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California Health Benefits Review Program

Analysis of California Senate Bill 473
Insulin Cost Sharing

A Report to the 2021–2022 California State Legislature

April 19, 2021

CALIFORNIA
HEALTH BENEFITS REVIEW PROGRAM

Key Findings

Analysis of California Senate Bill 473 Insulin Cost Sharing

Summary to the 2021–2022 California State Legislature, April 19, 2021

CALIFORNIA HEALTH BENEFITS REVIEW PROGRAM

SUMMARY

The version of California Senate Bill (SB) 473 analyzed by CHBRP would limit cost sharing (copayments, coinsurance, and deductibles) for insulin to $50 for a 30-day supply and no more than $100 per month total, regardless of the amount or type of insulin prescribed.

In 2022, of the 21.9 million Californians enrolled in state-regulated health insurance, 13.9 million of them would have insurance subject to, and potentially impacted by, SB 473.

Benefit Coverage: At baseline there are 118,014 enrollees who use insulin, where 64,619 enrollees using insulin have cost sharing that *does not exceed* the SB 473 cost-sharing cap (55%) and 53,395 enrollees using insulin have cost sharing that *exceeds* the SB 473 cap (45%). Postmandate, 100% of enrollees with cost sharing that exceeds the cap at baseline would have cost sharing below the cap. SB 473 appears not to exceed the definition of essential health benefits (EHBs) in California.

Medical Effectiveness: CHBRP found a *preponderance of evidence* that higher cost sharing reduces adherence to insulin and lower cost sharing increases adherence to insulin. There is *insufficient evidence* on the associated effect of cost sharing for insulin on diabetes-related health outcomes, including HbA1c levels, outpatient visits, emergency department visits, hospitalizations, long-term complications, and disability/absenteeism rates.

Cost and Health Impacts[1]: In 2022, SB 473 would increase total net annual expenditures by $23,663,000 or 0.02% for enrollees with DMHC-regulated plans and CDI-regulated policies. This is due to an increase in $51,527,000 in total health insurance premiums paid by employers and enrollees, adjusted by a $27,864,000 decrease in enrollee expenses.

The 45% of enrollees with cost sharing that exceeds the cap at baseline would experience a 55% reduction in cost sharing, which results in a 7% increase in utilization of insulin postmandate for those enrollees. Average cost sharing for these enrollees decreases from $88 per prescription to $39 per prescription.

Additionally, CHBRP assumed a 10% decrease in diabetes-related emergency department visits due to increased insulin utilization stemming from better adherence to insulin prescription regimens for those who underuse. Offsets stemming from this reduction in diabetes-related emergency department visits are estimated to result in $2,356,000 million lower allowed costs postmandate in 2022.

SB 473 may result in improved glycemic control, a reduction in healthcare utilization, a reduction in long-term complications attributable to diabetes, and improved quality of life for enrollees that experience a decrease in cost sharing and improved insulin adherence, or begin using insulin due to reduced costs.

CONTEXT

Diabetes mellitus (DM), frequently referred to as diabetes, is one of the most common chronic conditions in California and the United States. According to the 2019 data from the Behavioral Risk Factor Surveillance System, about 10% of the adult population in California has been diagnosed with diabetes. The incidence of diabetes is highest among adults aged 65 and older.

Diabetes is a chronic disease with short- and long-term health effects that prevent the proper production of and/or response to insulin, a hormone that facilitates the transfer of glucose into cells to provide energy.[2] Insulin can be used to treat all three types of diabetes: Type 1 diabetes mellitus (T1DM); Type 2 diabetes mellitus (T2DM); and gestational diabetes (GDM). The American Diabetes Association recommends different insulin regimens based on the type of diabetes a person has.

[1] Similar cost and health impacts could be expected for the following year, though possible changes in medical science and other aspects of health make stability of impacts less certain as time goes by.

[2] Refer to CHBRP's full report for full citations and references.

Insulin is necessary for the treatment of T1DM and sometimes necessary for the treatment of T2DM and GDM.

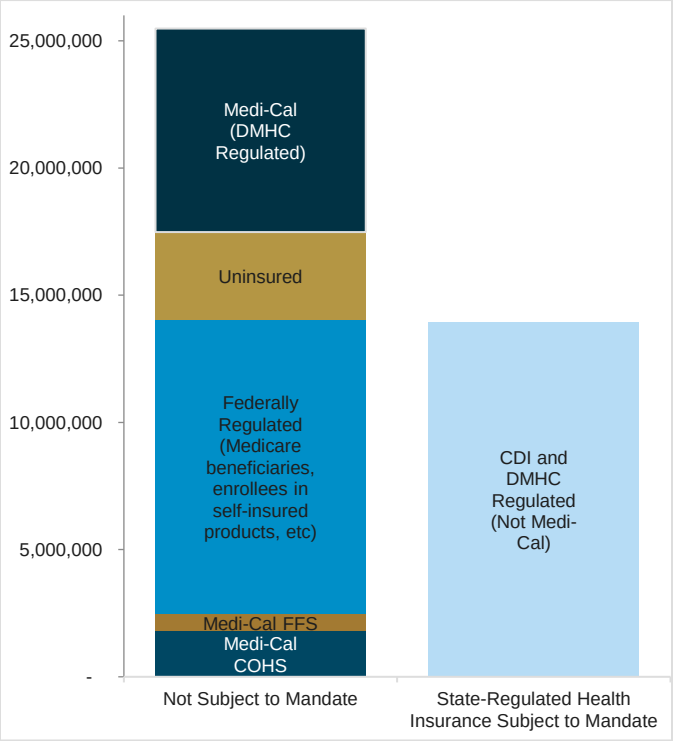
In general, insulin has become expensive for individuals living with diabetes; therefore, cost may be a barrier to insulin use for some individuals. Other identified barriers to insulin use that are independent of cost include regimen complexity and treatment tolerability, as well as injection-related factors.

BILL SUMMARY

Senate Bill (SB) 473 would limit allowed copayments for insulin to $50 for a 30-day supply and no more than $100 per month total, regardless of the amount or type of insulin prescribed. SB 473 also prohibits plans and policies from applying a deductible, coinsurance, and other cost-sharing requirements on insulin prescriptions. The $100 per month cap may impact enrollees using multiple insulin prescriptions per month.

Figure A notes how many Californians have health insurance that would be subject to SB 473 (approximately 35% of Californians).

Figure A. Health Insurance in CA and SB 473



Source: California Health Benefits Review Program, 2021.

Notes: *Medicare beneficiaries, enrollees in self-insured products, etc.

IMPACTS

Benefit Coverage, Utilization, and Cost

Benefit Coverage

CHBRP estimates that, at baseline, there are 118,014 enrollees who use insulin in plans regulated by the California Department of Managed Health Care (DMHC) and policies regulated by the California Department of Insurance (CDI), where 64,619 enrollees (55%) using insulin have cost sharing *that does not exceed* the SB 473 cost-sharing cap, and 53,395 enrollees (45%) using insulin have cost sharing *that exceeds* the SB 473 cap. Postmandate, 100% of enrollees with cost sharing that exceeds the cap at baseline would have cost sharing below the cap.

Utilization

Postmandate, the group whose claims exceeded the cost-sharing cap at baseline would experience an increase in utilization because this group would experience a decrease in cost sharing due to the bill. Utilization among enrollees who exceeded the cap at baseline is higher than those under the cap, which reflects the greater need for insulin in this group of enrollees.

To estimate changes in utilization postmandate, CHBRP applied an estimate of price elasticity of demand to enrollees exceeding the cap at baseline. CHBRP assumes that utilization increases by 8% when cost-sharing doubles. Based on this assumption, CHBRP estimates a 55% reduction in cost sharing for those enrollees who have cost sharing exceeding the cost-sharing cap at baseline, and therefore estimates a 7% increase in utilization of insulin postmandate for those enrollees.

Expenditures

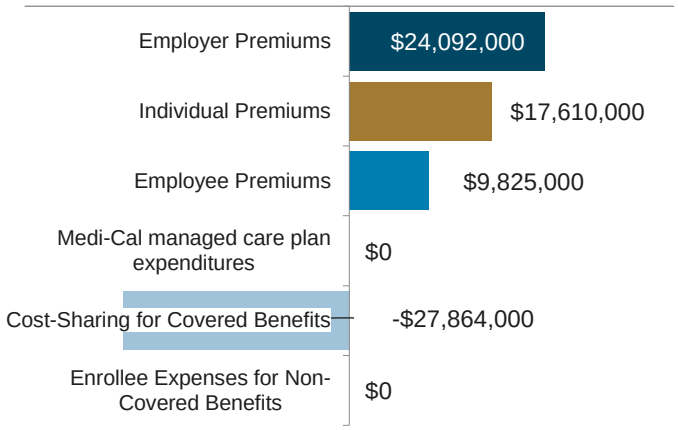
Based on Milliman's 2019 Consolidated Health Cost Guidelines Sources Database (CHSD) claims data, the average cost of insulin per prescription per month is $491. For enrollees whose claims do not exceed the cost-sharing cap at baseline, the average cost sharing for insulin is $19, and for those enrollees whose claims exceed the cost-sharing cap at baseline, the average cost sharing for insulin is $88. Postmandate, cost sharing for enrollees who had claims exceeding the cap would experience a 55% reduction in cost sharing, resulting in an average cost share of $39 per month.

SB 473 would increase total net annual expenditures by $23,663,000 or total net annual 0.02% for enrollees with DMHC-regulated plans and CDI-regulated policies. This is due to an increase in $51,527,000 in total health insurance premiums paid by employers and enrollees, adjusted by a $27,864,000 decrease in enrollee expenses.

CHBRP estimates that total premiums for private employers purchasing group health insurance would increase by $24,092,000, or 0.04%. Total premiums for purchasers of individual market health insurance would increase by $17,610,000, or 0.11%. The greatest change in premiums as a result of SB 473 is for the small-group plans (0.13% increase) and individual plans (0.11% increase) in the DMHC-regulated market.

Based on the medical effectiveness review, which examined the literature on outcomes associated with better adherence to insulin, CHBRP assumed a 10% decrease in diabetes-related emergency department visits due to increased insulin utilization stemming from better adherence to insulin prescription regimens for those who underuse. Offsets stemming from this reduction in diabetes-related emergency department visits are estimated to result in $2,356,000 lower allowed costs postmandate in 2022.

Figure B. Expenditure Impacts of SB 473



Source: California Health Benefits Review Program, 2021.

Enrollee Cost Sharing Expenses

For baseline insulin users, SB 473 caps on cost sharing only impact those enrollees who are above the cap at baseline. Overall, 45% of enrollees who use insulin at baseline would experience changes in cost sharing.

It is possible that some enrollees who had deferred insulin treatment due to cost could begin using insulin postmandate; thus, this group of enrollees would incur cost sharing postmandate, whereas they did not have cost sharing at baseline. However, this group is estimated to be relatively small. Literature suggests approximately 2.5% of people who were prescribed insulin never started their prescription in the past year due to cost. Thus, for some enrollees, cost sharing may be the sole barrier to filling their insulin prescription.

The enrollees most likely to experience the greatest cost sharing reductions postmandate are those who are enrolled in plans that require significant deductibles to be met before coinsurance or copayment is applied to the insulin purchase. Cost-sharing reductions due to SB 473 are the greatest for enrollees who have the highest cost sharing for insulin at baseline. Among the enrollees impacted by the cost-sharing cap, enrollees with cost sharing expenditures for insulin in the top 1% at baseline have an annual savings of greater than $3,111.

Medi-Cal

CHBRP assumes Medi-Cal's pharmacy benefit carve out transition will be complete by 2022. Because SB 473 only impacts DMCH-regulated pharmacy benefits, Medi-Cal managed care plans are not subject to the provisions of SB 473.

CalPERS

For CalPERS HMO enrollees, the impact on premiums is $0, because there are no enrollees for whom cost sharing for insulin prescription is higher than the cap at baseline.

Number of Uninsured in California

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 due to the enactment of SB 473.

Medical Effectiveness

CHBRP found a *preponderance of evidence*[3] from seven cross-sectional and retrospective studies on cost-related insulin use/adherence that cost sharing affects insulin use and adherence in patients with diabetes. These studies provided a *preponderance of evidence* that

[3] *Preponderance of evidence* indicates that the majority of the studies reviewed are consistent in their findings that treatment is either effective or not effective.

higher cost sharing reduces adherence to insulin, and lower cost sharing increases adherence to insulin.

CHBRP found *insufficient evidence*[4] on the associated effect of cost sharing for insulin on diabetes-related health outcomes, including HbA1c levels, outpatient visits, emergency department visits, hospitalizations, long-term complications, and disability/absenteeism rates. Though the studies presented did report on these health and utilization outcomes, the findings were not specific to the effect of insulin alone, but combined with use of other oral antidiabetic medications and testing supplies.

There were several limitations that contributed to the gradings provided in this review, most notably the inherent differences between the types of diabetes conditions and the multifaceted nature of diabetes treatment. This resulted in a literature base that is not as rigorous and thereby limiting the certainty of conclusions drawn from the evidence.

Public Health

In the first year postmandate, 53,395 enrollees who exceed the insulin cost-sharing cap at baseline would have reduced cost sharing. CHBRP projects that as a result, there would be a 7% increase in utilization of insulin. CHBRP found a preponderance of evidence that cost sharing for insulin is effective in improving adherence to insulin in patients with diabetes, and insufficient evidence on the effect of cost sharing for diabetes-related health outcomes. Therefore, SB 473 may result in improved glycemic control, a reduction in healthcare utilization such as emergency department visits, a reduction in long-term complications attributable to diabetes, and improved quality of life for enrollees that experience a decrease in cost sharing and improved insulin adherence, or begin using insulin due to reduced costs.

Long-Term Impacts

CHBRP estimates annual insulin utilization after the initial 12 months from the enactment of SB 473 would likely stay similar to utilization estimates during the first 12 months postmandate. Health care utilization due to improved diabetes management may change in the long term. Reductions in significant complications or comorbidities may take years to develop, but are not trivial.

Similarly, reductions in significant complications or comorbidities may take years to develop, as would significant differences in disability and absenteeism. SB 473 is unlikely to impact these public health outcomes statewide, but at a person-level it could make a substantial difference in long-term healthcare spending, morbidity, and mortality.

CHBRP estimates that SB 473 would improve disparities related to income for some enrollees who have cost-related barriers to insulin use. CHBRP is unable to estimate reductions in existing disparities. However, because the prevalence of diabetes is higher for Blacks than for Whites, and there is evidence that cost-related medication nonadherence is also more associated with Blacks, it is possible that this disparity may be reduced for the population SB 473 impacts.

The impact of SB 473 on premature mortality is unknown due to the lack of evidence that reduced cost sharing for insulin reduces mortality. However, well-controlled blood glucose results in fewer diabetes-related comorbidities (blindness, amputations, kidney disease, etc.). Therefore, for those patients who attain good glycemic control through increased adherence to insulin, these diabetes-related comorbidities that are known to lead to premature death could be prevented, delayed, or ameliorated.

Essential Health Benefits and the Affordable Care Act

SB 473 would not require coverage for a new state benefit mandate and instead modifies cost-sharing terms and conditions of an already covered medication. Therefore, SB 473 appears not to exceed the definition of EHBs in California.

[4] *Insufficient evidence* indicates that there is not enough evidence available to know whether or not a treatment is effective, either because there are too few studies of the treatment or because the available studies are not of high quality. It does not indicate that a treatment is not effective.

