for most enrollees, and utilization management is uncommon.

For further details on the underlying data sources and methods used in this analysis, please see Appendix C.

Baseline and Postmandate Benefit Coverage

At baseline:

- 100% of commercial and CalPERS enrollees with a pharmacy benefit regulated by DMHC or CDI that covers brand name drugs¹³ have coverage for nirmatrelvir/ritonavir (Paxlovid) and molnupiravir, oral drugs generally covered under a pharmacy benefit.
- 100% of commercial and CalPERS enrollees have coverage for bebtelovimab and remdesivir, infused/injected drugs generally administered by a clinician and generally covered under a medical benefit.
- Cost sharing for these drugs seems rare, and utilization management seems uncommon.

Additionally, so long as providers remain conservative regarding the prescribing/ordering of these drugs, SB 1473 would not be expected to measurably change the current mix of INN and ONN provider use.

Should these situations persist, there could be no measurable impact from implementation of SB 473 in 2023. In this scenario, baseline figures would look the same as the postmandate figures presented below.

Informative Examples

The following estimates (see also Tables 1, 2, and 3) are intended as informative examples of impacts that could occur, but which CHBRP cannot project as expected.

For this example, CHBRP has assumed that enrollees would, at baseline, have cost sharing consistent with similar medical and pharmacy benefits (see Table 1). Postmandate, no enrollees would have cost sharing for the four COVID-19 outpatient treatment drugs but may have cost sharing for office or facility visits for clinician administration of injected/infused drugs.

¹³ Almost all commercial and three of four CalPERS enrollees have a pharmacy benefit regulated by DMHC or CDI that covers brand name drugs – see CHBRP's resource, *Pharmacy Benefit Coverage in State Regulated Health Insurance*, available at http://chbrp.org/other_publications/index.php.

Cost sharing is common for treatment drugs, but not common for prevention drugs, and so CHBRP has not modeled any change for the pre-exposure prophylaxis drug, tixagevimab/cilgavimab.

Example – Baseline and Postmandate Utilization

A number of reasons unrelated to cost sharing or utilization management currently limit, and are likely to continue to limit, utilization of these outpatient COVID-19 treatment drugs. Age is a key issue. Almost all enrollees in DMHC-regulated plans and CDI-regulated policies are younger than 65 years, and younger persons, particularly those younger than 45 years, may be less likely to seek treatment for COVID-19 (or less likely to have comorbid conditions putting them at risk for hospitalization), which may limit use. Timing between system onset and medical care is also a key issue. All four of the treatment drugs are recommended for use within 5 to 7 days of symptom onset. Recognition of symptoms by the enrollee, timely access to COVID-19 testing, and contact with a provider to determine whether the drug is appropriate and then prescribe/order the drug may not always occur within that period, which may limit use.

CHBRP estimates there will be 2,466,000 COVID-19 infections among commercial and CalPERS enrollees in 2023. At baseline, among infected enrollees, 15% of those aged 12-49 years, 40% of those aged 50-64 years, and 60% of those aged 65+ years will use one of the four outpatient COVID-19 treatment drugs.¹⁴ Of those seeking treatment, 90% would use nirmatrelvir/ritonavir (Paxlovid), 5% molnupiravir, 2.5% remdesivir, and 2.5% bebtelovimab.¹⁵ Because molnupiravir is not approved for individuals under 18 years, the distribution of drugs for children aged 12-17 years is 94.7% nirmatrelvir/ritonavir (Paxlovid), 2.6% remdesivir, and 2.6% bebtelovimab.¹⁶

Postmandate, 3% more infected enrollees could use oral drugs and 10% more infected enrollees could use injections/infusions as a result of the prohibition on enrollee cost sharing on the drug portion of the cost of the treatment.

Nirmatrelvir/ritonavir (Paxlovid) treatments could increase from 426,100 at baseline to 438,900 postmandate as a result of elimination of cost sharing. Other treatments for COVID-19 infections could increase from 47,200 at baseline to 50,400 postmandate.

Example – Baseline and Postmandate Per-Unit Cost

Three of the four treatment drugs included in this analysis, bebtelovimab, nirmatrelvir/ritonavir (Paxlovid), and molnupiravir, are currently covered under EUA. The federal government secured inventory of the treatments approved under EUA for all individuals regardless of insurance status and is making them available at no charge (Tolbert et al., 2022). This analysis assumes that these three drugs will be FDA approved in 2023 such that all four drugs will be covered and paid for by plans/insurers (instead of by the federal government). With the exception of the FDA approved drug, remdesivir, the drug costs are currently negotiated by the federal government. The cost of the drugs may be greater as private companies negotiate prices for the commercially insured population. CHBRP included the cost of an initial evaluation visit and administration costs for remdesivir and bebtelovimab in the cost of treatment.

At baseline, CHBRP assumed all four drugs and administration costs associated with remdesivir and bebtelovimab will be the financial responsibility of the insurer and are subject to enrollee cost sharing.

Postmandate, CHBRP assumed all four drugs are the financial responsibility of the insurer without enrollee cost sharing and the administration of remdesivir and bebtelovimab are the financial responsibility of the insurer with enrollee cost sharing.

¹⁴ Personal communication, K. Yang, June 2022.

¹⁵ Personal communication, K. Yang, June 2022.

¹⁶ Personal communication, K. Yang, June 2022.

The per unit cost of treatment does not change as a result of the mandate. Treatment costs range from \$529 to \$3,145 (see Table 1).¹⁷ Office/facility administered drugs include one initial evaluation visit and an injection/infusion visit in the cost of administration.

Example – Baseline and Postmandate Expenditures

Table 2 and Table 3 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 1473 could increase total net annual expenditures by \$4,050,000 (0.003%) for commercial and CalPERS enrollees in DMHC-regulated plans and CDI-regulated policies. This is due to a \$39,633,000 increase in total health insurance premiums paid by employers and enrollees for newly covered benefits, adjusted by a \$35,583,000 decrease in enrollee expenses for covered and/or noncovered benefits.

Example – premiums

Changes in premiums as a result of SB 1473 could vary by market segment. Note that such changes are related to the number of enrollees (see Table 1, Table 2, and Table 3), with health insurance that would be subject to SB 1473.

In the commercial market, premium increases range from 0.0258% in the DMHC regulated large group market to 0.0875% in the CDI-regulated individual market. Among enrollees in non-Grandfathered individual market plans purchased through Covered California, premium increases range from 0.0596% for DMHC-regulated individual plans and 0.1545% for CDI-regulated individual plans.

Among publicly funded DMHC-regulated health plans, CalPERS premium increases 0.0094% and Medi-Cal Managed Care would have no impact.

Example – enrollee expenses

SB 1473–related changes in cost-sharing for covered benefits (deductibles, copays, etc.) and out-of-pocket expenses for noncovered benefits would vary by market segment. Note that such changes are related to the number of enrollees (see Table 1, Table 2, and Table 3) with health insurance that would be subject to SB 1473 expected to use the relevant treatments during the year after enactment.

Among commercial plans, enrollee expense reductions range from a savings of \$0.1432 PMPM in the DMHC-regulated large group plans to \$0.4463 PMPM in the CDI-regulated small group plans. CalPERS plan enrollee expense reduction is \$0.0605 PMPM.

Example – potential cost offsets or savings in the first 12 months after enactment

As an offset to the increase in treatments, hospitalization and emergency room visits could decrease. The hospitalization rate related to COVID-19 presented in this analysis reflects the observed Omicron BA.1 variant winter surge hospitalizations divided by the number of cases. The hospitalization rate is adjusted for projected 2023 vaccination status and the ages of affected enrollees.. The emergency department visit count is 2.1 times the inpatient visit count (Naleway et al., 2021).

¹⁷ Nirmatrelvir/ritonavir (Paxlovid) is currently administered as a 5-day treatment. Due to COVID-19 rebound, or reinfection after finishing a course of treatment, studies are in progress to determine whether the treatment should be administered for 10 days, which would make the unit cost twice what is presented in this analysis (Mishra, 2021).

CHBRP assumed the drugs and that their effectiveness at reducing the risk of hospitalizations will reflect what was observed in clinical trials. The most highly utilized drug in this analysis, nirmatrelvir/ritonavir (Paxlovid), reduces hospitalizations of the unvaccinated population under age 65 years by 85% (Hammond et al., 2022). Molnupiravir is the least effective drug with an observed 33% reduction for enrollees aged 60 years and younger (Bernal et al., 2022). Research is not available on the hospital rate reduction as a result of taking bebtelovimab. CHBRP conservatively assumed the hospitalization rate of those treated with bebtelovimab is equal to the hospitalization rate of the untreated population. Currently available treatments may be more or less effective at treating future COVID-19 variants.