A Report to the California State Legislature

Analysis of California Senate Bill 473
Insulin Cost Sharing

April 19, 2021

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

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

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

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Table 1. SB 473 Impacts on Benefit Coverage, Utilization, and Cost, 2022

	Baseline (2022)	Postmandate Year 1 (2022)	Increase/ Decrease	Change Postmandate
Benefit Coverage				
Total enrollees with health insurance subject to state-level benefit mandates (a)	21,945,000	21,945,000	0	0.00%
Total enrollees with health insurance subject to SB 473	13,940,470	13,940,470	0	0.00%
Total percentage of enrollees with coverage subject to SB 473	64%	64%	0%	0.00%
Utilization and Cost				
Number of enrollees using insulin	118,014	118,014	-	0.00%
Enrollees whose claims **do not exceed** the cost sharing cap	64,619	118,014	53,395	82.63%
Enrollees whose claims **do exceed** the cost sharing cap	53,395	0	-53,395	-100.00%
Utilization per insulin user (# of 30-day supply insulin prescriptions per month)	0.85	0.88	0.03	3.20%
Utilization for enrollees whose claims ***did not* exceed** the cost sharing cap at baseline	0.83	0.83	0	0.00%
Utilization for enrollees whose claims ***did* exceed** the cost sharing cap at baseline	0.87	0.93	0.06	6.92%
Average monthly cost sharing for insulin per insulin user	$50	$28	-$22	-43.45%
Average monthly cost sharing for enrollees whose claims **did not exceed** the cost-sharing cap at baseline	$19	$19	$0	0.00%
Average monthly cost sharing for enrollees whose claims ***did* exceed** the cost-sharing cap at baseline	$88	$39	-$48	-55.06%
Average cost of insulin per prescription per month	$491	$491	$0	0.00%
Expenditures				
Premium (expenditures) by Payer				
Private Employers for group insurance	$55,032,803,000	$55,056,895,000	$24,092,000	0.04%
CalPERS HMO employer expenditures (b) (c)	$5,765,017,000	$5,765,017,000	$0	0.00%
Medi-Cal Managed Care Plan expenditures	$24,150,529,000	$24,150,529,000	$0	0.00%
Enrollee Premiums (expenditures)				
Enrollees for individually purchased insurance	$15,847,507,000	$15,865,117,000	$17,610,000	0.11%
Individually Purchased – Outside Exchange	$4,890,852,000	$4,896,490,000	$5,638,000	0.12%
Individually Purchased – Covered California	$10,956,655,000	$10,968,627,000	$11,972,000	0.11%
Enrollees with group insurance, CalPERS HMOs, Covered California, and Medi-Cal Managed Care (c)	$20,753,446,000	$20,763,271,000	$9,825,000	0.05%
Enrollee out-of-pocket expenses				
Cost sharing for covered benefits (deductibles, copayments, etc.)	$13,168,032,000	$13,140,168,000	-$27,864,000	-0.21%
Expenses for noncovered benefits (d) (e)	$0	$0	$0	0.00%
Total Expenditures	$134,717,334,000	$134,740,997,000	$23,663,000	0.02%

Source: California Health Benefits Review Program, 2021.

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.

(b) About one in five (20.5%) of these enrollees has a pharmacy benefit not subject to DMHC. CHBRP has projected no impact for those enrollees. However, CalPERS could, postmandate, require equivalent coverage for all its members (which could increase the total impact on CalPERS).
(c) Enrollee premium expenditures include contributions by employees to employer-sponsored health insurance, health insurance purchased through Covered California, and contributions to Medi-Cal Managed Care
(d) Includes only expenses paid directly by enrollees (or other sources) to providers for services related to the mandated benefit that are not 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 tests before SB 473, 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 tests for which coverage is denied (through utilization management review), as some enrollees who always had compliant benefit coverage may have done and may continue to do, postmandate.

Key: CalPERS HMOs = California Public Employees' Retirement System Health Maintenance Organizations; CDI = California Department of Insurance; DMHC = Department of Managed Health; COHS = County Operated Health Systems, OPD = Outpatient Prescription Drug

POLICY CONTEXT

The California Assembly Committee on Health has requested that the California Health Benefits Review Program (CHBRP)[5] conduct an evidence-based assessment of the medical, financial, and public health impacts of Senate Bill (SB) 473, Insulin Cost Sharing, as amended on March 10, 2021.

Bill-Specific Analysis of SB 473, Insulin Cost Sharing

Bill Language

SB 473 would limit allowed copayments for insulin to $50 for a 30-day supply and no more than $100 per month total, regardless of the amount or type of insulin prescribed. AB 2203 also prohibits plans and policies from applying a deductible, coinsurance, and other cost-sharing requirements on insulin prescriptions exceeding these limits. The $100 per month cap may impact enrollees using multiple insulin prescriptions per month.

The full text of SB 473 as amended on March 10, 2021 can be found in Appendix A.

CHBRP previously analyzed a similar bill, AB 2203 Insulin Cost Sharing Caps, in 2020. Where applicable, this report builds on that analysis.

Relevant Populations

If enacted, SB 473 would apply to the health insurance of approximately 13.9 million enrollees (35% of all Californians). This represents 64% of the 21.9 million Californians who would have health insurance regulated by the state that may be subject to any state health benefit mandate law — health insurance regulated by the California Department of Managed Health Care (DMHC) or the California Department of Insurance (CDI). If enacted, the law would affect the health insurance of enrollees in DMHC-regulated plans and CDI-regulated policies, excluding enrollees with coverage through Medi-Cal managed care plans.

Although Medi-Cal managed care plans are subject to the Health and Safety Code, cost sharing for all Medi-Cal services is determined through the Welfare and Institutions Code (Section 14134).[6] Therefore, because SB 473 only impacts cost sharing, Medi-Cal managed care plans are not subject to the provisions of SB 473.

Additionally, as of a to-be- determined date[7], outpatient prescription drugs for Medi-Cal managed care beneficiaries are paid for on a fee-for-service basis and are “carved out” of care provided by Medi-Cal managed care plans. Although Medi-Cal managed care plans are subject to the Health & Safety Code, which SB 473 amends, the “carve out” of outpatient prescription drugs results in no impact to the coverage provided to Medi-Cal managed care plan beneficiaries. More information about outpatient prescription drug coverage among Californians with state-regulated health insurance is available in CHBRP’s resource *Estimates of Pharmacy Benefit Coverage in California for 2022*.

Table 2 below indicates the presence of enrollees in the various market segments regulated by DMHC or CDI with a pharmacy benefit deductible. Enrollees in HSA qualified HDHPs have a combined medical and pharmacy benefit deductible. Some enrollees in non-HSA plans and policies may also have a combined medical and pharmacy deductible, but this is rare.

[5] CHBRP’s authorizing statute is available at www.chbrp.org/faqs.php.
[6] Communication with the Department of Managed Health Care, March 2020; Communication with the Department of Health Care Services, April 2020.
[7] The implementation originally scheduled for April 1, 2021, was delayed due to contracting issues, not due to a change in approach. CHBRP assumes implementation will occur by January 1, 2022.

Table 2. Enrollment in Plans/Policies with a Pharmacy Deductible Among Enrollees with a Pharmacy Benefit, 2022

Pharmacy Deductible Enrollment					
Market Segment	Total Enrollment	No Deductible ($0)	Low (<$500)	High (a) (>=$500)	HSA Qualified HDHP
CDI/DMHC Large Group (e)	8,097,000	81%	13%	0%	6%
CDI/DMHC Small Group (b)(c)(d)(f)	2,129,000	64%	23%	5%	9%
CDI/DMHC Individual	2,093,000	39%	27%	24%	10%
DMHC CalPERS	672,000	100%	0%	0%	0%
Total	**12,991,000**	**72%**	**16%**	**5%**	**7%**

Source: California Health Benefits Review Program, 2021.

Notes: CHBRP assumes only enrollees in HDHPs have combined medical and pharmacy deductibles. (a) does not include enrollees in HSA Qualified HDHP plans.
(b) For this analysis, Small Group Gold plans are assumed to have no pharmacy deductible. In 2021, two of thirteen plans offered in this metal tier have a $250 pharmacy deductible and CHBRP is unable to estimate the number of enrollees in those two plans.
(c) For this analysis, Small Group Silver plans are assumed to be in the "Low Deductible" category. In 2021, nine of thirteen plans offered in this tier have a $300-$350 pharmacy deductible, three have $0 deductible, and one has a deductible of $500 and CHBRP is unable to estimate the varied enrollment among these plans.
(d) For this analysis, Small Group Bronze plans are assumed to have a $500 pharmacy deductible. In 2021, four of five plans offered in this tier have a $500 pharmacy deductible and one plan has no pharmacy deductible. CHBRP is unable to estimate enrollment in that plan.
(e) Large group distribution between no deductible and a deductible is from the Kaiser Family Foundation's 2019 Employer Health Benefits Survey (KFF, 2019), which reports the average pharmacy deductible of large groups with a pharmacy deductible is $190. For this analysis, all large group enrollees with a deductible are in the "Low Deductible" category. (f) According to the Kaiser Family Foundation's 2015 Employer Health Benefits Survey (KFF, 2015), the average pharmacy deductible of small groups with a pharmacy deductible is $160. For this analysis, all grandfathered small group enrollees with a deductible are assumed to be in the "Low Deductible" category.

Key: CalPERS HMOs = California Public Employees' Retirement System Health Maintenance Organizations; CDI = California Department of Insurance; DMHC = Department of Managed Health Care; HDHP = high deductible health; HSA = health savings account

Interaction with Existing Requirements

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

California Policy Landscape

California law and regulations

Pharmacy benefits regulated by DMHC or CDI are required to provide coverage for insulin.[8] As mentioned above, some enrollees with DMHC or CDI regulated health insurance do not have a pharmacy benefit or have a pharmacy benefit not regulated by DMHC or CDI.

DMHC-regulated plans and CDI-regulated policies are required to cover equipment and supplies for the management and treatment of insulin-using diabetes, non-insulin using diabetes, and gestational diabetes as medically necessary, even if the items are available without a prescription.[9] This provision is not specific to enrollees with a DMHC or CDI regulated pharmacy benefit.

[8] H&SC 1367.51; IC 10176.61.
[9] H&SC 1367.51; IC 10176.61.

Senate Bill (SB) 852, signed into law in 2020, requires the California Health and Human Services Agency to enter into partnerships to increase patient access to affordable drugs, including producing or distributing generic prescription drugs and at least one form of insulin. The Agency is required to submit a report to the Legislature by July 2023 that assesses the feasibility of these directives.

Existing California law limits cost sharing for prescription drugs to up to $250 for a 30-day supply.[10] Separate pharmacy deductibles are limited to $500 for nongrandfathered individual and small group plans and policies.[11]

Similar requirements in other states

At least ten states have passed laws that limit cost sharing (copayment, coinsurance, and deductibles) for insulin, as of March 2021. Colorado,[12] Illinois,[13] New York,[14] Washington,[15] Vermont,[16] and West Virginia[17] currently limit cost sharing for an insulin prescription to $100 per 30-day supply, regardless of the amount or type of insulin. Connecticut limits total cost sharing to $25 per 30-day supply, regardless of the amount or type of insulin.[18] Maine limits cost sharing for insulin to $35 for a 30-day supply, regardless of the amount.[19] New Mexico limits cost sharing for a 30-day supply of preferred formulary insulin or the medically necessary equivalent to $25.[20] Utah limits cost sharing for a 30-day supply of at least one insulin in each “therapy category” to $30 and prohibits insulin from being subject to the deductible.[21]

Similar legislation has recently been introduced in at least 18 other states and DC.[22] State bills would limit cost sharing for insulin prescriptions anywhere between $25 for a 30-day to $100 for a 30-day supply. A few states have legislation that would limit cost sharing for a 90-day supply. Additionally, several states have multiple proposals moving through the legislature with varying levels of cost sharing limits.

Federal Policy Landscape

On March 11, 2020, the Centers for Medicare & Medicaid Services (CMS) announced the Part D Senior Savings Model, a voluntary model that enables participating Part D enhanced plans[23] to lower Medicare beneficiaries’ cost sharing for insulin to a maximum $35 copay per 30-day supply throughout the benefit year.[24] The program began January 1, 2021.

Affordable Care Act

A number of Affordable Care Act (ACA) provisions have the potential to or do interact with state benefit mandates. Below is an analysis of how SB 473 may interact with requirements of the ACA as presently

[10] H&SC 1342.73; IC 10123.1932.
[11] Ibid.
[12] Colorado House Bill 19-1216.
[13] Illinois Senate Bill 667.
[14] New York State Senate Bill 7506-B.
[15] Washington Senate Bill 6087; although the bill language states cost sharing is limited regardless of amount of insulin prescribed, the bill does not state whether this applies regardless of type of insulin.
[16] Vermont House Bill 969
[17] West Virginia House Bill 4543.
[18] Connecticut House Bill 6003
[19] Maine Legislative Document 2096.
[20] New Mexico House Bill 292.
[21] Utah House Bill 207 Insulin Access Amendments, 2020.
[22] Legislative search through PoliticoPro, conducted on March 6, 2021.
[23] Approximately 60% of Medicare Part D prescription drug plans, nationally, are “enhanced” in 2020. KFF, Medicare Part D: A first look at prescription drug plans in 2020. 2019. Accessed on March 31, 2020 at https://www.kff.org/report-section/medicare-part-d-a-first-look-at-prescription-drug-plans-in-2020-issue-brief/.
[24] Centers for Medicare and Medicaid Services. 2020. CMS launches groundbreaking model to lower out of pocket expenses for insulin. Accessed on March 13, 2020. Available at: https://www.cms.gov/newsroom/press-releases/cms-launches-groundbreaking-model-lower-out-pocket-expenses-insulin.

exists in federal law, including the requirement for certain health insurance to cover essential health benefits (EHBs).[25,26]

For the 2021 plan year for nongrandfathered group plans, the annual out-of-pocket maximums for an individual are $8,550 and $17,100 for a family.[27] This means once an enrollee or a family reach these out-of-pocket maximums, they are no longer responsible for additional cost-sharing responsibilities for the remainder of the plan year.

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

Essential Health Benefits

Nongrandfathered plans and policies sold in the individual and small-group markets are required to meet a minimum standard of benefits as defined by the ACA as essential health benefits (EHBs). In California, EHBs are related to the benefit coverage available in the Kaiser Foundation Health Plan Small Group Health Maintenance Organization (HMO) 30 plan, the state's benchmark plan for federal EHBs.[28,29] CHBRP estimates that approximately 4.2 million Californians (11%) have insurance coverage subject to EHBs in 2022.[30]

States may require plans and policies to offer benefits that exceed EHBs.[31] However, a state that chooses to do so must make payments to defray the cost of those additionally mandated benefits, either by paying the purchaser directly or by paying the qualified health plan.[32,33] Health plans and policies sold outside of the health insurance marketplaces are not subject to this requirement to defray the costs. State rules related to provider types, cost sharing, or reimbursement methods would not meet the definition of state benefit mandates that could exceed EHBs.[34]

SB 473 would not require coverage for a new state benefit mandate and instead modifies cost-sharing terms and conditions of an already covered medication. Therefore, SB 473 appears not to exceed the definition of EHBs in California.

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[25] The ACA requires nongrandfathered small-group and individual market health insurance — including but not limited to QHPs sold in Covered California — to cover 10 specified categories of EHBs. Policy and issue briefs on EHBs and other ACA impacts are available on the CHBRP website: www.chbrp.org/other_publications/index.php.
[26] Although many provisions of the ACA have been codified in California law, the ACA was established by the federal government, and therefore, CHBRP generally discusses the ACA as a federal law.
[27] HealthCare.gov. Out-of-pocket maximum/limit. Accessed on March 6, 2021. Available at: https://www.healthcare.gov/glossary/out-of-pocket-maximum-limit/.
[28] CCIIO, Information on Essential Health Benefits (EHB) Benchmark Plans. Available at: https://www.cms.gov/cciio/resources/data-resources/ehb.html.
[29] H&SC Section 1367.005; IC Section 10112.27.
[30] CHBRP, *Estimates of Sources of Health Insurance in California in 2021*. Available at: www.chbrp.org/other_publications/index.php.
[31] ACA Section 1311(d)(3).
[32] State benefit mandates enacted on or before December 31, 2011, may be included in a state's EHBs, according to the U.S. Department of Health and Human Services (HHS). Patient Protection and Affordable Care Act: Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation. Final Rule. Federal Register, Vol. 78, No. 37. February 25, 2013. Available at: https://www.gpo.gov/fdsys/pkg/FR-2013-02-25/pdf/2013-04084.pdf.
[33] However, as laid out in the Final Rule on EHBs which 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.
[34] 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.

Trends in Cost of Insulin Prescriptions

The average list price of brand-name insulin nearly tripled between 2007 and 2018, increasing by 262% (Table 2) (Hernandez et al., 2020). While the average net price also increased, the increase was smaller (51%) and was offset by discounts such as those paid by manufacturers. The price increases were higher between 2012 and 2015, but began to level out in 2016. More recently, insulin has been increasing at a rate closer to 1.5% per year. The reasons insulin prices are increasing are not entirely clear, but they are due in part to the complexity of drug pricing in general and of insulin pricing in particular (Cefalu et al., 2018).

Table 3. Summary of 2007-2018 Changes in List and Net Prices

	All Drug Classes	Insulins
List Price		
Change from 2007-2018	159%	262%
Annual mean change per year	9.1%	12.6%
Net Price		
Change from 2007-2018	60%	51%
Annual mean change per year	4.5%	4.2%
List price increase offset by discounts	62%	81%

Source: California Health Benefits Review Program, 2021, as adapted from Hernandez et al., 2020.

Notes: List price is defined as the price of a product as listed by the manufacturer. Net price is defined as the ratio between company-reported sales for each product and the number of units sold in the US.

As the price of insulin has increased, so too have patient out-of-pocket costs. Between 2006 and 2013, average cost sharing per insulin user among Medicare Part D enrollees increased by 10% per year for all insulin types (Cefalu et al., 2018).

The increases in list price, net price, and out-of-pocket costs are substantially higher than increases due to inflation. Overall inflation between 2006 and 2013 was 2.2%, medical care service costs increased by 3.8%, and spending for all prescription drugs increased by an average of 2.8% (Cefalu et al., 2018).

Cost Sharing and Outpatient Prescription Drug Benefits

This section provides an overview of the cost-sharing structures used for health insurance benefits, including prescription drugs. Payment for 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 payments). There are a variety of cost-sharing mechanisms that can be applicable to covered benefits (Figure 3). 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.[35] Annual out-of-pocket maximums for covered benefits limit

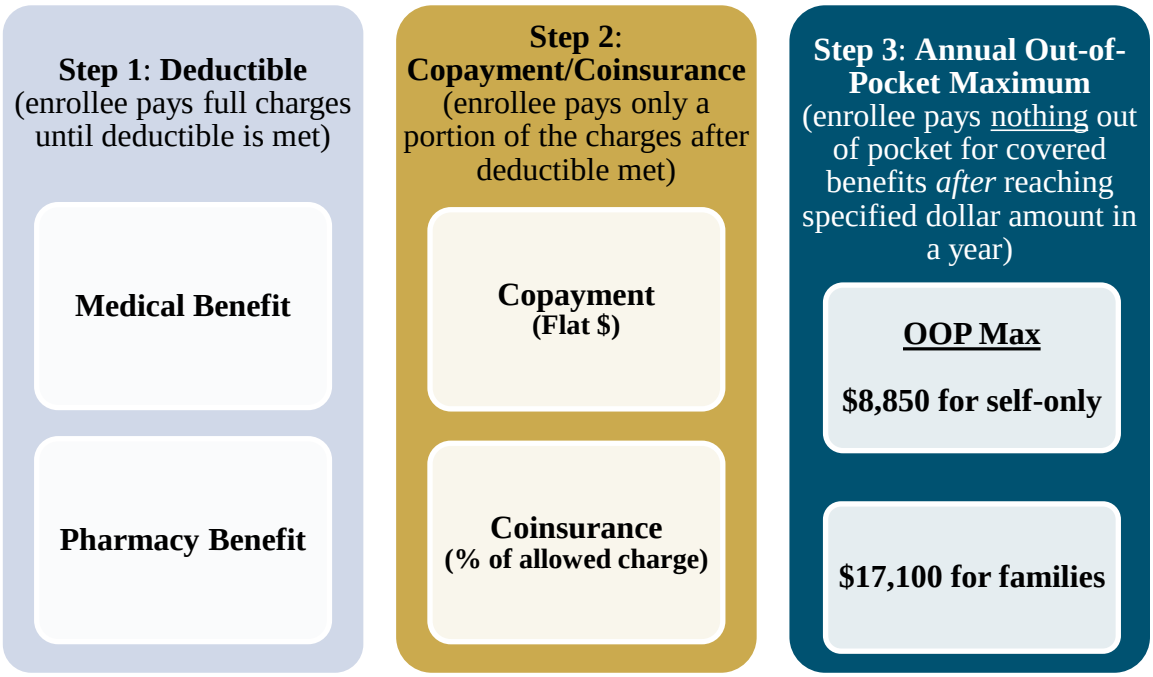
[35] Plans and policies sold within Covered California are required by federal law to meet specified actuarial values. The actuarial value is required to fall within specified ranges and dictates the average percent of health care costs a

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.

An enrollee using insulin may experience multiple forms of cost sharing. If an enrollee has a plan with a deductible and the enrollee has not yet met the deductible, the enrollee would be responsible for the full cost of care and prescriptions until that deductible is met. Once an enrollee has met their deductible, the enrollee would be responsible for the copayment or coinsurance associated with the insulin prescriptions. Should an enrollee's cost sharing expenses meet the annual out-of-pocket maximum, the enrollee would no longer be responsible for cost-sharing responsibilities.

SB 473 would instead require that an enrollee only pay the cost sharing for insulin prescriptions, regardless of whether they have met their deductible.

Figure 3. Overview of the Intersection of Cost-Sharing Methods Used in Health Insurance



Source: California Health Benefits Review Program, 2021.

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

High Deductible Health Plans (HDHPs)

Both DMHC-regulated plans and CDI-regulated policies may be designated HDHPs. HDHPs are a type of health plan and requirements are set by federal regulation.[36] As the name implies, these plans include 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.

[36] HealthCare.gov, Glossary: High Deductible Health Plans. Available at https://www.healthcare.gov/glossary/high-deductible-health-plan/#:~:text=For%202019%2C%20the%20IRS%20defines,or%20%2413%2C500%20for%20a%20family. Accessed on March 5, 2021.

deductible – but they are not allowed to have separate medical and pharmacy deductibles. For the 2020 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. Annual out-of-pocket expenses for coverage of in-network tests, treatments, and services, which would result from cost-sharing[37] applicable after the deductible is met, are not allowed to be more than $6,900 for an individual and $13,800 for a family.[38]

Health Savings Account (HSA) Qualified HDHPs

To be eligible to establish a Health Savings Accounts (HSA) for taxable years beginning after December 31, 2003,[39] (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.[40] 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.[41] Insulin is listed a treatment for chronic conditions and therefore the requirements of SB 473 would not interfere with an HDHP's qualification for an HSA.

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 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.

[37] Such as copays and coinsurance applicable to the covered test, treatment, or service.
[38] There is no annual out-of-pocket expenses limit for coverage of out-of-network tests, treatments, and services.
[39] 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
[40] For more information on screening services, see Notice 2004-23, 2004-15 I.R.B. 725, available at IRS.gov/irb/2004-15_IRB#NOT-2004-23.
For additional guidance on preventive care, see Notice 2004-50, 2004-2 C.B. 196, Q&A 26 and 27, available at IRS.gov/irb/2004-33_IRB#NOT-2004-50; and Notice 2013-57, 2013-40 I.R.B. 293, available at IRS.gov/pub/irs-drop/n-13-57.pdf.
[41] For information on preventive care for chronic conditions, see Notice 2019-45, 2019-32 I.R.B. 593, available at IRS.gov/pub/irs-drop/n-19-45.pdf.

BACKGROUND ON DIABETES MELLITUS AND INSULIN FOR GLYCEMIC CONTROL

Maintaining a proper blood sugar (glucose) level is critical to maintaining good health and preventing complications for people with diabetes mellitus (DM). This section defines DM, the prevalence of DM, and describes the subject of SB 473, insulin for management of diabetes.

What Is Diabetes Mellitus?

DM, commonly referred to as diabetes, is a chronic disease with short- and long-term health effects (discussed below) that prevent the proper production of and/or response to insulin, a hormone that facilitates the transfer of glucose into cells to provide energy (NIDDKD, 2017a). There are three primary types of diabetes, and insulin can be used to treat all three types:

- **Type 1 diabetes mellitus (T1DM)** is an autoimmune disease, most commonly diagnosed during childhood/adolescence that attacks and destroys the insulin-producing cells in the pancreas. In addition to dietary modifications, treatment requires lifetime use of daily insulin injections and/or an insulin pump used to replace the patient's impaired ability to produce insulin, and attention to diet.
- **Type 2 diabetes mellitus (T2DM)** is most commonly diagnosed in middle-aged or older adults, although it has been increasingly diagnosed in children and adolescents at a rate of 5% between 2002 and 2015 (CDC, 2015; CDC 2020). Type 2 diabetes prevents the body from properly responding to insulin (known as insulin resistance). In some cases, people with T2DM also do not make enough insulin. It is associated with obesity, genetics, and lifestyle patterns. Treatments for T2DM include diet modifications, exercise, weight loss, oral medications, non-insulin injected medications, and/or insulin depending on the severity of the disease, which progresses over time especially with inadequate treatment.
- **Gestational diabetes (GDM)** develops only in women who are pregnant and is generally diagnosed in the second trimester (Blumer et al., 2013). For most, this is a transient condition that resolves following delivery; however, these women remain at higher risk for T2DM later in life. Treatments include diet modifications, exercise, oral medication, and insulin.

Diabetes Mellitus: Short- and Long-Term Effects

Short-term effects

Achieving stable, healthy blood glucose levels is challenging for individuals with diabetes. On a daily basis, people with diabetes can experience swings between very high blood glucose levels (*hyperglycemia)* and extremely low blood glucose levels (*hypoglycemia).* Changes in stress, sleep, physical activity, diet, acute illnesses, and changes in non-diabetes medications can contribute to hyper- and hypoglycemic events. *Hyperglycemia* is exhibited through increased thirst or hunger, frequent urination, headache, and fatigue. Left untreated, particularly in T1DM, it may develop into ketoacidosis where the body develops a toxic amount of ketones (toxic acids) for energy, which can lead to coma or death.

Symptoms of *hypoglycemia* can begin as mild (e.g., anxiety, sleepiness, and tremors) and, if left untreated, escalate to serious health events such as cognitive dysfunction, seizures, coma, and death (Unger, 2012). Some patients (between 20% and 40% of T1DM patients and 10% of T2DM patients) are diagnosed with *hypoglycemia unawareness*, a condition in which individuals are unable to sense dangerously low blood sugar early enough to reverse it, which puts them at high risk for severe hypoglycemic events requiring hospitalization (Martin-Timon and Canizo-Gomez, 2015). People with this condition are required to perform more frequent blood glucose testing than those who can feel their blood glucose levels dropping. Vigersky et al. (2015) estimated that among people with hypoglycemic

unawareness, 2.4 to 8.1 hospitalizations occur annually among T1DM patients, and 2.1 to 5.9 hospitalizations per year among T2DM patients. Hypoglycemia unawareness occurs more frequently among those with a longer duration of diabetes, who are insulin dependent, and/or have a history of hypoglycemic events (Martin-Timon and Canizo-Gomez, 2015).

For pregnant women, uncontrolled GDM may lead to complications during pregnancy including abnormal fetal growth, need for extra testing during pregnancy, preeclampsia, and possible early and/or more invasive delivery methods including cesarean. Infants of women with GDM can suffer complications during and directly after birth, including hypoglycemia and hyperbilirubinemia (jaundice), but most are transient with some infants requiring NICU care (NIDDKD, 2017b).

Long-term effects

Time spent in hyperglycemia and frequency and severity of hyper- and hypoglycemia over a lifetime are associated with serious morbidity and mortality outcomes. In the United States, diabetes is the leading cause of blindness, amputations, and kidney failure, and a key contributor to stroke, heart disease, dental disease, nerve damage, and premature death (NIDDKD, 2017a) due to suboptimal blood sugar control. In the long term, uncontrolled GDM puts pregnant women and their infants at higher risk of developing T2DM later in life (NIDDKD, 2017b). Although people with diabetes may not avoid all associated comorbidities, tightly controlled blood glucose over time may prevent, delay, or ameliorate some comorbidities.

COVID-19 effects

According to the CDC, individuals with T2DM are at an increased risk of severe illness from COVID-19 and individuals with T1DM or GDM *might* be at an increased risk of severe illness from COVID-19 (CDC, 2021). The CDC and American Diabetes Association (ADA) indicate that individuals with well-managed diabetes are likely at lower risk from severe complications and recommend that individuals with diabetes take their insulin and other diabetes oral medications as prescribed, regularly test and keep track of blood glucose levels, and to ensure that individuals have a 30-day supply of all diabetes medications, including insulin (CDC, 2021; ADA, 2021). Viral infections, like COVID-19, as well as elevated blood glucose levels, can increase inflammation in individuals with diabetes and that dual effect on inflammation could contribute to more severe symptoms and complications. Tightly controlled blood glucose by adhering to prescribed insulin and diabetes medication regimens may help mitigate these effects (ADA, 2021).

Prevalence of Diabetes Mellitus in California

Diabetes is one of the most common chronic conditions in California and the United States. According to the 2019 Behavioral Risk Factor Surveillance System, about 10% of the adult population in California has been diagnosed with diabetes (America's Health Rankings, 2020). Approximately 2.6% of adults age 18 to 44, 13.9% of adults ages 45 to 64, and 22.8% of adults over age 65 have diabetes (America's Health Rankings, 2020)

The following are the most recent prevalence estimates for the privately insured population[42] by type of diabetes for adults, pregnant women, and youth:

- *Adults*: Of the estimated 6% (906,000) privately insured adult (aged 18–64 years) enrollees with diabetes, about 9.4% have T1DM and about 87.3% have T2DM (Table 3) (CHIS, 2019b).
- *Pregnant women*: The 2018 CHIS estimates that GDM occurs in 5.1% of pregnancies among non-diabetic enrollees (CHIS, 2018), which is similar to national estimates that range between 2% and 10% of pregnancies are affected by gestational (CDC, 2019a). According to the CDC, approximately 50% of women with GDM develop T2DM (CDC, 2019a).

[42] As discussed in the Policy Context section, Medi-Cal managed care plans are not impacted by SB 473.

- *Youth*: CHIS does not report diabetes in those under age 18 years after 2007; however, national data published by the CDC estimates that in 2018 0.25% of youth under age 20 years are diagnosed with T1DM (~89%) and T2DM (~11%) (CDC, 2020).

Table 4. Prevalence of Type 1 and Type 2 Diabetes among Privately Insured Californians Diagnosed with Diabetes, 2019

Diabetes Type	Percent (n) Diagnosed with Diabetes
California Adults Aged 18–64 Years with Diabetes (n=906,000)	
Type 1	9.4% (85,000)
Type 2	87.3% (791,000)
Unknown/another type*	3.3% (29,000)

Source: California Health Benefits Review Program, 2021. Based on 2019 data from the California Health Interview Survey (CHIS).

*CHIS reports these data as statistically unstable. CHIS permits respondents to select "Unknown or Another type" in response to its "type of diabetes" question. Examples of other types of diabetes may include maturity-onset diabetes of youth; from surgery, medications, infections, pancreatic disease, or other illnesses including cystic fibrosis.