SB 1473 could reduce hospitalizations for the 16,000 enrollees who got COVID-19 treatment because of the eliminated cost sharing. This could result in 260 fewer inpatient visits and 530 fewer emergency department visits postmandate compared to baseline (see Table 1). This could result in an offset of approximately \$16 million.

Example – postmandate administrative expenses and other expenses

CHBRP estimates that the increase in administrative costs of DMHC-regulated plans and/or CDI-regulated policies would 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.

Example – 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.

Example – postmandate changes in the number of uninsured persons

Because the change in average premiums does not exceed 1% for any market segment (see Table 1, Table 2, and Table 3), CHBRP would expect no measurable change in the number of uninsured persons due to the enactment of SB 1473.

Example - 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 1473.

Table 1. Example – Potential Impacts of SB 1473 on Benefit Coverage, Utilization, and Cost, 2023

	Baseline (2023)	Postmandate Year 1 (2023)	Increase/ Decrease	Change Postmandate
Benefit coverage				
Total enrollees with health insurance subject to state-level benefit mandates (a)	22,810,000	22,810,000	0	0.00%
Total enrollees with health insurance subject to SB 1473	14,776,000	14,776,000	0	0.00%
Total percentage of enrollees with coverage	100%	100%	0%	0.00%
Utilization and cost				
Number of COVID-19 infections	2,466,000	2,466,000	—	0.00%
Number of treatments				
nirmatrelvir/ritonavir (Paxlovid)	426,100	438,900	12,800	3.00%
molnupiravir	22,400	23,000	600	2.68%
remdesivir	12,400	13,700	1,300	10.48%
bebtelovimab	12,400	13,700	1,300	10.48%
Per unit cost of treatment				
nirmatrelvir/ritonavir (Paxlovid)	\$529	\$529	—	0.00%
molnupiravir	\$707	\$707	—	0.00%
remdesivir	\$3,145	\$3,145	—	0.00%
bebtelovimab	\$1,478	\$1,478	—	0.00%
Average cost sharing per treatment				
nirmatrelvir/ritonavir (Paxlovid)	\$64	\$0	-\$64	-100.00%
molnupiravir	\$64	\$0	-\$64	-100.00%
remdesivir	\$461	\$156	-\$305	-66.13%
bebtelovimab	\$217	\$41	-\$176	-81.16%
COVID-19–related hospitalizations	42,000	41,740	-260	-0.62%
COVID-19–related emergency department visits	86,630	86,100	-530	-0.61%
Average cost per hospitalization	\$53,673	\$53,673	—	0.00%
Average cost per emergency department visit	\$3,773	\$3,773	—	0.00%
Expenditures				
<i>Premium (expenditures) by payer</i>				
Private employers for group insurance	\$52,967,575,000	\$52,983,840,000	\$16,265,000	0.031%
CalPERS HMO employer expenditures (b) (c)	\$5,895,476,000	\$5,896,028,000	\$552,000	0.009%
Medi-Cal Managed Care Plan expenditures	\$25,989,411,000	\$25,989,411,000	—	0.000%
<i>Enrollee premiums (expenditures)</i>				
Enrollees for individually purchased insurance	\$24,029,788,000	\$24,045,028,000	\$15,240,000	0.063%
Individually purchased – outside Exchange	\$6,324,312,000	\$6,328,641,000	\$4,329,000	0.068%
Individually purchased – Covered California	\$17,705,476,000	\$17,716,387,000	\$10,911,000	0.062%
Enrollees with group insurance, CalPERS HMOs, Covered California, and Medi-Cal Managed Care (c)	\$24,504,936,000	\$24,512,512,000	\$7,576,000	0.031%
<i>Enrollee out-of-pocket expenses</i>				
Cost-sharing for covered benefits (deductibles, copayments, etc.)	\$15,807,011,000	\$15,771,428,000	-\$35,583,000	-0.225%
Expenses for noncovered benefits (d) (e)	\$0	\$0	—	0.000%
Total expenditures	\$149,194,197,000	\$149,198,247,000	\$4,050,000	0.003%

Source: California Health Benefits Review Program, 2022.

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.¹⁸

(b) Of the increase in CalPERS employer expenditures, about 51.7%, or \$1,349,000, would be state expenditures for CalPERS members who are state employees or their dependents. About one in five of these enrollees has a pharmacy benefit not subject to DMHC.¹⁹ CHBRP has projected no pharmacy benefit 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 covered by insurance at baseline. This only includes those expenses that will 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 treatments before SB 1473, 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 treatments 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) Includes only expenditures related to Medi-Cal beneficiaries enrolled in DMHC-regulated plans.

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

¹⁸ For more detail, see CHBRP's *Sources of Health Insurance in California for 2023*, a resource available at http://chbrp.org/other_publications/index.php.

¹⁹ For more detail, see CHBRP's *Pharmacy Benefit Coverage in in State-Regulated Health Insurance for 2023*, a resource available at http://chbrp.org/other_publications/index.php.

Table 2. Example – Baseline Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2023

	DMHC-Regulated						CDI-Regulated			Total
	Commercial Plans (by Market) (a)			Publicly Funded Plans			Commercial 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)	8,317,000	2,125,000	2,758,000	881,000	7,158,000	876,000	485,000	44,000	166,000	22,810,000
Total enrollees in plans/policies subject to SB 1473	8,317,000	2,125,000	2,758,000	881,000	0	0	485,000	44,000	166,000	14,776,000
Premium costs										
Average portion of premium paid by employer	\$407.24	\$369.14	\$0.00	\$557.65	\$238.69	\$521.94	\$465.60	\$379.33	\$0.00	\$84,852,462,000
Average portion of premium paid by enrollee	\$166.59	\$204.69	\$691.58	\$113.48	\$0.00	\$0.00	\$228.48	\$246.41	\$572.88	\$48,534,724,000
Total premium	\$573.83	\$573.83	\$691.58	\$671.13	\$238.69	\$521.94	\$694.08	\$625.74	\$572.88	\$133,387,186,000
Enrollee expenses										
Cost sharing for covered benefits (deductibles, copays, etc.)	\$48.46	\$124.44	\$175.87	\$58.77	\$0.00	\$0.00	\$146.18	\$200.65	\$200.15	\$15,807,011,000
Expenses 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	\$622.29	\$698.27	\$867.45	\$729.89	\$238.69	\$521.94	\$840.26	\$826.39	\$773.02	\$149,194,197,000

Source: California Health Benefits Review Program, 2022.

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

(b) Approximately 51.7% of CalPERS enrollees in DMHC-regulated plans are state retirees, state employees, or their dependents. About one in five of these enrollees has a pharmacy benefit not subject to DMHC. CHBRP has projected no pharmacy benefit impact for those enrollees. However, CalPERS could, postmandate, require equivalent coverage for all its members (which could increase the total impact on CalPERS).

(c) Medi-Cal Managed Care Plan expenditures for members over 65 years 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.

(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 covered by insurance at baseline. This only includes those expenses that will be newly covered, postmandate. Other components of expenditures in this table include all health care services covered by insurance.

(f) Includes only Medi-Cal beneficiaries enrolled in DMHC-regulated plans.

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.

Table 3. Example – Postmandate Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2023

	DMHC-Regulated						CDI-Regulated			Total
	Commercial Plans (by Market) (a)			Publicly Funded Plans			Commercial 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)	8,317,000	2,125,000	2,758,000	881,000	7,158,000	876,000	485,000	44,000	166,000	22,810,000
Total enrollees in plans/policies subject to SB 1473	8,317,000	2,125,000	2,758,000	881,000	0	0	485,000	44,000	166,000	14,776,000
Premium costs										
Average portion of premium paid by employer	\$0.1051	\$0.1914	\$0.0000	\$0.0523	\$0.0000	\$0.0000	\$0.1240	\$0.3225	\$0.0000	\$16,818,000
Average portion of premium paid by enrollee	\$0.0430	\$0.1062	\$0.4303	\$0.0106	\$0.0000	\$0.0000	\$0.0608	\$0.2095	\$0.5015	\$22,816,000
Total premium	\$0.1481	\$0.2976	\$0.4303	\$0.0629	\$0.0000	\$0.0000	\$0.1848	\$0.5321	\$0.5015	\$39,633,000
Enrollee expenses										
Cost-sharing for covered benefits (deductibles, copays, etc.)	-\$0.1432	-\$0.2583	-\$0.3640	-\$0.0605	\$0.0000	\$0.0000	-\$0.1726	-\$0.4463	-\$0.3878	-\$35,583,000
Expenses 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	\$0.0049	\$0.0393	\$0.0663	\$0.0024	\$0.0000	\$0.0000	\$0.0122	\$0.0858	\$0.1137	\$4,050,000
Postmandate percent change										
Percent change insured premiums	0.0258%	0.0519%	0.0622%	0.0094%	0.0000%	0.0000%	0.0266%	0.0850%	0.0875%	0.0297%
Percent change total expenditures	0.0008%	0.0056%	0.0076%	0.0003%	0.0000%	0.0000%	0.0015%	0.0104%	0.0147%	0.0027%

Source: California Health Benefits Review Program, 2022.