Diabetes Management Using Insulin

In individuals without diabetes, beta cells within the pancreas release the hormone insulin when food is ingested to help the body use or store blood sugar. As described earlier in this section, the hallmark difference between T1DM and T2DM is the body's ability to create or utilize insulin to regulate blood sugar levels. Clinical practice recommendations for prescribing insulin for glycemic control are presented in the *Medical Effectiveness* section. This section summarizes the types of insulin products available and mechanisms of delivery.

Types of insulin

Insulin is classified by the rate at which it acts in the body. The differences for each type depend on onset, peak, duration, concentration, and delivery method. Table 4 summarizes types of insulin products. Short or rapid-acting insulin (bolus or prandial) is used to control blood sugar during meals as fat tissue absorbs it quickly from the bloodstream. Intermediate or long-acting insulin (basal insulin) is absorbed at a slower stabilizing rate, which is used to control blood sugar during one's sleep or fasting periods (Shah et al., 2016). Premixed insulin products may be useful for those with poor eyesight or dexterity, or who have trouble measuring the correct dosages for injection (ADA, 2020b).

Insulin products may also be identified as animal, human, or analog. The first insulin products were isolated from animals, and later, the technology to create a synthetic insulin allowed for greater production volume. These synthetic versions were called *human* to distinguish them from the insulin derived from animals (Tibaldi, 2014). Later advances included the development of rapid-acting insulin analogs and long-acting basal analogs (Tibaldi, 2014). The long-acting basal analogs are one of the most widely prescribed, and have been used to help patients with T2DM achieve glycemic control with lower risk of hypoglycemia. However, the cost of insulin analogs is much greater than the original human and animal-derived insulins (Cefalu et al., 2018).

Patients with T1DM require insulin for their diabetes management, and will use both bolus and basal insulin. Therefore, the prevalence of insulin use among individuals with T1DM is 100%. Insulin may or may not be used for someone with T2DM, and for those who are prescribed insulin, they may use one or both types (ADA, 2019). The prevalence of insulin use among T2DM varies; however, the CDC reports that for adults aged 20 and older with diagnosed T1DM or T2DM, 10.9% started using insulin within a year of their diagnosis (CDC, 2020). Women with GDM may also be prescribed one or both types of insulin (ADA, 2019).

Table 5. Types of Insulin Products

Categories of Insulin	Delivery	Onset	Peaktime	Duration
Rapid-acting insulin	Vial, pen, cartridge, or inhaler	15 minutes	1-2 hours	3-4 hours
Regular or short-acting insulin	Vial	30 minutes	2-3 hours	3-6 hours
Intermediate-acting	Vial or pen	2-4 hours	4-12 hours	12-18 hours
Long-acting	Vial or pen	Several hours	Does not peak	Up to 24 hours
Ultra long-acting	Vial or pen	6 hours	Does not peak	36+ hours
Premixed insulin products	Vial or pen	Varies	Varies	Varies

Source: California Health Benefits Review Program, 2021, based on Cefalu et al., 2018; ADA, 2019; and ADA, 2020b.

Delivery mechanisms

There are various delivery methods of insulin, but subcutaneous injections with a vial and syringe or pre-filled pen are the most common forms (Shah et al., 2016; Zhang et al., 2019). Insulin pumps are devices that are worn by the individual and mimic the function of the pancreas to deliver small steady doses of insulin (HHN, 2018). Insulin pumps can deliver both basal and bolus insulin, and the decision to use one depends on the patient's needs and preferences (HHN, 2018). Conventional delivery mechanisms of syringes, pens, and pumps may be uncomfortable or inconvenient for some with diabetes. A non-injection insulin product available since 2015 is an inhaled insulin (ADA, 2020b). This delivery method is used as a rapid-acting insulin before meals and must be used in conjunction with injectable long-acting insulins (ADA, 2020b). Insulin is not available as a pill; because it is a peptide hormone, the body would digest it and it would not reach the blood stream (ADA, 2020a; Shah et al., 2016). Developments to oral routes of administration are currently under investigation, as are buccal, peritoneal, and transdermal (Shah et al., 2016).

Barriers to Diabetes Control

Insulin-Associated Barriers

In general, insulin has become expensive for individuals living with diabetes. See the *Policy Context* section for information on the rising cost of insulin and common cost-sharing mechanisms. As mentioned, for those with insurance, the patient is responsible for applicable cost sharing for insulin. See more details about the cost of insulin in the *Benefit Coverage, Utilization, and Cost Impacts* section. Additionally, the *Medical Effectiveness* section describes how the effects of cost sharing impact insulin use and adherence. Patients with T1DM have less flexibility in altering use due to cost as insulin is required for their glycemic control.

Other identified barriers to insulin use that are independent of cost include regimen complexity and treatment tolerability (Brod, 2012; Peyrot et al., 2010), as well as injection-related factors (Peyrot et al., 2010; Rubin et al., 2009). Patients reported that injections interfered with daily activities, caused pain at the injection site, and caused embarrassment in social situations (Pawaskar et al., 2007; Peyrot et al., 2010). A systematic review by Davies et al. (2013) also cited difficulty with insulin use while travelling,

challenging social situations, and forgetting as barriers. Additionally, fear of weight gain and hypoglycemia were cited as barriers to starting insulin therapy, though were less of a concern once insulin treatment had started (Davies et al., 2013). Following a set dosing schedule is also cited as challenging and inconvenient for patients (Pawaskar et al., 2007). The most common reasons for dosing irregularities range from inconsistent eating patterns to running low on insulin (Brod et al., 2012).

Additional Barriers to Diabetes Control

Barriers to insulin use present challenges in glycemic control for individuals with diabetes that are prescribed insulin therapy. However, additional barriers to glycemic control exist for patients that may or may not be taking insulin. In order to effectively manage diabetes, additional non-insulin prescription medications or medical supplies such as blood glucose testing strips and devices may be required. For example, affordability of blood glucose testing devices is one barrier. In a retrospective database analysis, Yeaw and colleagues identified that testing strips and supplies accounted for 27% of the cost of insulin prescription and supplies required for self-management of blood glucose levels (Yeaw et al., 2012). Similarly, it was reported that for patients with lower incomes, nearly two-thirds experienced challenges with affording diabetes equipment (Herkert et al., 2019). While the economic implications of insulin costs seem to be well-understood, there is a need for additional studies to provide greater understanding of costs associated with monitoring supplies. If a patient encounters barriers in accessing or using devices to monitor blood glucose levels regularly, they have reduced ability to administer insulin correctly and safely. Another important component to diabetes management is a change in behaviors and lifestyle factors, which each present a wide variety of barriers on their own. Lifestyle changes required for diabetes management include self-management education, weight control through diet and exercise, and regular medical care to monitor for comorbid conditions or complications from diabetes (ADA, 2018).

Disparities[43] and Social Determinants of Health[44] in Diabetes

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

Disparities

Race or ethnicity

In California, Hispanics (10.5%), Blacks (8.8%), American Indian/Alaska Natives (7.5%), and Asian/Pacific Islanders (6.2%) have higher prevalence of T2DM than non-Hispanic Whites (4.9%), and Hispanics and Blacks have two times higher prevalence: 1 in 20 non-Hispanic Whites have T2DM, compared with 1 in 10 Hispanics and 1 in 11 Blacks (Conroy et al., 2014). This is consistent with racial/ethnic differences found nationally: prevalence of diagnosed diabetes was highest among American Indians/Alaska Natives (14.7%), people of Hispanic origin (12.5%), and non-Hispanic blacks (11.7%), followed by non-Hispanic Asians (9.2%) and non-Hispanic Whites (7.5%) (CDC, 2020). However, Whites are more likely to develop T1DM than Blacks and Hispanic/Latino Americans (CDC, 2019b).

These differences may be attributed to biological factors, health system factors, and social factors (Spanakis et al., 2013). Multiple studies have shown that compared to non-Hispanic Whites, non-Hispanic

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

[44] CHBRP defines social determinants of health as conditions in which people are born, grow, live, work, learn, and age. These social determinants of health (economic factors, social factors, education, physical environment) are shaped by the distribution of money, power, and resources and impacted by policy (adapted from: CDC, 2014; Healthy People 2020, 2019). See CHBRP’s SDOH White paper for further information: http://chbrp.com/analysis_methodology/public_health_impact_analysis.php.

blacks and Mexican Americans have increased insulin resistance and differences in insulin secretion (Golden et al., 2012; Spanakis et al., 2013). Evidence is mixed regarding significant racial or ethnic differences in adherence to diabetes medication, including insulin (Brod et al., 2012; Golden, 2012). However, Kang et al. (2018) report significant racial/ethnic disparities for cost-related medication nonadherence for non-Hispanic blacks compared to non-Hispanic Whites. Obesity is correlated with diabetes risk in racial or ethnic minority populations (Golden et al., 2012). This is due in part to racial disparities observed in obesity, particularly among non-Hispanic blacks and Hispanics (Golden et al., 2012). Additional research is needed to establish the underlying risk factors that contribute to disparities in obesity rates, but it is hypothesized that cultural norms, obesity definition cut-points, and immigration status may be factors (Golden et al., 2012).

Gender[45]

The prevalence of T2DM is higher in men (7.2%) than women (6.4%) in California (Conroy et al., 2014). This trend is consistent with national prevalence rates: approximately 11% of men in the United States have diabetes, while 9.5% of women do (CDC, 2020). Gender was also found as a correlate of nonadherence to insulin therapy in a large systematic review (Davies et al., 2013). Female gender was associated with lower adherence. Among younger females in particular, intentional insulin omission may be related to weight control and eating disorders (Peyrot et al., 2010).

Age

Across all age groups, the prevalence of T1DM is low in California (<2%) (Conroy et al., 2014). However, differences exist across age groups in the state: the prevalence of T2DM is less than 2% for adults aged 44 years and under, but rises sharply to 10% for those aged 45 to 64 years, and to 17% for those aged 65 years and older (Conroy et al., 2014). Similarly, in the United States, the rate of adults with diagnosed diabetes (T1DM or T2DM) increases with age, though national rates report reaching 26.8% among those aged 65 years and older (CDC, 2020). Davies et al. (2013) noted that for studies within the review (one study of T1DM, two studies of T2DM, one study of both T1DM and T2DM, and one with type of diabetes not reported), age was a predictor for adherence to insulin therapy; however, two studies indicated older patients were more adherent, while one showed that younger patients were more adherent. Peyrot et al. found no association between age and intentional insulin omission among patients with T1DM, and it was proposed that perhaps patients “age-out” of the behavior as they get older (Peyrot et al., 2010). Conversely, when including cost as a factor, younger age (<55) was at significantly greater risk for cost-related medication nonadherence for diabetes when compared to older adults age 75 and over (Kang et al., 2018).

Social Determinants of Health (SDOH)

SDOH include factors outside of the traditional medical care system that influence health status and health outcomes (e.g., income, education, geography). CHBRP found literature that level of education, income, and health literacy have a role in diabetes.

Education

The prevalence of diagnosed T2DM is twice as high in California adults without a high-school diploma (9.9%) compared to those with a college degree (4.8%) (Conroy et al., 2014). Studies show that there is a relationship between low educational attainment and high prevalence of T2DM (Borrell et al., 2006). Those with more education are thought to utilize resources and knowledge to prevent or better control their diabetes (Borrell et al., 2006). Higher levels of education are associated with better health outcomes

[45] CHBRP uses the NIH distinction between “sex” and “gender:” “’Sex’ refers to biological differences between females and males, including chromosomes, sex organs, and endogenous hormonal profiles. ‘Gender’ refers to socially constructed and enacted roles and behaviors which occur in a historical and cultural context and vary across societies and over time.” (NIH, 2019).

as research shows that individuals will take part in more preventive measures (Clark and Utz, 2014). Additionally, a higher level of education is associated with higher socioeconomic stability, which in turn promotes healthy behaviors (Borrell et al., 2006).

Income

The percentage of adults in California with diagnosed T1DM or T2DM is almost double for those with family incomes below 200% of the federal poverty level (FPL) (100–199% below FPL have 9.1% diagnosed diabetes, 0–99% below FPL have 8.7% diagnosed diabetes) compared to those whose income is 300% or more above the FPL (5.3%) (Conroy et al., 2014). In a systematic review and meta-analysis of 23 studies, socioeconomic status was strongly associated with an increased risk of T2DM (Agardh et al., 2011).

Peyrot and colleagues (2010) also found that respondents with higher household income were less likely to skip insulin injections as prescribed. This may be due in part to easier access to medications and supplies among individuals with higher income, but it is also likely that higher socioeconomic status is associated with more access to diabetes education, higher health literacy, greater control over one's daily routines, and better problem-solving skills (Peyrot et al., 2010). In addition, individuals with better socioeconomic status have lower cost-related medication nonadherence for diabetes (Herkert et al., 2019; Kang et al., 2018). The rate of cost-related nonadherence decreased as annual household income level increased. The rate is tripled for those without insurance compared to those with insurance, and is higher for individuals on insulin therapy compared to those who are not on insulin therapy (Kang et al., 2018).

Health literacy

Health literacy refers to an individual's capacity to read, understand, and make use of healthcare-related information for decision making and self-care. CHBRP did not find that lower health literacy was a risk factor for diabetes diagnosis. However, there was strong evidence in the literature that for individuals diagnosed with diabetes, health literacy was significantly correlated with management of diabetes and health outcomes.

In diabetes, health literacy is particularly important for disease management elements such as understanding treatment regimens, reading and interpreting food labels, carbohydrate counting, and appropriate insulin administration (Ahola and Groop, 2013). While low levels of health literacy are not necessarily shown to prevent blood glucose monitoring, interpreting the results and acting accordingly in response may be compromised among individuals with low health literacy. Poor health literacy is also related to reduced ability to recall oral medical instructions (Ahola and Groop, 2013). In a study examining the relationship between racial disparities and poor glycemic control in diabetes, the authors concluded that health literacy was associated with diabetes medication adherence (Osborn et al., 2011).

Societal Impact of Diabetes in California

The presence of diabetes in California creates a societal impact. In dollar terms, the societal impact can be indirect (e.g. lost wages, etc.), as well as direct (e.g. medical care, etc.). Total economic costs for T1DM and T2DM (direct plus indirect costs) in California were reported to be $55.5 billion in 2013 (median $5.9 billion) (Shrestha et al., 2018). For non-Medicare or Medicaid payers (private insurance, other payers, and out of pocket from patients), medical costs were $11.7 billion in California (Shrestha et al., 2018). According to the American Diabetes Association[46], total direct medical expenses in California were estimated to be $27.6 billion in 2012 for diagnosed and undiagnosed diabetes, prediabetes, and GDM. An additional $9.5 billion was spent on indirect costs due to lost productivity. Indirect costs have

[46] American Diabetes Association (ADA). The Burden of Diabetes in California. Available at: http://main.diabetes.org/dorg/PDFs/Advocacy/burden-of-diabetes/california.pdf

also been reported as high as $32.6 billion when including morbidity and premature mortality costs (Shrestha et al., 2018). Please note, the societal impact discussed here is relevant to a broader population than SB 473 impacts, which would affect the health insurance of a subset of Californians (see *Policy Context*). See the *Benefit Coverage, Utilization, and Cost Impacts* section for estimates of cost impacts for the specific population targeted by SB 473.

MEDICAL EFFECTIVENESS

As discussed in the *Policy Context* section, SB 473 would limit cost sharing (copayment, coinsurance, or deductible) for insulin to $50 for a 30-day supply and no more than $100 per month total, regardless of the amount or type of insulin prescribed. Additional information on the management of diabetes and insulin cost sharing is included in the *Background* section. The medical effectiveness review summarizes findings from evidence[47] on the effects of cost sharing on insulin use and adherence for patients with diabetes (type 1 diabetes mellitus [T1DM], type 2 diabetes mellitus [T2DM], and gestational diabetes [GDM]) and how insulin treatment adherence affects the management of diabetes.

Clinical Practice Guidelines for Diabetes Mellitus

The American Diabetes Association (ADA, 2020b) recommends different insulin regimens based on the type of diabetes a person has. Insulin is necessary for the treatment of T1DM and sometimes necessary for the treatment of T2DM and GDM usually after diet, lifestyle, and oral anti-diabetic medications are insufficient to lower HbA1c levels to a goal of less than 7% for most adults. According to the guidelines, T1DM patients typically inject insulin subcutaneously in two patterns, one basal (continuous) form of insulin and one bolus (mealtime) form of insulin. This is achieved by four injections per day of insulin (of a long-acting insulin analog, typically dosed one to two times daily, and a rapid-acting insulin analog dosed three times daily before meals) or using an insulin pump (where a rapid-acting insulin is delivered both as the basal and bolus insulin). The most common types of insulin used are rapid-acting insulins (reaches bloodstream 15 minutes after injection, peaks at 1 to 2 hours, continues to work for 3 to 4 hours), and long-acting insulins (takes several hours to reach bloodstream and maintains glucose levels throughout a 24-hour period). Less frequently used insulins are regular human insulin (30 minutes to reach bloodstream, peaks at 2 to 3 hours, works for 3 to 6 hours) and intermediate-acting insulin (2 to 4 hours to reach bloodstream, peaks 4 to 12 hours, works for 12 to 18 hours) (see Table 5 in the *Background* section). Insulin regimens (i.e., types, timing, and doses) are typically determined by health care providers' recommendations, but may vary, and be self-adjusted by an individual based on diet, exercise, and other factors. Despite the variety of insulin regimens, the long-term complications of diabetes (e.g., eye, kidney, and nerve damage) can be best prevented by reaching glycemic targets/A1c goals with intensive insulin therapy or continuous subcutaneous administration through an insulin pump (ADA, 2020b).

T2DM is a progressive disease and use of insulin is often required for its management, especially with increased diabetes duration (ADA, 2020b). According to the guidelines, Metformin, an oral glucose-lowering medication, is the preferred initial pharmacologic agent for the treatment of T2DM, in combination with lifestyle modifications. The choice for the next step in therapy depends on patient-specific factors (e.g., presence of atherosclerotic cardiovascular disease, heart failure, chronic kidney disease, obesity). For patients who are on combination therapy, insulin therapy is generally initiated after a patient is on a class of medications called glucagon-like peptide-1 receptor agonists (GLP-1). When insulin is initiated in a patient with T2DM, usually a long-acting insulin is added as one injection daily to the medication regimen. Over time, a patient may require prandial insulin, and a rapid-acting insulin is added at mealtimes. Similar to T2DM, treatment of GDM may require insulin therapy and depends on patient-specific factors (ADA, 2020b).

[47] Much of the discussion in this section is focused on reviews of available literature. However, as noted in the section on Implementing the Hierarchy of Evidence on page 11 of the Medical Effectiveness Analysis and Research Approach document (posted at http://chbrp.com/analysis_methodology/medical_effectiveness_analysis.php), in the absence of fully applicable to the analysis peer-reviewed literature on well-designed randomized controlled trials (RCTs), CHBRP's hierarchy of evidence allows for the inclusion of other evidence.

Research Approach and Methods

Studies of cost sharing related to insulin use and adherence for diabetes were identified through searches of PubMed, the Cochrane Library, Web of Science, and the Cumulative Index of Nursing and Allied Health Literature. Websites maintained by the following organizations that produce and/or index meta-analyses and systematic reviews were also searched: the Agency for Healthcare Research and Quality (AHRQ), the International Network of Agencies for Health Technology Assessment (INAHTA), the National Health Service (NHS) Centre for Reviews and Dissemination, the National Institute for Health and Clinical Excellence (NICE), and the Scottish Intercollegiate Guideline Network. The American Diabetic Association (ADA) website and available resources were also searched as pertinent to this bill and reviewed.

The search was limited to abstracts of studies published in English. The search was limited to studies published from 2020 to present because CHBRP had previously conducted thorough literature searches on these topics in 2020 for AB 2203. Of the 122 articles found in the literature review, 19 were reviewed for potential inclusion in this report on SB 473, and a total of two new studies were included in the medical effectiveness review for this report, as well as five studies that were included in the previous review for AB 2203. The other articles were eliminated because they did not focus on a specific treatment, were from outside the United States, were of poor quality, or did not report findings from clinical research studies. A more thorough description of the methods used to conduct the medical effectiveness review and the process used to grade the evidence for each outcome measure is presented in Appendix B.

The conclusions below are based on the best available evidence from peer-reviewed and grey literature.[48] Unpublished studies are not reviewed because the results of such studies, if they exist, cannot be obtained within the 60-day timeframe for CHBRP reports.

Key Questions

1. What are the effects of cost sharing (i.e., copayments, coinsurance, deductibles) on insulin use/adherence for patients with T1DM, T2DM, or GDM?

2. What are the associated effects of cost sharing for insulin on health outcomes and utilization?

Methodological Considerations

The primary focus of this review and analysis is on insulin use and adherence related to cost sharing, as related to the bill language. Thus, it does not include adherence for overall diabetes management, for which there are multiple components. Additionally, this bill would apply to patients with T1DM, T2DM, or GDM diagnosis, and there are disease differentiations between the types that inherently affect adherence. It should also be noted that there are several barriers to conducting randomized controlled trials (RCTs) of differential cost sharing on insulin use (i.e. ethical considerations, medical necessity of insulin for treatment of type 1 diabetes, multi-faceted treatment regimens required to effectively treat diabetes), resulting in a literature base that is not as rigorous and thereby limiting the certainty of conclusions drawn from the evidence.

CHBRP did not review the evidence on the effectiveness of insulin for the treatment of diabetes in general, as this has been well documented, and is included in the American Diabetic Association (ADA) treatment guidelines as referenced in the “clinical practice guidelines for diabetes mellitus” section above.

[48] Grey literature consists of material that is not published commercially or indexed systematically in bibliographic databases. For more information on CHBRP’s use of grey literature, visit http://chbrp.com/analysis_methodology/medical_effectiveness_analysis.php.

Outcomes Assessed

The primary outcome of interest for the effect of cost sharing on insulin use for patients with diabetes is utilization of insulin, defined as fills after prescription and adherence to prescribed insulin regimens. The associated effect of insulin adherence on health was measured by glycemic control (HbA1c levels), healthcare utilization (e.g., emergency department visits, hospitalizations), productivity (disability, absenteeism) and diabetes-related complications or comorbidities (e.g., amputations, ulcers, blindness, heart attack, stroke). No literature included in the medical effectiveness review examined hyperglycemic events or ketoacidosis events specifically, so while these are common health outcomes associated with diabetes, they are not reflected in these studies.

Study Findings

This section summarizes CHBRP's findings regarding the strength of evidence for the effects of cost sharing on insulin use and adherence for patients with diabetes. Each section is accompanied by a corresponding figure. The title of the figure indicates the test, treatment, or service for which evidence is summarized. The statement in the box above the figure presents CHBRP's conclusion regarding the strength of evidence about the effect of a particular test, treatment, or service based on a specific relevant outcome and the number of studies on which CHBRP's conclusion is based. Definitions of CHBRP's grading scale terms is included in the box below, and more information is included in Appendix B.

CHBRP found a *preponderance of evidence* on the effect of cost sharing on insulin use for diabetes treatment.

The following terms are used to characterize the body of evidence regarding an outcome:

Clear and convincing evidence indicates that there are multiple studies of a treatment and that the large majority of studies are of high quality and consistently find that the treatment is either effective or not effective.

Preponderance of evidence indicates that the majority of the studies reviewed are consistent in their findings that treatment is either effective or not effective.

Limited evidence indicates that the studies have limited generalizability to the population of interest and/or the studies have a fatal flaw in research design or implementation.

Inconclusive evidence indicates that although some studies included in the medical effectiveness review find that a treatment is effective, a similar number of studies of equal quality suggest the treatment is not effective.

Insufficient evidence indicates that there is not enough evidence available to know whether or not a treatment is effective, either because there are too few studies of the treatment or because the available studies are not of high quality. It does not indicate that a treatment is not effective.

More information is available in Appendix B.

Cost Sharing for Prescription Drugs

It is well established in the literature that persons who face higher cost sharing use fewer services than persons with lower cost sharing (CHBRP, 2018). In addition, there is a preponderance of evidence across multiple health conditions that, as cost sharing increases, adherence to drug regimens decreases, with a majority of studies indicating that decreased adherence is associated with worse outcomes (CHBRP, 2014). Goldman et al. (2007) found that for every 10% increase in cost sharing, there was a 2% to 6%

decrease in utilization. The results are clear for those with chronic conditions that increased cost sharing is associated with decreased adherence and worse health outcomes (Goldman et al., 2007). Similar results were found in a meta-analysis of publicly insured patients (Sinnott et al., 2013). However, there is also evidence that the effect of cost sharing may differ depending on the specific disease and the specific drug (CHBRP, 2018).

Effect of Cost Sharing on Insulin Use and Adherence for Diabetes Mellitus

CHBRP identified seven studies that examined the effects of cost sharing on insulin use for diabetes treatment. In a cross-sectional survey study by Herkert et al. (2019), the authors analyzed the prevalence of cost-related insulin underuse and its association with glycemic control. The survey was administered at the Yale Diabetic Center to patients with T1DM or T2DM for whom insulin was prescribed in the past 6 months. Cost-related insulin underuse was defined by a "yes" response to any of the six questions: "In the last 12 months did you… (1) use less insulin than prescribed, (2) try to stretch out your insulin, (3) take smaller doses of insulin than prescribed, (4) stop using insulin, (5) not fill an insulin prescription, (6) not start insulin… because of cost." Of 354 eligible patients, 199 completed the survey and 51 (25.5%) reported cost-related underuse. Cost-related insulin underuse did not significantly differ between patients with T1DM and T2DM.

A systematic review by Davies et al. (2013), identified studies reporting factors associated adherence to insulin therapy in adults with T1DM or T2DM. Seventeen studies were identified and two of these studies examined the effects of financial burden on adherence.

The first of these studies was a retrospective pre-post comparison study of a cohort of patients with T1DM and T2DM who switched from a traditional formulary to a value-based insurance design, which reduces or eliminates copayments for highly effective preventive medications (Nair et al., 2009). This involved placing all diabetic drugs and testing supplies on the lowest copay tier for one employer group (n=225) of which 53 patients were receiving insulin. Differences in insulin adherence (proportion of days covered [PDC] ratio) were found to be significant at both year 1 (7.7% increase; p=.0068) and year 2 (7.48%; p=.0251) compared to the pre-period. However, the proportion of adherent patients (defined as ≥ 80% PDC ratio) did not significantly change between the three time points and remained at about 20% (20.8% pre-period, 22.6% Y1, 20.8% Y2). It should be noted that these rates of adherent patients include both T1DM and T2DM patients, for which adherence to insulin is known to inherently differ.

In the second of these studies, a large (n=20,176) retrospective database study of patients with primarily type 2 diabetes (approximately 90%) who switched to a value-based insurance design was compared to a random control sample of n=190,889 who remained on a traditional tiered formulary design (Chang et al., 2010). They found that adherence to insulin improved over the first year in those in the value-based insurance group, compared to a decline over the same period in the traditional formulary group. They also found the initiation rate for T2DM patients starting on insulin was significantly higher at year one in the value-based insurance group than in the control group.

A 2016 systematic review by Capoccia et al. synthesized the evidence on general medication adherence with prescribed glucose-lowering agents (including insulin and oral anti-diabetics). They identified a total of 98 studies and found cost and copays to significantly affect adherence, among several other factors. Of these, CHBRP identified two retrospective studies that specifically related to cost sharing and insulin adherence as relevant to SB 473.

One was a second retrospective pre-post comparison study by Nair et al. (2010), in which they examined the effects of a value-based insurance design for diabetics within a different employer group. The sample consisted of n=589 patients with T1DM and T2DM, with n=132 of these patients receiving insulin. Differences in mean insulin adherence rates were again found to be significant at both year 1, with a 9.4% increase of baseline mean adherence, and year 2, with a 11.3% increase of baseline mean adherence. Contrary to their first study, they did find significant differences in the percentage of insulin

adherent individuals (defined as ≥ 80% PDC ratio) from the pre-period to year 1 (22% vs. 30.3%; *OR*=1.57) and the pre-period to year 2 (22% vs. 33.3%; *OR*=1.80).

In the second, a retrospective, cross-sectional study by Gibson et al. (2010) assessed the relationship between cost sharing and adherence to medications in patients with T2DM. This study combined insulin and oral antidiabetic medications (OAD) in their examination of adherence rates to prescribed regimens and did not analyze results by insulin alone. The analysis included 96,734 patients on a combination of OADs and insulin with employer-sponsored insurance in the 2003–2006 MarketScan Database. They reported that an increase from $10 to $20 in the cost-sharing index resulted in an average 4.8% reduction in adherence (defined as ≥ 80% PDC ratio).

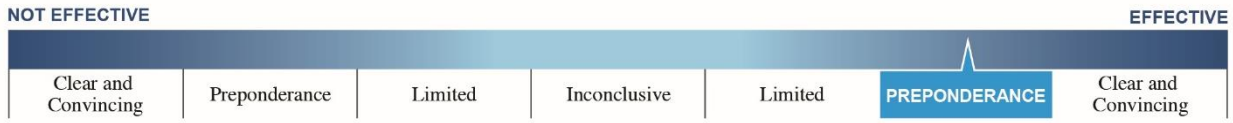
A 2021 retrospective analysis by Chandra et al., examined the effects of cost sharing on prescription drug utilization in a 20% random sample of all Medicare Part D enrollees from 2007-2012. After applying their inclusion criteria, their total analytic sample was 358,706 beneficiaries across a variety of health conditions. Approximately 16% (n=57,392) of the sample was observed to have a diagnosis of T1DM or T2DM. Using predictive modeling strategies based on changes in percent coverage from Medicare's drug benefit structure, the authors estimated changes in prescriptions filled for specific drug classes. They found that for every one percent increase in coinsurance costs for diabetes drugs that lower blood sugar, including insulin and other OADs, patients made .00288 fewer diabetes prescription fills. This translates to approximately a 3% decrease in adherence to insulin and other OADs for every 10% increase in cost-sharing expense.

In another retrospective analysis of Medicare Part D beneficiaries, Trish et al. (2021) examined the association between out-of-pocket spending and insulin adherence. Specifically, the authors sought to assess the potential outcomes associates with the newly announced Medicare program to limit out-of-pocket spending on insulin to $35 per month (refer to the *Policy Context* section for more information on the Senior Savings Model). To analyze the potential outcomes of this cost sharing limit, changes in insulin use (defined as change in PDC ratio) were compared between beneficiaries in individual plans and those in employer group-waiver plan across three coverage phases.[49] The study used a 100% sample of Medicare Part D claims from 2018, which included a total sample of 474,929 individuals with a prescription for insulin with n=303,616 in individual plans and n=171,313 in employer plans. The mean cost sharing for insulin per 30-day supply among individual plan enrollees in the initial coverage phase was $50.57, $117 in the coverage gap, and $36.86 in catastrophic coverage. The mean cost sharing among employer plan enrollees across the same phases was $32.73 (initial), $31.99 (coverage gap), and $19.73 (catastrophic coverage). They found that beneficiaries in individual plans who were in the coverage gap reduced their insulin use by 5.4% (PDC=67.5% during initial coverage vs. PDC=62.1% in the coverage gap). Comparatively, beneficiaries in employer plans increased their insulin use by 2.8% in the coverage gap (PDC=70.1% during initial coverage vs. PDC=72.9% in the coverage gap). Compared to the initial coverage phase, there was no change in insulin use for individual plan enrollees who ended the year in catastrophic coverage and a 2.4% increase for employer plan enrollees.