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

(b) Approximately 51.7% of CalPERS enrollees in DMHC-regulated plans are state retirees, state employees, or their dependents. About one in five of these enrollees has a pharmacy benefit not subject to DMHC. CHBRP has projected no pharmacy benefit impact for those enrollees. However, CalPERS could, postmandate, require equivalent coverage for all its members (which could increase the total impact on CalPERS).

(c) Medi-Cal Managed Care Plan expenditures for members over 65 years 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.

(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 covered by insurance at baseline. This only includes those expenses that will be newly covered, postmandate. Other components of expenditures in this table include all health care services covered by insurance.

(f) Includes only Medi-Cal beneficiaries enrolled in DMHC-regulated plans.

Key: CalPERS HMOs = California Public Employees' Retirement System Health Maintenance Organizations; CDI = California Department of Insurance; COHS = County Organized

Appendix A **TEXT OF BILL ANALYZED**

On June 1, 2022, the California Senate Committee on Health requested that CHBRP analyze SB 1473.

AMENDED IN ASSEMBLY JUNE 06, 2022

AMENDED IN SENATE MARCH 10, 2022

SENATE BILL

NO. 1473

Introduced by Senator Pan

February 18, 2022

An act to amend ~~Section~~ *Sections 1342.2, 1342.3, and 1399.848* of the Health and Safety Code, and to amend ~~Section~~ *Sections 10110.7, 10110.75, and 10965.4* of the Insurance Code, relating to health care coverage.

LEGISLATIVE COUNSEL'S DIGEST

SB 1473, as amended, Pan. Health care ~~coverage: enrollment periods: coverage.~~

~~Existing~~

(1) Existing federal law, the Patient Protection and Affordable Care Act (PPACA), requires each state to establish an American Health Benefit Exchange to facilitate the purchase of qualified health benefit plans by qualified individuals and qualified small employers. Existing state law creates the California Health Benefit Exchange (Exchange), also known as Covered California, to facilitate the enrollment of qualified individuals and qualified small employers in qualified health plans as required under PPACA.

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 a special enrollment period for individual health benefit plans offered through the Exchange from December 16 of the preceding calendar year to January 31 of the benefit year, inclusive, for policy years beginning on or after January 1, 2020. Under existing law, February 1 of the benefit year is the effective coverage date for individual health benefit plans offered outside and through the Exchange that are selected from December 16 to January 31, inclusive.

This bill would eliminate the above-described special enrollment period for individual health benefit plans offered through the Exchange for policy years on or after January 1, 2023, and would instead create an annual enrollment period from November 1 of the preceding calendar year to January 31 of the benefit year, inclusive. The bill would specify that the effective date of coverage for individual health benefit plans offered outside and through the Exchange would be no later than January 1 of the benefit year for plan selection made from November 1 to December 31 of the preceding calendar year, inclusive, and would be no later than February 1 of the benefit year for plan selection made from January 1 to January 31 of the benefit year, inclusive. Because a willful violation of these provisions by a health care service plan would be a crime, the bill would impose a state-mandated local program.

(2) Existing law requires a health care service plan contract or a disability insurance policy that provides coverage for hospital, medical, or surgical benefits, excluding a specialized health care service plan contract or health insurance policy, to cover the costs of testing and immunization for COVID-19, or a future disease when declared a public health emergency by the Governor, and prohibits the contract or policy from imposing cost sharing or prior authorization requirements for that coverage. Under existing law, the requirement to cover COVID-19 testing and immunizations delivered by an out-of-network provider without cost sharing does not apply to testing and immunizations furnished on or after the expiration of the federal public health emergency. A violation of these provisions by a health care service plan is a crime.

This bill would provide that a health care service plan or disability insurer is not required to cover the cost sharing for COVID-19 testing and immunizations delivered by an out-of-network provider beginning 12 months after the federal public health emergency expires. The bill would prohibit a provider from reporting adverse information to a consumer credit reporting agency or commence civil action against an enrollee or insured for payment of COVID-19-related items, services, or immunizations. The bill would extend these and the above-described provisions to therapeutics approved or granted emergency use authorization by the federal Food and Drug Administration for COVID-19 when prescribed or furnished by a licensed health care provider acting within their scope of practice and the standard of care. The bill would require a contract or policy to cover therapeutics approved or granted emergency use authorization by the federal Food and Drug Administration for a disease that the Governor has declared a public health emergency. The bill would eliminate a health care service plan's criminal liability for a violation of COVID-19 testing and immunization coverage requirements that occurred before January 1, 2022.

The

(3) 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.

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

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

SECTION 1. *Section 1342.2 of the Health and Safety Code is amended to read:*

1342.2. (a) Notwithstanding any other law, a health care service plan contract that covers medical, surgical, and hospital benefits, excluding a specialized health care service plan contract, shall cover the costs for COVID-19 diagnostic and screening testing and health care services related to diagnostic and screening testing approved or granted emergency use authorization by the federal Food and Drug Administration for COVID-19, regardless of whether the services are provided by an in-network or out-of-network provider. Coverage required by this section shall not be subject to copayment, coinsurance, deductible, or any other form of cost sharing. Services related to COVID-19 diagnostic and screening testing include, but are not limited to, hospital or health care provider office visits for the purposes of receiving testing, products related to testing, the administration of testing, and items and services furnished to an enrollee as part of testing.

(1) To the extent a health care provider would have been entitled to receive cost sharing but for this section, the health care service plan shall reimburse the health care provider the amount of that lost cost sharing.

(2) A health care service plan contract shall not impose prior authorization or any other utilization management requirements on COVID-19 diagnostic and screening testing.

(3) With respect to an enrollee, a health care service plan shall reimburse the provider of the testing according to either of the following:

(A) If the health plan has a specifically negotiated rate for COVID-19 diagnostic and screening testing with such provider in effect before the public health emergency declared under Section 319 of the Public Health Service Act (42 U.S.C. Sec. 247d), such negotiated rate shall apply throughout the period of such declaration.

(B) If the health plan does not have a specifically negotiated rate for COVID-19 diagnostic and screening testing with such provider, the plan may negotiate a rate with such provider.

(4) ~~(A)~~ For an out-of-network provider with whom a health care service plan does not have a specifically negotiated rate for COVID-19 diagnostic and screening testing and health care services related to testing, a plan shall reimburse the provider for all testing items or services in an amount that is reasonable, as determined in comparison to prevailing market rates for testing items or services in the geographic region where the item or service is rendered. An out-of-network provider shall accept this payment as payment in ~~full~~ and full, shall not seek additional remuneration from an enrollee for services related to ~~testing~~ testing, and shall not report adverse information to a consumer credit reporting agency or commence civil action against the enrollee.

~~(B) The requirement in this subdivision~~

(5) *Beginning 12 months after the federal public health emergency expires, a health care service plan shall no longer be required to cover the cost sharing for COVID-19 diagnostic and screening*

testing and health care services related to testing ~~without cost sharing~~, when delivered by an out-of-network provider, ~~shall not apply with respect to COVID-19 diagnostic and screening testing and services related to testing furnished on, or after, the expiration of the federal public health emergency.~~ *except as otherwise required by law.* All other requirements of this subdivision shall remain in effect after the federal public health emergency expires.

(5)

(6) Changes to a contract between a health care service plan and a provider delegating financial risk for diagnostic and screening testing related to a declared public health emergency shall be considered a material change to the parties' contract. A health care service plan shall not delegate the financial risk to a contracted provider for the cost of enrollee services provided under this section unless the parties have negotiated and agreed upon a new provision of the parties' contract pursuant to Section 1375.7.

(b) (1) A health care service plan contract that covers medical, surgical, and hospital benefits shall cover without cost sharing any item, service, or immunization that is intended to prevent or mitigate COVID-19 and that is either of the following with respect to the individual enrollee:

(A) An evidence-based item or service that has in effect a rating of "A" or "B" in the current recommendations of the United States Preventive Services Task Force.

(B) An immunization that has in effect a recommendation from the Advisory Committee on Immunization Practices of the federal Centers for Disease Control and Prevention, regardless of whether the immunization is recommended for routine use.

(2) The item, service, or immunization covered pursuant to paragraph (1) shall be covered no later than 15 business days after the date on which the United States Preventive Services Task Force or the Advisory Committee on Immunization Practices of the federal Centers for Disease Control and Prevention makes a recommendation relating to the item, service, or immunization. A recommendation from the Advisory Committee on Immunization Practices of the federal Centers for Disease Control and Prevention is considered in effect after it has been adopted, or granted emergency use EUA, by the Director of the Centers for Disease Control and Prevention.

(3) (A) A health care service plan subject to this subdivision shall not impose any cost-sharing requirements, including a copayment, coinsurance, or deductible, for any item, service, or immunization described in paragraph (1), regardless of whether such service is delivered by an in-network or out-of-network provider.

(B) To the extent a health care provider would have been entitled to receive cost sharing but for this section, the health care service plan shall reimburse the health care provider the amount of that lost cost sharing.

(C) With respect to an enrollee, a health care service plan shall reimburse the provider of the immunization according to either of the following:

(i) If the health plan has a negotiated rate with such provider in effect before the public health emergency declared under Section 319 of the Public Health Service Act (42 U.S.C. Sec. 247d), such negotiated rate shall apply throughout the period of such declaration.

(ii) If the health plan does not have a negotiated rate with such provider, the plan may negotiate a rate with such provider.

(D) A health care service plan shall not impose cost sharing for any items or services that are necessary for the furnishing of an item, service, or immunization described in paragraph (1), including, but not limited to, provider office visits and vaccine administration, regardless of whether the service is delivered by an in-network or out-of-network provider.

(E) (i) For an out-of-network provider with whom a health care service plan does not have a negotiated rate for an item, service, or immunization described in paragraph (1), a health care service plan shall reimburse the provider for all related items or services, including any items or services that are necessary for the furnishing of an item, service, or immunization described in paragraph (1), in an amount that is reasonable, as determined in comparison to prevailing market rates for such items or services in the geographic region in which the item or service is rendered. An out-of-network provider shall accept this payment as payment in ~~full and~~ full, shall not seek additional remuneration from an ~~insured enrollee~~, and shall not report adverse information to a consumer credit reporting agency or commence civil action against the enrollee for items, services, and immunizations described in subdivision (b), including any items or services that are necessary for the furnishing of an item, service, or immunization described in paragraph (1).

~~(ii) The requirement in this paragraph~~

~~(ii) Beginning 12 months after the federal public health emergency expires, a health care service plan shall no longer be required to cover the cost sharing for any item, service, or immunization described in paragraph (1) and to cover items or services that are necessary for the furnishing of the items, services, or immunizations described in subparagraph (D) without cost sharing paragraph (1) when delivered by an out-of-network provider will not apply with respect to an item, service, or immunization furnished on or after the expiration of the federal public health emergency. provider, except as otherwise required by law. All other requirements of this section shall remain in effect after the federal public health emergency expires.~~

(4) A health care service plan subject to this subdivision shall not impose prior authorization or any other utilization management requirements on any item, service, or immunization described in paragraph (1) or to items or services that are necessary for the furnishing of the items, services, or immunizations described in subparagraph (D) of paragraph (3).

(5) Changes to a contract between a health care service plan and a provider delegating financial risk for immunization related to a declared public health emergency, shall be considered a material change to the parties' contract. A health plan shall not delegate the financial risk to a contracted provider for the cost of enrollee services provided under this section unless the parties have negotiated and agreed upon a new provision of the parties' contract pursuant to Section 1375.7.

(c) The director may issue guidance to health care service plans regarding compliance with this section. This guidance shall not be subject to the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code). The department shall consult with the Department of Insurance in issuing the guidance specified in this subdivision.

(d) ~~This section~~ *section, excluding subdivision (h), shall apply retroactively beginning from the Governor's declared State of Emergency related to the SARS-CoV-2 (COVID-19) pandemic on March 4, 2020. Notwithstanding Section 1390, this subdivision does not create criminal liability for transactions that occurred before January 1, 2022.*

(e) For purposes of this section:

(1) "Diagnostic testing" means all of the following:

(A) Testing intended to identify current or past infection and performed when a person has signs or symptoms consistent with COVID-19, or when a person is asymptomatic but has recent known or suspected exposure to SARS-CoV-2.

(B) Testing a person with symptoms consistent with COVID-19.

(C) Testing a person as a result of contact tracing efforts.

(D) Testing a person who indicates that they were exposed to someone with a confirmed or suspected case of COVID-19.

(E) Testing a person after an individualized clinical assessment by a licensed health care provider.

(2) "Screening testing" means tests that are intended to identify people with COVID-19 who are asymptomatic and do not have known, suspected, or reported exposure to SARS-CoV-2. Screening testing helps to identify unknown cases so that measures can be taken to prevent further transmission. Screening testing includes all of the following:

(A) Workers in a workplace setting.

(B) Students, faculty, and staff in a school setting.

(C) A person before or after travel.

(D) At home for someone who does not have symptoms associated with COVID-19 and does not have a known exposure to someone with COVID-19.

(f) This section does not relieve a health care service plan from continuing to cover testing as required by federal law and guidance.

(g) The department shall hold health care service plans accountable for timely access to services required under this section and coverage requirements established under federal law, regulations, or guidelines.

(h) (1) A health care service plan contract issued, amended, or renewed on or after the operative date of this subdivision that covers medical, surgical, and hospital benefits, excluding a specialized health care service plan contract, shall cover therapeutics approved or granted emergency use EUA by the federal Food and Drug Administration for COVID-19 when prescribed or furnished by a licensed health care provider acting within their scope of practice and the standard of care.

(2) A health care service plan shall reimburse a provider for the therapeutics described in paragraph (1) at the specifically negotiated rate for those therapeutics, if the plan and provider have negotiated a rate. If the plan does not have a negotiated rate with a provider, the plan may negotiate a rate with the provider.

(3) For an out-of-network provider with whom a health care service plan does not have a negotiated rate for the therapeutics described in paragraph (1), a health care service plan shall reimburse the provider for the therapeutics in an amount that is reasonable, as determined in comparison to prevailing market rates for the therapeutics in the geographic region in which the therapeutic was delivered. An out-of-network provider shall accept this payment as payment in full, shall not seek additional remuneration from an enrollee, and shall not report adverse information to a consumer credit reporting agency or commence civil action against the enrollee for therapeutics described in this subdivision.

(4) A health care service plan shall cover COVID-19 therapeutics without cost sharing, regardless of whether the therapeutics are provided by an in-network or out-of-network provider, and without utilization management. If a provider would have been entitled to receive cost sharing but for this section, the health care service plan shall reimburse the provider for the amount of that lost cost sharing. A provider shall accept this payment as payment in full, shall not seek additional remuneration from an enrollee, and shall not report adverse information to a consumer credit reporting agency or commence civil action against the enrollee for therapeutics pursuant to this subdivision.

(5) Beginning 12 months after the federal public health emergency expires, a health care service plan shall no longer be required to cover the cost sharing for COVID-19 therapeutics delivered by an out-of-network provider, unless otherwise required by law. All other requirements of this subdivision shall remain in effect after the federal public health emergency expires.

SEC. 2. *Section 1342.3 of the Health and Safety Code is amended to read:*

1342.3. (a) A health care service plan contract that covers medical, surgical, and hospital benefits, excluding a specialized health care service plan contract, shall cover, without cost sharing and without prior EUA or other utilization management, the costs of the following health care services to prevent or mitigate a disease when the Governor of the State of California has declared a public health emergency due to that disease:

(1) An evidence-based item, service, or immunization that is intended to prevent or mitigate a disease as recommended by the United States Preventive Services Task Force that has in effect a rating of “A” or “B” or the Advisory Committee on Immunization Practices of the federal Centers for Disease Control and Prevention.

(2) A health care service or product related to diagnostic and screening testing for the disease that is approved or granted emergency use authorization by the federal Food and Drug Administration, or is recommended by the State Department of Public Health or the federal Centers for Disease Control and Prevention.