Summary of findings regarding cost sharing on insulin use and adherence: There is a *preponderance of evidence* from one cross-sectional self-report study, one retrospective cross-sectional study, three retrospective pre-post studies, and 2 retrospective cohort studies on cost-related insulin use/adherence that cost sharing affects insulin use and adherence in patients with diabetes; higher cost sharing reduces adherence and lower cost sharing increases adherence. Some of the limiting factors that contributed to this evidence grading are the quality of the studies, the inherent differences between the types of diabetes conditions, and confounding adherence issues (i.e., insulin side effects, fear of injection, social factors, health literacy).

[49] These included (1) The initial coverage phase (2) The coverage gap phase and (3) The catastrophic coverage phase

Figure 4. Effect of Cost Sharing for Insulin Use & Adherence



Effect of Cost Sharing for Insulin on Health Outcomes and Utilization

CHBRP identified no studies that examined the effects of cost sharing for insulin alone on diabetes-related health outcomes. Four of the studies discussed above reported health outcome and utilization results, though these findings are not specific to insulin alone, and include the effect of cost for insulin, other OADs, and diabetic testing supplies. These findings are discussed in this section to provide the available evidence on cost sharing for insulin and the related health outcomes.

The Herkert et al. (2019) cross-sectional survey study found that patients who reported cost-related insulin underuse, compared to those who did not, were significantly more likely to have poor glycemic control (p=.03). Poor glycemic control was defined has HbA1c ≥ 9% collected at time of the visit or within 3 months.

The Nair et al. (2009) retrospective pre-post comparison study of switching to a value-based insurance design examined changes in medical utilization at each of the three time points (pre-period, year 1, year 2). The authors reported a 25% decrease in diabetes-specific emergency department visits and a 20% decrease in hospitalizations in year 2 compared to year 1, though these comparisons were not found to be statistically significant. It should be noted that these outcomes included the entire sample of patients with diabetes, not only those patients using insulin.

The 2010 study by Nair et al. also examined the effects of switching to a value-based insurance design, within a different employer group than the 2009 study, and reported on diabetes-related medical utilization effects for the entire sample at each of the three time points (pre-period, year 1, year 2). The authors reported a 12% decrease in diabetes-specific office visits, a 31% decrease in emergency room visits, and a 53% decrease in hospitalizations in year 1 compared to the pre-period. However, only the comparisons for office visits and emergency department visits from the pre-period to year 1 were found to be statistically significant. These effects include the entire sample of patients, not only those on insulin, and the associated effects of the lowered cost of diabetic testing supplies and other diabetic drugs should also be considered.

The Gibson et al. (2010) retrospective cross-sectional study also assessed the relationship between cost sharing for diabetes medications and the associated health outcomes in patients with T2DM that resulted from improved adherence. They examined the relationship between improved adherence to the prescribed diabetes treatment regimen (OADs with and without insulin) and health outcomes and found significant reductions in long term complications, emergency department visits and hospitalizations. However, number of physician visits (non-ED visits) were higher among adherent patients. For measures of productivity and quality of life, they also reported that the number of short-term disability days was significantly lower for adherent patients, but found no significant difference in absenteeism.

Summary of findings regarding cost sharing for insulin on health outcomes and utilization: There is *insufficient evidence* on the effect of cost sharing for insulin on diabetes-related health outcomes and utilization. Though the studies presented in the above section provide some evidence on health and utilization outcomes, these findings were not specific to insulin alone, but to patients on insulin and other OADs. Additional limiting factors that contributed to this evidence grading are the quality of studies, the inability to separate outcomes based on type of diabetes, confounding variables (i.e., lowered cost of

testing supplies), and the multifaceted nature of diabetes treatment. A grading of insufficient evidence does not indicate that there is no effect, but rather means that the effect is unknown.

Figure 5. Effect of Cost Sharing for Insulin on Health Outcomes & Utilization

Summary of Findings

CHBRP found a *preponderance of evidence* from seven cross-sectional and retrospective studies on cost-related insulin use/adherence that cost sharing affects insulin use and adherence in patients with diabetes. These studies provided a *preponderance of evidence* that higher cost sharing reduces adherence to insulin and lower cost sharing increases adherence to insulin. CHBRP found *insufficient evidence* on the associated effect of cost sharing for insulin on diabetes-related health outcomes, including HbA1c levels, outpatient visits, emergency department visits, hospitalizations, long-term complications, and disability/absenteeism rates. Though the studies presented did report on these health and utilization outcomes, the findings were not specific to the effect of insulin alone, but combined with use of other OADs and testing supplies. There were several limitations that contributed to the gradings provided in this review, most notably the inherent differences between the types of diabetes conditions and the multifaceted nature of diabetes treatment, resulting in a literature base that is not as rigorous and thereby limiting the certainty of conclusions drawn from the evidence.

BENEFIT COVERAGE, UTILIZATION, AND COST IMPACTS

As discussed in the *Policy Context* section, SB 473 requires all commercial and CalPERS DMHC-regulated plans and CDI-regulated policies to limit enrollee cost sharing (copayments, coinsurance, and deductibles) for insulin to $50 for a 30-day supply and no more than $100 per month total, regardless of the amount or type of insulin needed.

This section reports the potential incremental impacts of SB 473 on estimated baseline benefit coverage, utilization, and overall cost. This analysis makes the following assumptions:

- The population subject to SB 473 includes individuals covered by DMHC-regulated commercial insurance plans, CDI-regulated policies, and publicly funded plans (including CalPERS) subject to the requirements of the Knox-Keene Health Care Service Plan Act. Based on DMHC and DHCS guidance, Medi-Cal managed care enrollees are not subject to SB 473 since the pharmacy benefit is carved out from DMHC-regulated plans.
- CHBRP assumes the insulin products available in Milliman's 2019 Consolidated Health Cost Guidelines Sources Database (CHSD) that was used for this analysis will continue to be available in 2022. These claims data do not incorporate insulins newly available between 2019 and 2021. CHBRP is unable to predict the number, type, or price of new insulin products that may come to the market in 2022, nor how new products might affect the price and cost sharing for existing products.
- The estimated changes in cost sharing reported here include deductible amounts incurred by enrollees in plans where deductible amounts must be reached (e.g., high deductible health plans [HDHPs], Bronze and Silver plans offered through Covered California). More information about enrollees with deductibles is presented in Table 2 in the *Policy Context* section.

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

Baseline and Postmandate Benefit Coverage

All of the 13,940,000 enrollees in commercial and CalPERS DMHC-regulated plans and CDI-regulated policies would be subject to SB 473. The 13,940,000 enrollees in DMHC-regulated plans and CDI-regulated policies make up 64% of all enrollees subject to state-level benefit mandates and excludes enrollees in DMHC-regulated Medi-Cal managed care plans.

CHBRP estimates at baseline there are 118,014 enrollees who use insulin in commercial and CalPERS DMHC-regulated plans and CDI-regulated policies, where 64,619 enrollees using insulin have cost sharing that *does not exceed* the SB 473 cost-sharing cap (55%). CHBRP estimates 53,395 enrollees using insulin have cost sharing *that exceeds* the SB 473 cap (see estimates in Table 1). Postmandate, 100% of enrollees with cost sharing that exceeds the cap at baseline would have cost sharing below the cap.

A majority – over 93% – of enrollees in commercial and CalPERS plans and policies regulated by DMHC or CDI have a pharmacy benefit regulated by DMHC or CDI that covers both generic and brand-name outpatient prescription medications.[1] Approximately 3.1% do not have a pharmacy benefit and 3.6% have a pharmacy benefit that is not regulated by DMHC or CDI. Because SB 473 does not require creation of a pharmacy benefit — only compliant benefit coverage when a pharmacy benefit is present — baseline benefit coverage for enrollees without a pharmacy benefit or whose pharmacy benefit is not regulated by DMHC or CDI is compliant.

Baseline and Postmandate Utilization

Using relevant codes from the International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM), and National Drug Codes (NDCs), CHBRP used data from Milliman's 2019 Consolidated Health Cost Guidelines Sources Database (CHSD) to develop baseline estimates of utilization of insulin. CHBRP calculated utilization rates for enrollees whose claims for insulin exceed the cost-sharing cap at baseline and for those who did not exceed the cap. See estimates in Table 1. Utilization (measured as number of 30-day supply insulin prescriptions per month per user) is 0.83 for enrollees whose claims did not exceed the cost-sharing cap at baseline and 0.87 for enrollees whose claims did exceed the cost-sharing cap. Postmandate, the group whose claims exceeded the cost-sharing cap at baseline would experience an increase in utilization because this group would experience a decrease in cost sharing due to the bill. Utilization among enrollees who exceeded the cap at baseline is higher than those under the cap, which reflects the greater need for insulin in this group of enrollees.

To estimate changes in utilization postmandate, CHBRP applied an estimate of price elasticity of demand to enrollees exceeding the cap at baseline. CHBRP assumes reduced cost sharing for insulin increases the utilization of outpatient prescription insulin based on literature that establishes evidence of price elasticity of demand for prescription drugs (Goldman et al., 2004).

There is limited literature on the price elasticity of demand for insulin specifically; recent studies examining the effect of value-based insurance design (VBID) on insulin use also include oral antidiabetic (OAD) medications in the impacts of cost sharing. Because these OADs are in a different medication class than insulin, they may impact the elasticity measure due to different cost sharing levels for that drug class. Because of this, CHBRP bases the estimate of price elasticity on a Goldman et al. (2004) article that found use of insulin specifically decreased by 8% when copayments doubled. Thus, CHBRP applied this elasticity estimate to calculate increase in insulin utilization postmandate for enrollees who would experience a decrease in cost sharing postmandate.

As shown in Table 1, CHBRP estimates a 55% reduction in cost sharing for those enrollees who have cost sharing exceeding the cost-sharing cap at baseline, and therefore estimates a 7% increase in utilization of insulin postmandate for those enrollees. Because this analysis is based on claims data and there are no data sources on insulin purchases made outside of the enrollee's health insurance plan, CHBRP is unable to estimate utilization among enrollees who obtain insulin outside of their health insurance plan (e.g., those who travel abroad to buy insulin).

Baseline and Postmandate Per-Unit Cost

The average cost of insulin per prescription per month is $491. Using 2019 CHSD data, per-unit cost is calculated based on the allowed costs and is trended to 2022; the per-unit cost is not reduced by potential rebates that may be received by the health plans. SB 473 would not change the unit or per-prescription cost for insulin.

Baseline and Postmandate Expenditures

Table 7 and Table 8 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 473 would increase total net annual expenditures by $23,663,000 or 0.02% for enrollees with DMHC-regulated plans and CDI-regulated policies. This is due to an increase in $51,527,000 in total health insurance premiums paid by employers and enrollees due to the cost-sharing cap, adjusted by a $27,864,000 decrease in enrollee expenses.

Premiums

CHBRP estimates that the mandate would increase premiums by about $51,527,000. Total premiums for private employers purchasing group health insurance would increase by $24,092,000, or 0.04%. Total premiums for purchasers of individual market health insurance would increase by $17,610,000, or 0.11%. Changes in premiums as a result of SB 473 would vary by market segment. Note that such changes are related to the number of enrollees (see Table 1, Table 7, and Table 8), with health insurance that would be subject to SB 473. The greatest change in premiums as a result of SB 473 is for small-group (0.13% increase) and individual (0.11%) plans in the DMHC-regulated market.

Among publicly funded plans, DMHC-regulated Medi-Cal managed care is not subject to SB 473. For CalPERS HMO enrollees, the impact on premiums is $0, because there are no enrollees for whom cost sharing for insulin prescription is higher than the cap at baseline.

Enrollee Out-of-Pocket Expenses

SB 473-related changes in enrollee expenses for covered benefits (e.g. deductibles, copays, coinsurance, etc.) and enrollee expenses for noncovered benefits would vary by market segment. Note that such changes are related to the number of enrollees (see Table 1, Table 7, and Table 8) with health insurance that would be subject to SB 473 that are expected to use insulin during the year after enactment.

The largest reduction in enrollee cost-sharing expenditures due to SB 473 would be for DMHC-regulated small-group and individual plans and CDI-regulated small group policies, with reductions of approximately $0.40 per member per month.

Average enrollee cost-sharing expenses per user

For baseline insulin users, SB 473 caps on cost sharing only impact those enrollees who are above the cap at baseline. Overall, 45% of enrollees who use insulin at baseline would experience changes in cost sharing. For enrollees whose claims do not exceed the cost-sharing cap at baseline, the average monthly cost sharing for insulin is $19. For enrollees whose claims exceed the cost-sharing cap at baseline, the average monthly cost sharing for insulin is $88 at baseline and would decrease by 55% to $39 per month postmandate (Table 1).

It is possible that some enrollees who had deferred insulin treatment due to cost could begin using insulin postmandate; thus, this group of enrollees would incur cost sharing postmandate where they did not have cost sharing at baseline. However, this group is estimated to be relatively small. Per CHBRP's content expert, forgoing insulin completely after a physician has prescribed it is something that will occur among only those with type 2 diabetes mellitus (T2DM) where symptoms or the clinical consequences of not having the insulin are not felt by the patient. Literature suggests approximately 2.5% of people who were prescribed insulin never started their prescription in the past year due to cost.[50] Thus, for some enrollees, cost sharing may be the sole barrier to filling their insulin prescription; however, it is not known what the baseline cost sharing is for this group if they did fill their prescription (i.e., what proportion of non-users are above the cap), nor is it known what cost-sharing threshold would stimulate utilization among these enrollees. While CHBRP expects some demand response from this group when cost sharing is lowered postmandate, CHBRP expects it would be a relatively low utilization increase that would not substantially change the results of this analysis.

The enrollees most likely to experience the greatest cost-sharing reductions postmandate are those who are enrolled in plans that require significant deductibles to be met before coinsurance is applied to the insulin purchase, e.g., HDHPs, Bronze, and Silver plans. CHBRP's cost model estimates indicate that for enrollees subject to SB 473, approximately 19% of large-group, 37% of small-group, and 61% of

[50] Personal communication with corresponding author of Herkert et al., 2019, on March 10, 2020

individual market enrollees are in plans or policies with prescription drug deductibles, where deductibles may have a material impact on insulin cost sharing. The estimates of cost-sharing reductions presented below include the total impact on cost-sharing incurred by the enrollee, including deductibles, coinsurance, and copays. CHBRP modeled the impact of deductibles using the underlying benefit designs for members in the CHSD data source.

Cost-sharing reductions due to SB 473 are the greatest for enrollees who have the highest cost-sharing expense for insulin at baseline. Among the enrollees impacted by the cost-sharing cap, enrollees with out-of-pocket expenditures for insulin in the top 1% at baseline have an annual savings of greater than $3,111 (Table 6). The annual savings for the top 5%, 10%, and 20% of enrollees based on cost-sharing expenditures for insulin is greater than $1,712, $1,221, and $659, respectively. The median annual savings for an enrollee is $162.

It is possible that at baseline some enrollees incurred insulin-related expenses when coverage was denied, delivered through another vendor or purchased outside of the health insurance plan, but CHBRP cannot estimate the frequency with which such situations occur and so cannot offer a calculation of impact.

Table 6. Enrollee Cost Sharing Impact of SB 473 (Among Enrollees Exceeding the Cost-Sharing Cap at Baseline)

Cost Sharing Expenses	Baseline (Uncapped Annual Cost)	Postmandate (Capped Annual Cost)	Annual Savings
Top 1% of enrollees have cost/savings greater than	$3,915	$1,203	$3,111
Top 5% of enrollees have cost/savings greater than	$2,316	$911	$1,712
Top 10% of enrollees have cost/savings greater than	$1,743	$736	$1,221
Top 20% of enrollees have cost/savings greater than	$1,199	$584	$659
Median enrollee cost/savings	$560	$323	$162

Source: California Health Benefits Review Program, 2021.
Note: Because the top 1% of uncapped enrollees are not the same exact group of people as the top 1% of capped enrollees, savings does not equal baseline cost-sharing expenses minus postmandate cost-sharing expenses. Not all members have coverage for a full 12 months, so annualized costs and savings could be greater. For the purpose of this table, CHBRP applied the induced utilization factor from Goldman (2004) and the monthly cost sharing cap to the observed experience for every enrollee using insulin. In practice, not all enrollees will follow this pattern, particularly the outliers.