(3) *Therapeutics approved or granted emergency use authorization by the federal Food and Drug Administration for the disease.*

(b) The item, service, or immunization covered pursuant to paragraph (1) of subdivision (a) shall be covered no later than 15 business days after the date on which the United States Preventive Services Task Force or the Advisory Committee on Immunization Practices of the federal Centers for Disease Control and Prevention makes a recommendation relating to the item, service, or immunization.

SECTION 1. ~~SEC. 3.~~ Section 1399.848 of the Health and Safety Code is amended to read:

1399.848. (a) Notwithstanding paragraph (1) of subdivision (c) of Section 1399.849, with respect to individual health benefit plans offered outside of the Exchange, a plan shall provide an annual enrollment period for policy years beginning on or after January 1, 2020, from November 1 of the preceding calendar year, to January 31 of the benefit year, inclusive.

(b) Notwithstanding paragraphs (2) and (3) of subdivision (c) of Section 1399.849, with respect to individual health benefit plans offered through the Exchange, for policy years beginning on or after January 1, 2023, a plan shall provide an annual enrollment period from November 1 of the preceding calendar year to January 31 of the benefit year, inclusive.

(c) Notwithstanding paragraph (3) of subdivision (c) of Section 1399.849, with respect to individual health benefit plans offered outside and through the Exchange, the effective date of coverage shall be as follows:

(1) No later than January 1 of the benefit year for plan selection made from November 1 to December 31 of the preceding calendar year, inclusive.

(2) No later than February 1 of the benefit year for plan selection made from January 1 to January 31 of the benefit year, inclusive.

SEC. 4. *Section 10110.7 of the Insurance Code is amended to read:*

10110.7. (a) This section applies to a disability insurance policy that provides coverage for hospital, medical, or surgical benefits, excluding a specialized health insurance policy and a policy

that provides excepted benefits as described in Sections 2722 (42 U.S.C. Sec. 300gg-21) and 2791 (42 U.S.C. Sec. 300gg-91) of the federal Public Health Service Act, subject to Section 10198.61.

(b) Notwithstanding any other law, a disability insurance policy shall cover the costs for COVID-19 diagnostic and screening testing and health care services related to the diagnostic and screening testing approved or granted emergency use authorization by the federal Food and Drug Administration for COVID-19, regardless of whether the services are provided by an in-network or out-of-network provider. Coverage required by this section shall not be subject to copayment, coinsurance, deductible, or any other form of cost sharing. Services related to COVID-19 diagnostic and screening testing include, but are not limited to, hospital or health care provider office visits for the purposes of receiving testing, products related to testing, the administration of testing, and items and services furnished to an insured as part of testing.

(1) To the extent a health care provider would have been entitled to receive cost sharing but for this section, the insurer shall reimburse the health care provider the amount of that lost cost sharing.

(2) A disability insurance policy shall not impose prior authorization or any other utilization management requirements on COVID-19 diagnostic and screening testing.

(3) With respect to an insured, a health insurer shall reimburse the provider of the testing according to either of the following:

(A) If the health insurer has a specifically negotiated rate for COVID-19 diagnostic and screening testing with such provider in effect before the public health emergency declared under Section 319 of the Public Health Service Act (42 U.S.C. Sec. 247d), such negotiated rate shall apply throughout the period of such declaration.

(B) If the health insurer does not have a specifically negotiated rate for COVID-19 diagnostic and screening testing with such provider, the insurer may negotiate a rate with such provider.

(4) (A) For an out-of-network provider with whom an insurer does not have a specifically negotiated rate for COVID-19 diagnostic and screening testing and health care services related to testing, an insurer shall reimburse the provider for all testing items or services in an amount that is reasonable, as determined in comparison to prevailing market rates for testing items or services in the geographic region where the item or service is rendered. An out-of-network provider shall accept this payment as payment in ~~full and~~ full, shall not seek additional remuneration from an insured for services related to ~~testing.~~ *testing, and shall not report adverse information to a consumer credit reporting agency or commence civil action against the insured.*

~~(B) The requirement in this subdivision~~

~~(5) Beginning 12 months after the federal public health emergency expires, an insurer shall no longer be required to cover the cost sharing for COVID-19 diagnostic and screening testing and health care services related to testing without cost sharing when delivered by an out-of-network provider will not apply with respect to COVID-19 diagnostic and screening testing and health care services related to testing furnished on or after the expiration of the federal public~~

~~health emergency~~ provider, except as otherwise required by law. All other requirements of this subdivision shall remain in effect after the federal public health emergency expires.

(c) (1) A disability insurance policy shall cover without cost sharing any item, service, or immunization that is intended to prevent or mitigate COVID-19 and that is either of the following with respect to the individual insured:

(A) An evidence-based item or service that has in effect a rating of “A” or “B” in the current recommendations of the United States Preventive Services Task Force.

(B) An immunization that has in effect a recommendation from the Advisory Committee on Immunization Practices of the federal Centers for Disease Control and Prevention regardless of whether the immunization is recommended for routine use.

(2) To the extent a health care provider would have been entitled to receive cost sharing but for this section, the insurer shall reimburse the health care provider the amount of that lost cost sharing.

(3) The item, service, or immunization covered pursuant to paragraph (1) shall be covered no later than 15 business days after the date on which the United States Preventive Services Task Force or the Advisory Committee on Immunization Practices of the federal Centers for Disease Control and Prevention makes a recommendation relating to the item, service, or immunization. A recommendation from the Advisory Committee on Immunization Practices of the federal Centers for Disease Control and Prevention is considered in effect after it has been adopted, or granted emergency use authorization, by the Director of the Centers for Disease Control and Prevention.

(4) (A) A disability insurance policy subject to this subdivision shall not impose any cost-sharing requirements, including a copayment, coinsurance, or deductible, for any item, service, or immunization described in paragraph (1), regardless of whether such service is delivered by an in-network or out-of-network provider.

(B) A disability insurance policy shall not impose cost sharing for any items or services that are necessary for the furnishing of an item, service, or immunization described in paragraph (1), including, but not limited to, provider office visits and vaccine administration, regardless of whether the service is delivered by an in-network or out-of-network provider.

(C) With respect to an insured, a health insurer shall reimburse the provider of the immunization according to either of the following:

(i) If the health insurer has a negotiated rate with such provider in effect before the public health emergency declared under Section 319 of the Public Health Service Act (42 U.S.C. Sec. 247d), such negotiated rate shall apply throughout the period of such declaration.

(ii) If the health insurer does not have a negotiated rate with such provider, the insurer may negotiate a rate with such provider.

(D) For an out-of-network provider with whom a disability insurer does not have a negotiated rate for an item, service, or immunization described in paragraph (1), an insurer shall reimburse the provider for all such items or services, including any items or services that are necessary for the furnishing of an item, service, or immunization described in paragraph (1), in an amount that is reasonable, as determined in comparison to prevailing market rates for such items or services in the geographic region in which the item or service is rendered. An out-of-network provider shall accept this payment as payment in ~~full and~~ full, shall not seek additional remuneration from an ~~insured~~ insured, and shall not report adverse information to a consumer credit reporting agency or commence civil action against the insured for items, services, and immunizations described in paragraph (1), including any items or services that are necessary for the furnishing of an item, service, or immunization described in paragraph (1).

(E) ~~The requirement in this subdivision~~ *Beginning 12 months after the federal public health emergency expires, an insurer shall no longer be required to cover the cost sharing for any item, service, or immunization described in paragraph (1) and to cover any items or services that are necessary for the furnishing of the items, services, or immunizations described in subparagraph (B), without cost sharing* paragraph (1) when delivered by an out-of-network provider will not apply with respect to an item, service, or immunization furnished on or after the expiration of the federal public health emergency. *provider, except as otherwise required by law.* All other requirements of this section shall remain in effect after the federal public health emergency expires.

(5) A disability insurer subject to this subdivision shall not impose prior authorization or any other utilization management requirements on any item, service, or immunization described in paragraph (1) or to items or services that are necessary for the furnishing of the items, services, or immunizations described in subparagraph (B) of paragraph (4).

(d) The commissioner may issue guidance to insurers regarding compliance with this section. This guidance shall not be subject to the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code). The department shall consult with the Department of Managed Health Care in issuing the guidance specified in this subdivision.

(e) ~~This section~~ *section, excluding subdivision (i), shall apply retroactively beginning from the Governor's declared State of Emergency related to the SARS-CoV-2 (COVID-19) pandemic on March 4, 2020.*

(f) For purposes of this section:

(1) "Diagnostic testing" means all of the following:

(A) Testing intended to identify current or past infection and performed when a person has signs or symptoms consistent with COVID-19, or when a person is asymptomatic but has recent known or suspected exposure to SARS-CoV-2.

(B) Testing a person with symptoms consistent with COVID-19.

(C) Testing a person as a result of contact tracing efforts.

(D) Testing a person who indicates that they were exposed to someone with a confirmed or suspected case of COVID-19.

(E) Testing a person after an individualized clinical assessment by a licensed health care provider.

(2) “Screening testing” means tests that are intended to identify people with COVID-19 who are asymptomatic and do not have known, suspected, or reported exposure to SARS-CoV-2. Screening testing helps to identify unknown cases so that measures can be taken to prevent further transmission. Screening testing includes all of the following:

(A) Workers in a workplace setting.

(B) Students, faculty, and staff in a school setting.

(C) A person before or after travel.

(D) At home for someone who does not have symptoms associated with COVID-19 and does not have a known exposure to someone with COVID-19.

(g) This section does not relieve an insurer from continuing to cover testing as required by federal law and guidance.

(h) The department shall hold insurers accountable for timely access to services required under this section and coverage requirements established under federal law, regulations, or guidelines.

(i) (1) A disability insurance policy issued, amended, or renewed on or after the operative date of this subdivision that covers medical, surgical, and hospital benefits, excluding a specialized disability insurance policy, shall cover therapeutics approved or granted emergency use authorization by the federal Food and Drug Administration for COVID-19 when prescribed or furnished by a licensed health care provider acting within their scope of practice and the standard of care.

(2) A disability insurer shall reimburse a provider for the therapeutics described in paragraph (1) at the specifically negotiated rate for those therapeutics, if the insurer and provider have negotiated a rate. If the insurer does not have a negotiated rate with a provider, the insurer may negotiate a rate with the provider.

(3) For an out-of-network provider with whom a disability insurer does not have a negotiated rate for the therapeutics described in paragraph (1), a disability insurer shall reimburse the provider for the therapeutics in an amount that is reasonable, as determined in comparison to prevailing market rates for the therapeutics in the geographic region in which the therapeutic was delivered. An out-of-network provider shall accept this payment as payment in full, shall not seek additional remuneration from an insured, and shall not report adverse information to a consumer credit

reporting agency or commence civil action against the insured for therapeutics described in this subdivision.

(4) A disability insurer shall cover COVID-19 therapeutics without cost sharing, regardless of whether the therapeutics are provided by an in-network or out-of-network provider, and without utilization management. If a provider would have been entitled to receive cost sharing but for this section, the disability insurer shall reimburse the provider for the amount of that lost cost sharing. A provider shall accept this payment as payment in full, shall not seek additional remuneration from an insured, and shall not report adverse information to a consumer credit reporting agency or commence civil action against the insured for therapeutics pursuant to this subdivision.

(5) Beginning 12 months after the federal public health emergency expires, a disability insurer shall no longer be required to cover the cost sharing for COVID-19 therapeutics delivered by an out-of-network provider, unless otherwise required by law. All other requirements of this subdivision shall remain in effect after the federal public health emergency expires.

SEC. 5. *Section 10110.75 of the Insurance Code is amended to read:*

10110.75. (a) This section applies to a disability insurance policy that provides coverage for hospital, medical, or surgical benefits, excluding a specialized health insurance policy.

(b) (1) A disability insurance policy shall cover, without cost sharing and without prior authorization or other utilization management requirements, the costs of the following health care services to prevent or mitigate a disease when the Governor of the State of California has declared a public health emergency due to that disease:

(A) An evidence-based item, service, or immunization that is intended to prevent or mitigate a disease as recommended by the United States Preventive Services Task Force that has in effect a rating of “A” or “B” or the Advisory Committee on Immunization Practices of the federal Centers for Disease Control and Prevention.

(B) A health care service or product related to diagnostic and screening testing for the disease that is approved or granted emergency use authorization by the federal Food and Drug Administration, or is recommended by the State Department of Public Health or the federal Centers for Disease Control and Prevention.

(C) Therapeutics approved or granted emergency use authorization by the federal Food and Drug Administration for the disease.

(2) The item, service, or immunization covered pursuant to subparagraph (A) of paragraph (1) shall be covered no later than 15 business days after the date on which the United States Preventive Services Task Force or the Advisory Committee on Immunization Practices of the federal Centers for Disease Control and Prevention makes a recommendation relating to the item, service, or immunization.

~~SEC. 2.~~**SEC. 6.** Section 10965.4 of the Insurance Code is amended to read:

10965.4. (a) Notwithstanding paragraph (1) of subdivision (c) of Section 10965.3, with respect to individual health benefit plans offered outside of the Exchange, a health insurer shall provide an annual enrollment period for policy years beginning on or after January 1, 2020, from November 1 of the preceding calendar year, to January 31 of the benefit year, inclusive.

(b) Notwithstanding paragraphs (2) and (3) of subdivision (c) of Section 10965.3, with respect to individual health benefit plans offered through the Exchange, for policy years beginning on or after January 1, 2023, a health insurer shall provide an annual enrollment period from November 1 of the preceding calendar year to January 31 of the benefit year, inclusive.

(c) Notwithstanding paragraph (3) of subdivision (c) of Section 10965.3, with respect to individual health benefit plans offered outside and through the Exchange, the effective date of coverage shall be as follows:

(1) No later than January 1 of the benefit year for plan selection made from November 1 to December 31 of the preceding calendar year, inclusive.

(2) No later than February 1 of the benefit year for plan selection made from January 1 to January 31 of the benefit year, inclusive.

~~SEC. 3.~~**SEC. 7.** 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 SHARING AND UTILIZATION MANAGEMENT

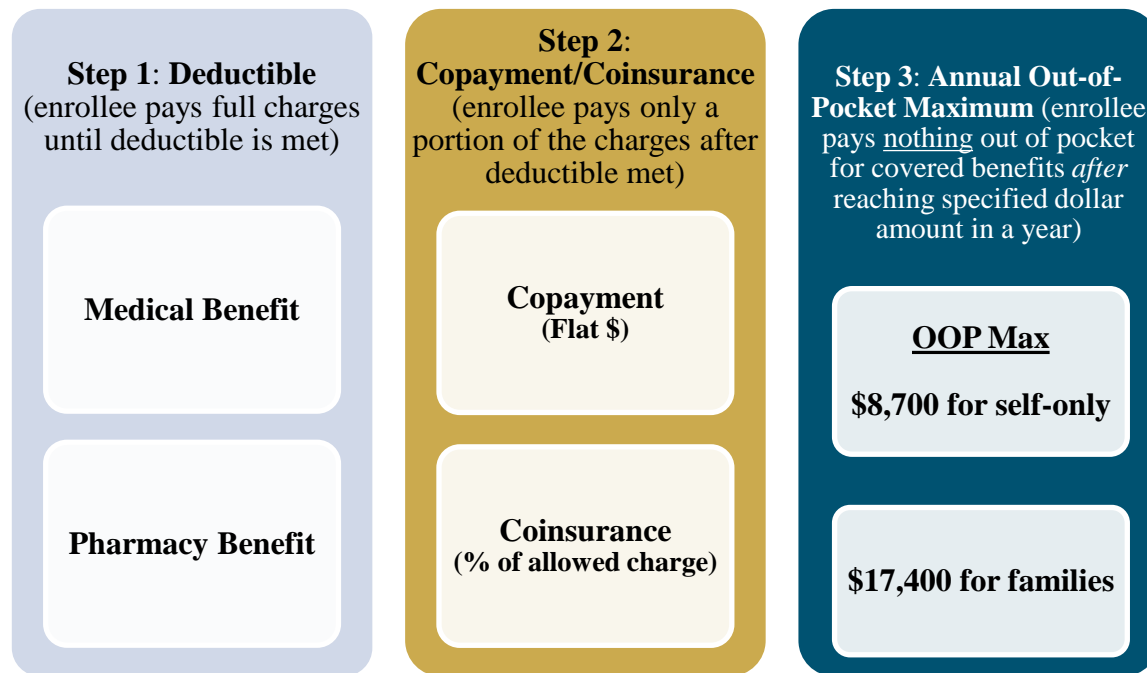
This appendix provides an overview of the cost-sharing and utilization management structures used for health insurance benefits, including coverage of prescription drugs.