Out-of-pocket spending for covered and noncovered expenses

CHBRP estimates that the 53,395 enrollees with covered expenses above the cap at baseline would receive a total $27,864,000 reduction in their out-of-pocket spending for covered and noncovered expenses associated with SB 473 (Table 1).

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

CHBRP used Nair et al. (2010), to estimate changes in offsets postmandate. In Nair et al. (2010), diabetes-related emergency room visits decreased by 31% with the introduction of the VBID program. Based on this finding, CHBRP assumed approximately one third of the reduction seen in the VBID study that included all diabetes medications was attributable to insulin; thus, CHBRP assumed there would be a 10% decrease in diabetes-related ER visits due to increased insulin utilization stemming from better adherence to insulin prescription regimens for those who underuse postmandate. Offsets stemming from

this reduction in diabetes-related ER visits are estimated to result in $2,356,000 lower allowed costs postmandate in 2022.

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.

Other Considerations for Policymakers

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

Postmandate Changes in the Number of Uninsured Persons

Because the change in average premiums does not exceed 1% for any market segment (see Table 1, Table 7, and Table 8), CHBRP would expect no measurable change in the number of uninsured persons due to the enactment of SB 473.

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 473.

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

Enrollees may take part in cost-sharing assistance programs to help offset high copayments or coinsurance. CHBRP is unable to provide a quantifiable estimate of the number of enrollees who take part in patient assistance programs and the potential impact SB 473 would have on the number of enrollees who use these programs.

Table 7. Baseline Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2022

	DMHC-Regulated						CDI-Regulated			
	Privately Funded Plans (by Market) (a)			Publicly Funded Plans			Privately Funded Plans (by Market) (a)			
	Large Group	*Small Group*	*Individual*	*CalPERS HMOs (b)*	*MCMC (Under 65) (c)*	*MCMC (65+) (c)*	*Large Group*	*Small Group*	*Individual*	**Total**
Enrollee counts										
Total enrollees in plans/policies subject to state mandates (d)	8,405,000	2,086,000	1,989,000	889,000	7,218,000	787,000	384,000	43,000	144,000	21,945,000
Total enrollees in plans/policies subject to SB 473	8,405,000	2,086,000	1,989,000	889,000	0	0	384,000	43,470	144,000	13,940,470
Premiums										
Average portion of premium paid by employer	$426.28	$374.49	$0.00	$540.40	$226.61	$478.87	$530.80	$421.81	$0.00	$84,948,349,000
Average portion of premium paid by employee	$141.02	$180.89	$624.47	$96.86	$0.00	$0.00	$186.55	$212.07	$545.57	$36,600,954,000
Total premium	**$567.30**	**$555.38**	**$624.47**	**$637.27**	**$226.61**	**$478.87**	**$717.35**	**$633.88**	**$545.57**	**$121,549,303,000**
Enrollee expenses										
For covered benefits (deductibles, copays, etc.)	$43.61	$121.70	$173.51	$50.75	$0.00	$0.00	$134.75	$197.13	$184.11	$13,168,032,000
For noncovered benefits (e)	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0
Total expenditures	**$610.91**	**$677.07**	**$797.97**	**$688.02**	**$226.61**	**$478.87**	**$852.10**	**$831.01**	**$729.68**	**$134,717,335,000**

Source: California Health Benefits Review Program, 2021.

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

(b) As of January 2021, approximately 54.1% of CalPERS enrollees in DMHC-regulated plans are state retirees, state employees, or their dependents. About one in five (20.5%) of these enrollees has a pharmacy benefit not subject to DMHC. CHBRP has projected no impact for those enrollees. However, CalPERS could, postmandate, require equivalent coverage for all its members (which could increase the total impact on CalPERS).

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

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

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

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

Table 8. Postmandate Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2022

	DMHC-Regulated						CDI-Regulated			
	Privately Funded Plans (by Market) (a)			Publicly Funded Plans			Privately Funded Plans (by Market) (a)			
	Large Group	*Small Group*	*Individual*	*CalPERS HMOs (b)*	*MCMC (Under 65) (c)*	*MCMC (65+) (c)*	*Large Group*	*Small Group*	*Individual*	**Total**
Enrollee counts										
Total enrollees in plans/policies subject to state mandates (d)	8,405,000	2,086,000	1,989,000	889,000	7,218,000	787,000	384,000	43,000	144,000	21,945,000
Total enrollees in plans/policies subject to SB 473	8,405,000	2,086,000	1,989,000	889,000	0	0	384,000	43,470	144,000	13,940,470
Premiums										
Average portion of premium paid by employer	$0.1138	$0.4731	$0.0000	$0.0000	$0.0000	$0.0000	$0.1151	$0.4669	$0.0000	$24,092,000
Average portion of premium paid by employee	$0.0376	$0.2285	$0.6997	$0.0000	$0.0000	$0.0000	$0.0404	$0.2347	$0.5267	$27,435,000
Total premium	$0.1515	$0.7016	$0.6997	$0.0000	$0.0000	$0.0000	$0.1555	$0.7016	$0.5267	**$51,527,000**
Enrollee expenses										
For covered benefits (deductibles, copays, etc.)	-$0.0713	-$0.4012	-$0.4002	$0.0000	$0.0000	$0.0000	-$0.0731	-$0.4012	-$0.3062	-$27,863,000
For noncovered benefits (e)	$0.0000	$0.0000	$0.0000	$0.0000	$0.0000	$0.0000	$0.0000	$0.0000	$0.0000	$0
Total expenditures	$0.0801	$0.3003	$0.2995	$0.0000	$0.0000	$0.0000	$0.0824	$0.3003	$0.2205	**$23,663,000**
Percent change										
Premiums	0.0267%	0.1263%	0.1120%	0.0000%	0.0000%	0.0000%	0.0217%	0.1107%	0.0965%	0.0424%
Total expenditures	0.0131%	0.0444%	0.0375%	0.0000%	0.0000%	0.0000%	0.0097%	0.0361%	0.0302%	0.0176%

Source: California Health Benefits Review Program, 2021.

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

(b) As of January 2021, approximately 54.1% of CalPERS enrollees in DMHC-regulated plans are state retirees, state employees, or their dependents. About one in five (20.5%) of these enrollees has a pharmacy benefit not subject to DMHC. CHBRP has projected no impact for those enrollees. However, CalPERS could, postmandate, require equivalent coverage for all its members (which could increase the total impact on CalPERS).

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

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

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

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

PUBLIC HEALTH IMPACTS

As discussed in the *Policy Context* section, SB 473 would limit cost sharing (copayments, coinsurance, and deductibles) for insulin to $50 for a 30-day supply and up to $100 per month total, regardless of the amount or type of insulin needed to fill the covered person's prescription(s). The public health impact analysis includes estimated impacts in the short term (within 12 months of implementation) and in the long term (beyond the first 12 months postmandate).

Estimated Public Health Outcomes

Measurable health outcomes relevant to SB 473 included utilization of insulin and the associated effects of insulin adherence on health as measured by glycemic control (i.e. HbA1c levels), healthcare utilization (e.g., emergency department visits, hospitalizations), productivity (e.g. disability, absenteeism), and diabetes-related complications or comorbidities (e.g., amputations, ulcers, blindness, heart attack, stroke). As presented in the *Medical Effectiveness* section, there is a *preponderance of evidence* in the literature that cost sharing affects insulin use and adherence in patients with diabetes, and *insufficient evidence* on the effect of cost sharing for insulin on diabetes-related health and utilization outcomes listed above.

As presented in the *Benefit Coverage, Utilization, and Cost Impacts* section, 53,395 enrollees who have claims that exceed the cost-sharing cap at baseline would experience an average of a 55% reduction in cost sharing, reducing average monthly cost sharing from $88 to $39. Additionally, in the first year postmandate, CHBRP estimates there would be notable cost offsets, specifically from reductions in emergency department visits.

The segment of the insured population most impacted by SB 473 would be enrollees for whom a deductible applies before the copay, or for enrollees with high-deductible plans, which require the enrollee to pay list price for insulin until the deductible is met for the year. Also affected are enrollees with diabetes who are prescribed more than one type of insulin or a higher-tiered insulin (Cefalu et al., 2018). Enrollees with type 2 diabetes mellitus (T2DM) are more likely than those with type 1 diabetes mellitus (T1DM) to increase utilization owing to the inability of patients with T1DM to limit insulin intake without adverse effects on their health.

In the first year postmandate, 53,395 enrollees who exceed the insulin cost-sharing cap at baseline would have reduced cost sharing. CHBRP projects that as a result, there would be a 7% increase in utilization of insulin. CHBRP found a *preponderance of evidence* that cost sharing for insulin is effective in improving adherence to insulin in patients with diabetes, and *insufficient evidence* on the effect of cost sharing for diabetes-related health outcomes. SB 473 may result in improved glycemic control, a reduction in healthcare utilization, a reduction in long-term complications attributable to DM, and improved quality of life for enrollees that experience a decrease in cost-sharing and improved insulin adherence, or begin using insulin due to reduced costs.

Glycemic Control

For the population that would be impacted by SB 473, achieving stable blood glucose levels, measured as HbA1c, could reduce the frequency and severity of episodes of hyperglycemia and hypoglycemia. In the most severe cases, hyperglycemia can lead to ketoacidosis, followed by coma or death. Similarly, escalation of hypoglycemia can lead to cognitive dysfunction, seizures, coma, and death. Additionally, hypoglycemia unawareness occurs more frequently among those who are insulin dependent (Martin-Timon and Canizo-Gomez, 2015). Therefore, achievement of more stable HbA1c levels through increased utilization and adherence to insulin could avoid these serious health consequences associated with diabetes.

Healthcare Utilization

For the population that would be impacted by SB 473, impacts to healthcare utilization may include reduced hospitalizations and outpatient appointments, and measurable offsets from reductions in insulin-related ED visits. This would reduce costly emergency services and also have direct impacts on the patient. Reduced time in hospitals and EDs also reduces the exposure to hospital-acquired infections and infectious diseases that are prevalent in these settings. This may be a considerable positive health outcome for patients with diabetes who have a compromised immune system and possible other comorbidities.

Long-Term Complications

Time spent in hyperglycemia and frequency and severity of hyper- and hypoglycemia over a lifetime are associated with serious morbidity and mortality outcomes. In the United States, diabetes is the leading cause of blindness, amputations, and kidney failure, and a key contributor to stroke, heart disease, dental disease, nerve damage, and premature death. To the extent that SB 473 can help individuals taking insulin afford their prescribed dose, it is possible that rates of these comorbid conditions attributable to diabetes could be reduced.

Quality of Life

CHBRP found no literature specifically addressing the impact of reduced cost sharing for insulin on health-related quality of life. However, quality-of-life improvements have been evaluated with regards to outcomes associated with SB 473. In one cross-sectional study, insulin utilization was found to be positively associated with quality of life: significant differences were observed for T2DM insulin users for diet, monitoring, disease-specific knowledge, and adherence to treatment as compared to oral antidiabetic medications (OAD) users (Gillani, 2019). Additionally, Hajós and colleagues (2011) found improvements in quality-of-life scores with improved HbA1c levels due to optimized insulin therapy for those with T2DM who had suboptimal glycemic control (Hajós et al., 2011). There is also evidence that quality of life in patients with diabetes is affected more so by the presence of complications, and not necessarily by the diagnosis itself (Venkataraman, 2013). Peripheral neuropathy was the complication most strongly associated with reduced quality of life (Venkataraman, 2013).

Impact on Disparities[51]

Insurance benefit mandates that bring more state-regulated plans and policies to parity may change an existing disparity. As described in the *Background* section, disparities in diabetes exist by race/ethnicity, age, gender, education, income, and health literacy. CHBRP did not find evidence indicating differential use of insulin by any reported disparity within the first 12 months postmandate; therefore, it is projected that SB 473 would have no impact on these diabetes disparities statewide (for a discussion of potential impacts beyond the first 12 months of implementation [including SDOH], see *Long-Term Impacts*). For enrollees who have cost-related barriers to insulin use, SB 473 would improve disparities related to income by reducing the allowed cost-sharing amounts. However, it is worth noting that reduced cost sharing generally shifts the cost to premiums for all enrollees, and this shift could impact lower income enrollees disproportionately.

Despite SB 473 applying only to privately insured enrollees, SB 473 would not exacerbate racial or ethnic disparities due to differences in populations represented in private insurance and Medi-Cal, as Medi-Cal beneficiaries do not have cost sharing.

[51] For details about CHBRP's methodological approach to analyzing disparities, see the *Benefit Mandate Structure and Unequal Racial/Ethnic Health Impacts* document here: http://chbrp.com/analysis_methodology/public_health_impact_analysis.php.

LONG-TERM IMPACTS

In this section, CHBRP estimates the long-term impact of SB 473, which CHBRP defines as impacts occurring beyond the first 12 months after implementation. These estimates are qualitative and based on the existing evidence available in the literature. CHBRP does not provide quantitative estimates of long-term impacts because of unknown improvements in clinical care, changes in prices, implementation of other complementary or conflicting policies, and other unexpected factors.

Long-Term Utilization and Cost Impacts

Utilization Impacts

CHBRP estimates annual insulin utilization per user after the initial 12 months from the enactment of SB 473 would likely stay similar to utilization estimates during the first 12 months postmandate. Utilization changes may occur if new diabetes products or medications change the landscape of insulin use for enrollees with diabetes; however, CHBRP is unable to predict these types of changes. Similarly, health care utilization due to improved diabetes management may change in the long term. Reductions in significant complications or comorbidities may take years to develop, but are not trivial.

Cost Impacts

CHBRP estimates cost after the initial 12 months from the enactment of SB 473 are likely to remain similar in the subsequent years; however, with the potential improvements in health outcomes due to better glycemic control among enrollees with diabetes, the cost offsets may become more substantial such that the cost savings from potential decreases in diabetes-related hospitalizations and other health care visits become greater over time. CHBRP is unable to estimate these changes quantitatively due to the lack of data on long-term utilization and cost due to improved insulin adherence.

Long-Term Public Health Impacts

Some interventions in proposed mandates provide immediate measurable impacts (e.g., maternity service coverage or acute care treatments), whereas other interventions may take years to make a measurable impact (e.g., coverage for tobacco cessation or vaccinations). When possible, CHBRP estimates the long-term effects (beyond 12 months postmandate) to the public's health that would be attributable to the mandate, including impacts on social determinants of health, premature death, and economic loss.

CHBRP estimates that some of the outcomes discussed may take longer than 12 months to observe. Specifically, reductions in significant complications or comorbidities may take years to develop, as would significant differences in disability and absenteeism. SB 473 is unlikely to impact these public health outcomes statewide, but at a person-level it could make a substantial difference in long-term healthcare spending, morbidity, and mortality.

Impacts on Disparities and the Social Determinants of Health[52]

In the case of SB 473, evidence shows that although variances in education, income, and health literacy exist for the population with diabetes mellitus (DM) and contribute to differences in insulin adherence, CHBRP projects no statewide changes in these social determinants of health (SDOH) that would be attributable to SB 473. However, it is possible that at the person-level, a reduction in cost sharing for insulin therapy could reduce differences in adherence due to income and socioeconomic status.