Cost Sharing

Payment for use of covered health insurance benefits is shared between the payer (e.g., health plan/insurer or employer) and the enrollee. Common cost-sharing mechanisms include copayments, coinsurance, and/or deductibles (but do not include premium expenses²⁰). There are a variety of cost-sharing mechanisms that can be applicable to covered benefits (Figure 1). Some health insurance benefit designs incorporate higher enrollee cost sharing in order to lower premiums. Reductions in allowed copayments, coinsurance, and/or deductibles can shift the cost to premium expenses or to higher cost sharing for other covered benefits.²¹

Annual out-of-pocket maximums for covered benefits limit annual enrollee cost sharing (medical and pharmacy benefits). After an enrollee has reached this limit through payment of coinsurance, copayments, and/or deductibles, insurance pays 100% of the covered services. The enrollee remains responsible for the full cost of any tests, treatments, or services that are not covered benefits.

Figure 1. Overview of the Intersection of Cost-Sharing Methods Used in Health Insurance



Source: California Health Benefits Review Program, 2022; CMS, 2021b.

²⁰ Premiums are paid by most enrollees, regardless of their use of any tests, treatments, or services. Some enrollees may not pay premiums because their employers cover the full premium, they receive premium subsidies through Covered California, or they receive benefits through Medi-Cal.

²¹ Plans and policies sold within Covered California are required by federal law to meet specified actuarial values. The actuarial value is required to fall within specified ranges and dictates the average percent of health care costs a plan or policy covers. If a required reduction in cost sharing impacts the actuarial value, some number of these plans or policies might have to alter other cost-sharing components of the plan and/or premiums in order to keep the overall benefit design within the required actuarial value limits.

Note: Steps 1 and 2 are not mutually exclusive. Under certain circumstances (i.e., preventive screenings or therapies), enrollees may pay coinsurance or copayments prior to their deductible being met; also copayments and coinsurance may be applied against the deductible in some circumstances. The figure assumes that the enrollee is in a plan with a deductible. If no deductible, then enrollee pays a coinsurance and/or a copayment beginning with the first dollar spent (Step 2).

The annual out-of-pocket maximums listed in Step 3 increase each year according to methods detailed in CMS' Notice of Benefit and Payment Parameters (CMS, 2021b).

Key: OOP Max = annual out-of-pocket maximum.

High Deductible Health Plans (HDHPs)

Both DMHC-regulated plans and CDI-regulated policies may be designated high deductible health plans (HDHPs).²² HDHPs are a type of health plan, and requirements are set by federal regulation (Healthcare.gov, 2021). As the name implies, these plans include a deductible – but they are not allowed to have separate medical and pharmacy deductibles. For the 2022 plan year, the Internal Revenue Service (IRS) defines an HDHP as any plan with a deductible of at least \$1,400 for an individual and \$2,800 for a family.²³ Annual out-of-pocket expenses for coverage of in-network tests, treatments, and services, which would result from cost sharing²⁴ applicable after the deductible is met, are not allowed to be more than \$7,050 for an individual and \$14,100 for a family.²⁵

Health Savings Account (HSA) Qualified HDHPs

To be eligible to establish a Health Savings Account (HSA) for taxable years beginning after December 31, 2003²⁶ (and so to be eligible to make tax-favored contributions to an HSA), a person must be enrolled in an HSA-qualified HDHP.

In order for a HDHP to be HSA qualified, it must follow specified rules regarding cost sharing and deductibles, as set by the IRS. Generally, an HDHP may not provide benefits for any year until the deductible for that year is satisfied – but federal law provides a safe harbor for the absence of a deductible applicable to preventive care.²⁷ Therefore an HDHP may cover preventive care benefits without any deductible or with a deductible below the minimum annual deductible – but is not required to do so for a specified list of preventive services. The list of preventive services for which application of a deductible is not required includes treatments for chronic conditions.²⁸

Allowed cost amounts for medical services

Insurers usually negotiate how much they will pay for the costs of covered health care services with health care providers and suppliers (Center on Budget and Policy Priorities, 2018). These negotiated amounts are known as the “allowed cost amount.” Health care providers, including hospitals and physicians, participating in a plan’s network agree to accept these payment amounts when an enrollee covered by the plan uses covered services. The cost-sharing charges that the enrollee owes (for example, a 20% coinsurance rate) are based on this allowed cost amount. If an enrollee uses a service that is not covered or sees a provider that is not within the insurer’s network, the overall charge, including an enrollee’s cost sharing, could be higher than the allowed amount.

²² For enrollment estimates, see CHBRP's resource, *Estimates, Deductibles in State-Regulated Health Insurance*, available at https://chbrp.org/other_publications/index.php.

²³ Internal Revenue Service (IRS). Publication 969. *Health Savings Accounts and Other Tax-Favored Health Plans. (2021).*

²⁴ Such as copays and coinsurance applicable to the covered test, treatment, or service.

²⁵ There is no annual out-of-pocket expenses limit for coverage of out-of-network tests, treatments, and services.

²⁶ Section 1201 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, added section 223 to the Internal Revenue Code.

²⁷ Internal Revenue Service (IRS). Internal Revenue Bulletin: 2004-15. Notice 2004-23. (2004).

Internal Revenue Service (IRS). Internal Revenue Bulletin: 2004-33. Notice 2004-50. (2004).

; and Internal Revenue Service (IRS). Section 223 – Health Savings Accounts. Notice 2013-57 (2013).

²⁸ Internal Revenue Service (IRS). Additional Preventative Care Benefits Permitted to be Provided by a High Deductible Health Plan Under § 223. Notice 2019-45. (2019).

Utilization Management

Utilization management techniques are used by health plans and insurers to control costs, ensure medication compatibility, and manage safety. Examples include benefit coverage requirements related to prior authorization, step therapy, quantity limits, and limits related to the age or sex of the enrollee (such as prescription-only infant formula or prostate cancer screening for men). A brief description of some key utilization management techniques follows.

Prior authorization

Prior authorization – also known as precertification, prior approval, or prospective review – is a utilization management technique commonly used by health insurance carriers to ensure that a given medical intervention meets the insurance plan or policy’s criteria for coverage (Newcomer et al., 2017). Prior authorization developed as a tool for insurers to assess the appropriateness of treatment that would result in a hospital admission or a high-cost procedure (Resneck, 2020). The process typically requires providers to establish eligibility and submit documentation demonstrating medical need to the plan/insurer for approval of coverage before either medical services are provided or a prescription is filled in order to qualify for payment. Health plans/insurers may also impose prior authorization requirements on nonpreferred medications in an effort to promote the use of preferred medications that they can procure at lower prices.

Step therapy

Step therapy or “fail-first” protocols may be applied to prescription medications by health plans and insurers to control costs, ensure medication compatibility, and manage safety. Health plans/insurers may use step therapy protocols to apply clinical guidelines established by professional societies and other recognized organizations to treatment plans. They require an enrollee to try and fail one or more medications prior to receiving coverage for the initially prescribed medication. Step therapy protocols usually recommend starting with a medication that is less expensive (generics) and/or has more “post-marketing safety experience” (PBMI, 2015). In addition, they sometimes require starting with a less potent medication or dosage, perhaps with fewer side effects, and graduating to more potent medications as necessary (e.g., from prescription Motrin to OxyContin to treat pain). Generally, more expensive or more potent medications are covered when the patient fails to respond to the step therapy–required medication (PBMI, 2018).

Appendix C **COST IMPACT ANALYSIS: DATA SOURCES, CAVEATS, AND ASSUMPTIONS**

With the assistance of CHBRP's contracted actuarial firm, Milliman, Inc, the cost analysis presented in this report was prepared by the faculty and researchers connected to CHBRP's Task Force with expertise in health economics.²⁹ 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.³⁰

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

Analysis-Specific Data Sources

Current coverage of the five outpatient COVID-19 drugs for commercial enrollees was determined by a survey of the largest (by enrollment) health plans and health insurers in California. Responses to this survey represent 71% of commercial enrollees with health insurance that can be subject to state benefit mandates.

Analysis-Specific Caveats and Assumptions

The analytic approach and key assumptions are determined by the subject matter and language of the bill being analyzed by CHBRP. As a result, analytic approaches may differ between topically similar analyses, and therefore the approach and findings may not be directly comparable.

Methodology and Assumptions for Baseline Utilization

CHBRP projected that there will be 6.3 million COVID-19 cases in California in 2023. This projection is based on the reported California COVID-19 cases for the period from June 2021 to May 2022 (NY Times, 2021), accessed June 8, 2022). CHBRP assumed the number of reported cases would increase by 5% as a result of people seeking more testing because treatments are available. This value could vary in magnitude and direction depending on the COVID-19 variants in 2023.

CHBRP allocated the infections across the population by age and vaccination status. CHBRP included a vaccine for children under 5 years (approved in 2022). CHBRP assumed 39.5% of children under 5 and aged 5-11 years, 68.7% of children aged 12-17 years, 79.2% of adults aged 18-49 years, 85.0% of adults aged 50-64 years, and 87.0% of adults 65 years and older will be vaccinated in 2023. The vaccination rate is based on California's 2022 vaccination trends projected to 2023 (California for All, 2022). The cases by age distribution was from California's cases by age as of June 2, 2022 (CDPH, 2022). CHBRP assumed the unvaccinated risk of infection is three times the risk of a vaccinated infection (CDC, 2022a).

Methodology and Assumptions for Baseline Cost

For the oral drugs, CHBRP assumed the cost of nirmatrelvir/ritonavir (Paxlovid) and molnupiravir are \$529 and \$707, respectively (ICER, 2022).

²⁹ CHBRP's authorizing statute, available at https://chbrp.org/about_chbrp/index.php, requires that CHBRP use a certified actuary or "other person with relevant knowledge and expertise" to determine financial impact.

³⁰ See method documents posted at http://chbrp.com/analysis_methodology/cost_impact_analysis.php; in particular, see 2022 Cost Analyses: Data Sources, Caveats, and Assumptions.

For the injection, CHBRP assumed the cost of bebtelovimab is \$1,200 per dose (Lilly Investors, 2022). Because this is an office/facility administered drug, an initial visit and an administration visit was added to the cost of treatment, assuming the average cost of an evaluation and management visit in California (\$139). The visit cost is based on Milliman's 2019 Consolidated Health Cost Guidelines Sources Database (CHSD).

Remdesivir is an intravenous infusion administered over 3 days. CHBRP assumed the cost of the treatment is \$2,080 (Huang, 2022). Added to the treatment cost is the average cost of one evaluation and management visit, three units of first hour infusion, and one unit of an additional hour of infusion in California from the 2019 CHSD. The total cost per treatment is \$3,145.

With the exception of remdesivir, the drug costs are currently negotiated by the federal government. The cost of the treatments may be greater because private companies negotiate prices for the commercially insured population.

Methodology and Assumptions for Baseline Cost Sharing

CHBRP assumed nirmatrelvir/ritonavir (Paxlovid) and molnupiravir will be on the second or third tier of an insurance formulary. CHBRP assumed the following copayments:

Nongrandfathered large-group plans: \$51 based on the average reported in the Kaiser Family Foundation's 2021 Employer Health Benefits Survey (KFF, 2021).

Grandfathered plans: \$38.50 based on the KFF 2015 Employer Health Benefits Survey (KFF, 2015).

Nongrandfathered small-group plans: \$30, \$60, \$85, and \$250 for platinum, gold, silver, and bronze, respectively. The assumed copays are based on a review of the 2022 small-group Covered California plan designs.

Nongrandfathered individual plans: \$30, \$68, \$70, \$13, \$35, \$70, and \$250 for platinum, gold, silver 70% AV, silver 94% AV, silver 87% AV, silver 73% AV, and bronze, respectively. The assumed copays are based on the average of the tier 2 and 3 2022 individual Covered California plan design (Covered California, 2022).

Enrollees with HSA-qualified health plans may pay the full amount of the treatment and individuals who have met their out-of-pocket maximum may pay nothing for the treatment at baseline. The outpatient drug copayments do not take deductibles and out of pocket maximums into consideration. The copayment assumptions are a proxy for the average cost sharing per drug for the population.

CHBRP assumed the cost share of the office/facility-administered drugs is the lesser of one minus the actuarial value of the plan multiplied by the cost of treatment including clinician charges or the out-of-pocket maximum. Enrollees with deductibles may pay the full cost of treatment, and those who have out-of-pocket maximum may pay nothing for the treatment at baseline. The copayment assumptions are a proxy of the average cost sharing per treatment for the population.

Methodology and Assumptions for Postmandate Utilization

CHBRP assumed utilization rate postmandate increases as a result of the elimination of cost sharing. CHBRP assumed the following utilization increases based on the cost of the treatment and induced utilization factors for Milliman's Health Cost Guidelines:

- nirmatrelvir/ritonavir (Paxlovid) and molnupiravir: 3%; and
- remdesivir and bebtelovimab: 10%.

Methodology and Assumptions for Postmandate Cost

CHBRP expects no change in the average cost per treatment as a result of SB 1473.

Methodology and Assumptions Related to Hospitalizations and Emergency Department Visits

To determine the number of hospitalizations for the enrollees who do not utilize COVID-19 drugs, CHBRP calculated the risk of hospitalization with a COVID-19 infection by age and vaccination status. The relative risk of hospitalization by age, percentage of cases by age, and California COVID-19 hospitalization rate from cases spanning December 2021 through April 2022 were used to calculate the percentage of COVID-19 cases hospitalized by age (CDC, 2022a; CDPH, 2022; CHHS, 2022). The average US COVID-19 hospitalization rate by age and vaccination status in January 2022 was used to calculate the relative risk of hospitalization by vaccination and age group. (CDC, 2022b) This relative risk was applied to the percentage of COVID-19 cases resulting in hospitalization by age assuming California's vaccination rate as of June 1, 2022 (California for All, 2022). The resulting hospitalizations by age and vaccination status were reweighted such that the total vaccinated and unvaccinated hospitalization rates are equal to California's hospitalizations per case by vaccination status for the December 2021 through April 2022 period.

The hospitalization rate varies depending on the severity of the COVID-19 variant (Nyberg et al., 2022). The hospitalization rate may be greater or less than the assumed rate to the extent that 2023 variants are different from the dominant variant in the observed period.

To determine the hospitalization rate for enrollees who use treatments, the hospitalization rate for enrollees who do not utilize treatments was adjusted for drug efficacy. Because the clinical trials determining the effectiveness of the drugs were performed on an unvaccinated population, the following were applied to the unvaccinated hospitalization rate:

Paxlovid: 84.8% reduction for enrollees under 65 years, and 94.8% reduction for enrollees aged 65 years and older (Hammond et al., 2022).

Molnupiravir: 33.0% reduction for enrollees aged 60 years and younger, and 19.3% reduction for enrollees over age 60 years (Bernal et al., 2022).

Remdesivir: 83.3% reduction for enrollees under age 60 years, and 88.4% reduction for enrollees aged 60 years and older (Gottlieb et al., 2022).

CHBRP assumed that the reduction in the hospitalization rate for vaccinated population as a result of the treatments will be 93% of the reduction in the hospitalization rate for the unvaccinated population nirmatrelvir/ritonavir (Paxlovid) users and 55% of the reduction in the hospitalization rate for the unvaccinated population of molnupiravir users as a result of the drugs (Wong et al., 2022). The drug effectiveness relationship for vaccinated/unvaccinated remdesivir users was assumed to be the same as the relationship for nirmatrelvir/ritonavir (Paxlovid) users because they are similarly effective. The hospitalization rate of the vaccinated population using treatments was adjusted to be less than or equal to the hospitalization rate of the unvaccinated population using treatments by age.

Research is not available on the hospital rate reduction as a result of taking bebtelovimab. CHBRP conservatively assumed the hospitalization rate of those treated with bebtelovimab is equal to the hospitalization rate of the untreated population.

The hospitalization rates by whether or not a treatment was used and vaccination status were multiplied by the number of infections in each category to determine the total number of hospitalizations.

CHBRP assumed the emergency department utilization is 2.1 times the hospitalization rates by treatment and vaccination status. This value is based on the relative number of emergency department visits to inpatient admits from a CDC study on COVID-19 encounters (Naleway et al., 2021).

CHBRP assumed the average cost of a COVID-19–related intensive care unit (ICU) visit in California is \$127,281 and a non-ICU inpatient stay is \$42,674 based on rates published by Fair Health (FAIR Health, 2021). According to a CDC study on ICU trends, 13% of hospitalizations were ICU visits during Omicron (Iuliano et al., 2022). Applying this distribution to the ICU and non-ICU inpatient admissions results in an average cost per visit of \$53,673.

CHBRP assumed the average cost of an emergency department visit is \$3,773 based on Milliman's 2022 Health Cost Guidelines trended to 2023 using a 4.3% annual trend.

CHBRP assumed the cost share of the hospitalizations and emergency department visits is the lesser of one minus the actuarial value of the plan multiplied by the cost of admission/visit or the out-of-pocket maximum.

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ABOUT CHBRP

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.

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** works with Task Force members in preparing parts of the analysis, and manages 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. Information on CHBRP's analysis methodology and authorizing statute, as well as all CHBRP reports and other publications, are available at www.chbrp.org.

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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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