[52] For more information about SDOH, see CHBRP's publication Incorporating Relevant Social Determinants of Health Into CHBRP Benefit Mandate Analyses at http://chbrp.com/analysis_methodology/public_health_impact_analysis.php.

In the long term, CHBRP estimates that SB 473 would improve disparities related to income for some enrollees who have cost-related barriers to insulin use. CHBRP is unable to estimate reductions in existing disparities. However, because the prevalence of diabetes is higher for Blacks than for Whites, and there is evidence that cost-related medication nonadherence is also more associated with Blacks, it is possible that this disparity may be reduced for the population SB 473 impacts.

Impacts on Premature Death and Economic Loss

Premature death is often defined as death occurring before the age of 75 years (NCI, 2019).[53] In California, it is estimated that there were nearly 5,300 years of potential life lost (YPLL) per 100,000 population each year between 2015 and 2017 (CDPH, 2019; County Health Rankings, 2019).[54]

Diabetes contributes significantly to premature death and economic loss in California. In addition to complications from diabetes, hypoglycemia is prevalent among those with T1DM and contributes to increased risk of death from diabetes (McCoy, et al., 2012). In addition, diabetes is the seventh leading cause of death in California, and an overall contributor to premature death (e.g., people with diabetes aged 50 years or older die almost 8 years earlier than those without diabetes) (Conroy et al., 2014). The CDC reports that almost 6,000 Californians with diabetes died prematurely in 2013. Despite the diabetes mortality rate decreasing since 1999 for Blacks and Hispanics, these groups still experience twice the mortality rate as non-Hispanic Whites, with Asian/Pacific Islanders remaining stable and American Indian and Alaskan Natives fluctuating over time (Conroy et al., 2014).

As discussed in the *Background on Diabetes Mellitus and Insulin for Glycemic Control* section, total direct medical expenses in California were estimated to be $27.6 billion. An additional $9.5 billion was spent on indirect costs due to lost productivity. Indirect costs have also been reported as high as $32.6 billion when including morbidity and premature mortality costs (Shrestha et al., 2018). For non-Medicare or Medicaid payers (private insurance, other payers, and out-of-pocket from patients), medical costs related to diabetes are $11.7 billion in California (Shrestha et al., 2018).

In the long term, the quantified impact of SB 473 on premature mortality is unknown due to the lack of evidence that reduced cost sharing for insulin reduces mortality. However, well-controlled blood glucose results in fewer diabetes-related comorbidities (e.g. blindness, amputations, kidney disease, etc.). Therefore, for those patients who attain good glycemic control through increased adherence to insulin, these diabetes-related comorbidities that are known to lead to premature death could be prevented, delayed, or ameliorated.

The quantified impact of SB 473 on economic loss is unknown due to the lack of literature on this topic. However, to the extent that better glycemic control is achieved, and comorbidities and lost productivity reduced, there is the potential for reduced economic loss.

[53] For more information about CHBRP's public health methodology, see http://chbrp.com/analysis_methodology/public_health_impact_analysis.php.

[54] The overall impact of premature death due to a particular disease can be measured in years of potential life lost prior to age 75 and summed for the population (generally referred to as "YPLL") (Gardner and Sanborn, 1990).

APPENDIX A TEXT OF BILL ANALYZED

On February 18, 2021, the California Senate Committee on Health requested that CHBRP analyze SB 473. SB 473 was amended on March 10, 2021.

SENATE BILL **NO. 473**

Introduced by Senator Bates

February 17, 2021

An act to amend Section 1367.51 of the Health and Safety Code, and to amend Section 10176.61 of the Insurance Code, relating to health care coverage.

LEGISLATIVE COUNSEL'S DIGEST

SB 473, as introduced, Bates. Health care coverage: insulin cost sharing.

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's requirements a crime. Existing law provides for the regulation of health insurers by the Department of Insurance. Existing law requires a health care service plan contract or health insurance policy issued, amended, delivered, or renewed on or after January 1, 2000, to include coverage for equipment, supplies, and, if the contract or policy covers prescription benefits, prescriptive medications for the management and treatment of insulin-using diabetes, non-insulin-using diabetes, and gestational diabetes, as medically necessary.

This bill would prohibit a health care service plan contract or a health insurance policy that is issued, amended, delivered, or renewed on or after January 1, 2022, from imposing cost sharing on a covered insulin prescription, except for a copayment not to exceed $50 per 30-day supply of insulin, or $100 ~~for a supply exceeding 30 days,~~ *total per month,* regardless of the amount or type of ~~insulin.~~ *insulin needed to fill the enrollee's or insured's prescription or prescriptions.* 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.

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

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

SECTION 1. The Legislature finds and declares that:

(a) Approximately 263,000 Californians are diagnosed with type 1 diabetes each year. Approximately 4,037,000 Californian adults have diabetes.

(b) Every Californian with type 1 diabetes, and many with type 2 diabetes, rely on daily doses of insulin to survive.

(c) Insulin prices have nearly tripled, creating financial hardships for people who rely on it to survive.

(d) One in four people using insulin have reported insulin underuse due to the high cost of insulin.

(e) Diabetes is the seventh leading cause of death and a leading cause of disabling and life-threatening complications, including heart disease, stroke, kidney failure, amputation of the lower extremities, and new cases of blindness among adults.

(f) Studies have shown that managing diabetes can prevent the complications associated with diabetes.

(g) Therefore, it is important to enact policies to reduce the costs for Californians with diabetes to obtain life-saving and life-sustaining insulin.

SEC. 2. Section 1367.51 of the Health and Safety Code is amended to read:
1367.51 (a) ~~Every~~ *A* health care service plan contract, except a specialized health care service plan contract, that is issued, amended, delivered, or renewed on or after January 1, 2000, ~~and that covers hospital, medical, or surgical expenses~~ shall include coverage for the following equipment and supplies for the management and treatment of insulin-using diabetes, non-insulin-using diabetes, and gestational diabetes as medically necessary, even if the items are available without a prescription:

(1) Blood glucose monitors and blood glucose testing strips.

(2) Blood glucose monitors designed to assist the visually impaired.

(3) Insulin pumps and all related necessary supplies.

(4) Ketone urine testing strips.

(5) Lancets and lancet puncture devices.

(6) Pen delivery systems for the administration of insulin.

(7) Podiatric devices to prevent or treat diabetes-related complications.

(8) Insulin syringes.

(9) Visual aids, excluding eyewear, to assist the visually impaired with proper dosing of insulin.

(b) ~~Every~~ *A* health care service plan contract, except a specialized health care service plan contract, that is issued, amended, delivered, or renewed on or after January 1, 2000, that covers prescription benefits shall include coverage for the following prescription items if the items are determined to be medically necessary:

(1) Insulin.

(2) Prescriptive medications for the treatment of diabetes.

(3) Glucagon.

(c) The copayments and deductibles for the benefits specified in subdivisions (a) and (b) shall not exceed those established for similar benefits within the given plan.

(d) (1) Notwithstanding subdivision (c), for a health care service plan contract that is issued, amended, delivered, or renewed on or after January 1, 2022, the copayment for an insulin prescription covered pursuant to subdivision (b) shall not exceed fifty dollars ($50) per 30-day supply, or one hundred dollars ($100) ~~for a supply exceeding 30 days,~~ total per month, regardless of the amount or type of insulin ~~prescribed.~~ needed to fill the enrollee's prescription or prescriptions.

(2) A health care service plan contract that is issued, amended, delivered, or renewed on or after January 1, 2022, shall not impose a deductible, coinsurance, or other cost-sharing requirement on an insulin prescription, except for a copayment subject to the limitations in paragraph (1).

(e) A health care service plan shall provide coverage for diabetes outpatient self-management training, education, and medical nutrition therapy necessary to enable an enrollee to properly use the equipment, supplies, and medications set forth in subdivisions (a) and (b), and additional diabetes outpatient self-management training, education, and medical nutrition therapy upon the direction or prescription of those services by the enrollee's participating physician. If a plan delegates outpatient self-management training to contracting providers, the plan shall require contracting providers to ensure that diabetes outpatient self-management training, education, and medical nutrition therapy are provided by appropriately licensed or registered health care professionals.

(f) The diabetes outpatient self-management training, education, and medical nutrition therapy services identified in subdivision (e) shall be provided by appropriately licensed or registered health care professionals as prescribed by a participating health care professional legally authorized to prescribe the service. These benefits shall include, but not be limited to, instruction

that will enable diabetic patients and their families to gain an understanding of the diabetic disease process, and the daily management of diabetic therapy, in order to thereby avoid frequent hospitalizations and complications.

(g) The copayments for the benefits specified in subdivision (e) shall not exceed those established for physician office visits by the plan.

(h) ~~Every~~ A health care service plan governed by this section shall disclose the benefits covered pursuant to this section in the plan's evidence of coverage and disclosure forms.

(i) A health care service plan shall not reduce or eliminate coverage as a result of this section.

(j) This section does not deny or restrict ~~in any way~~ the department's authority to ensure plan compliance with this chapter if a plan provides coverage for prescription drugs.

SEC. 3. Section 10176.61 of the Insurance Code is amended to read:

10176.61. (a) ~~Every insurer issuing, amending, delivering, or renewing a disability insurance policy~~ *A health insurance policy issued, amended, or renewed* on or after January 1, 2000, ~~that covers hospital, medical, or surgical expenses~~ shall include coverage for the following equipment and supplies for the management and treatment of insulin-using diabetes, non-insulin-using diabetes, and gestational diabetes as medically necessary, even if the items are available without a prescription:

(1) Blood glucose monitors and blood glucose testing strips.

(2) Blood glucose monitors designed to assist the visually impaired.

(3) Insulin pumps and all related necessary supplies.

(4) Ketone urine testing strips.

(5) Lancets and lancet puncture devices.

(6) Pen delivery systems for the administration of insulin.

(7) Podiatric devices to prevent or treat diabetes-related complications.

(8) Insulin syringes.

(9) Visual aids, excluding eyewear, to assist the visually impaired with proper dosing of insulin.

~~(b)Every insurer issuing, amending, delivering, or renewing a disability insurance policy~~

(b) A health insurance policy that is issued, amended, or renewed on or after January 1, 2000, that covers prescription benefits shall include coverage for the following prescription items if the items are determined to be medically necessary:

(1) Insulin.

(2) Prescriptive medications for the treatment of diabetes.

(3) Glucagon.

(c) The coinsurances and deductibles for the benefits specified in subdivisions (a) and (b) shall not exceed those established for similar benefits within the given policy.

(d) (1) Notwithstanding subdivision (c), for a health insurance policy that is issued, amended, or renewed on or after January 1, 2022, the copayment for an insulin prescription covered pursuant to subdivision (b) shall not exceed fifty dollars ($50) per 30-day supply, or one hundred dollars ($100) ~~for a supply exceeding 30 days,~~ total per month, regardless of the amount or type of insulin ~~prescribed.~~ needed to fill the insured's prescription or prescriptions.

(2) A health insurance policy that is issued, amended, or renewed on or after January 1, 2022, shall not impose a deductible, coinsurance, or other cost-sharing requirement on an insulin prescription, except for a copayment subject to the limitations in paragraph (1).

~~(d)Every~~

(e) A health insurer shall provide coverage for diabetes outpatient self-management training, education, and medical nutrition therapy necessary to enable an insured to properly use the equipment, supplies, and medications set forth in subdivisions (a) and (b) and additional diabetes outpatient self-management training, education, and medical nutrition therapy upon the direction or prescription of those services by the insured's participating physician. If an insurer delegates outpatient self-management training to contracting providers, the insurer shall require contracting providers to ensure that diabetes outpatient self-management training, education, and medical nutrition therapy are provided by appropriately licensed or registered health care professionals.

~~(e)~~

(f) The diabetes outpatient self-management training, education, and medical nutrition therapy services identified in subdivision ~~(d)~~ *(e)* shall be provided by appropriately licensed or registered health care professionals as prescribed by a health care professional legally authorized to prescribe the services.

~~(f)~~

(g) The coinsurances and deductibles for the benefits specified in subdivision ~~(d)~~ *(e)* shall not exceed those established for physician office visits by the insurer.

~~(g)Every disability~~

(h) A health insurer governed by this section shall disclose the benefits covered pursuant to this section in the insurer's evidence of coverage and disclosure forms.

~~(h)An~~

(i) A health insurer ~~may~~ *shall* not reduce or eliminate coverage as a result of ~~the requirements of~~ this section.

~~(i)~~

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

SEC. 4. 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 LITERATURE REVIEW METHODS

This appendix describes methods used in the literature review conducted for this report. A discussion of CHBRP's system for medical effectiveness grading evidence, as well as lists of MeSH Terms, publication types, and keywords, follows.

Studies of cost sharing related to insulin use and adherence for diabetes were identified through searches of PubMed, the Cochrane Library, Web of Science, and the Cumulative Index of Nursing and Allied Health Literature. Websites maintained by the following organizations that produce and/or index meta-analyses and systematic reviews were also searched: the Agency for Healthcare Research and Quality (AHRQ), the International Network of Agencies for Health Technology Assessment (INAHTA), the National Health Service (NHS) Centre for Reviews and Dissemination, the National Institute for Health and Clinical Excellence (NICE), and the Scottish Intercollegiate Guideline Network. The American Diabetic Association (ADA) website and available resources were also searched as pertinent to this bill and reviewed.

The search was limited to studies published from 2020 to present, because CHBRP had previously reviewed this literature using the same search terms in 2020 for the AB 2203 analysis. Articles were eliminated if they did not focus on a specific treatment, were from outside the United States, were of poor quality, or did not report findings from clinical research studies. The American Diabetic Association (ADA) website and available resources were also searched as pertinent to this bill and reviewed.

Reviewers screened the title and abstract of each citation retrieved by the literature search to determine eligibility for inclusion. The reviewers acquired the full text of articles that were deemed eligible for inclusion in the review and reapplied the initial eligibility criteria.

Medical Effectiveness Review

The medical effectiveness literature review returned abstracts for 122 articles, of which 19 were reviewed for inclusion in this report. A total of two new studies since 2020 were included in the medical effectiveness review for AB 97, as well as five studies that were included in the previous review for AB 2203.

Medical Effectiveness Evidence Grading System

In making a "call" for each outcome measure, the medical effectiveness lead and the content expert consider the number of studies as well the strength of the evidence. Further information about the criteria CHBRP uses to evaluate evidence of medical effectiveness can be found in CHBRP's *Medical Effectiveness Analysis Research Approach*.[55] To grade the evidence for each outcome measured, the team uses a grading system that has the following categories:

- Research design;
- Statistical significance;
- Direction of effect;
- Size of effect; and
- Generalizability of findings.

The grading system also contains an overall conclusion that encompasses findings in these five domains. The conclusion is a statement that captures the strength and consistency of the evidence of an intervention's effect on an outcome. The following terms are used to characterize the body of evidence regarding an outcome:

[55] Available at: http://chbrp.com/analysis_methodology/medical_effectiveness_analysis.php.

- *Clear and convincing evidence;*
- *Preponderance of evidence;*
- *Limited evidence;*
- *Inconclusive evidence;* and
- *Insufficient evidence.*

A grade of *clear and convincing evidence* indicates that there are multiple studies of a treatment and that the large majority of studies are of high quality and consistently find that the treatment is either effective or not effective.

A grade of *preponderance of evidence* indicates that the majority of the studies reviewed are consistent in their findings that treatment is either effective or not effective.

A grade of *limited evidence* indicates that the studies had limited generalizability to the population of interest and/or the studies had a fatal flaw in research design or implementation.

A grade of *inconclusive evidence* indicates that although some studies included in the medical effectiveness review find that a treatment is effective, a similar number of studies of equal quality suggest the treatment is not effective.

A grade of *insufficient evidence* indicates that there is not enough evidence available to know whether or not a treatment is effective, either because there are too few studies of the treatment or because the available studies are not of high quality. It does not indicate that a treatment is not effective.

Search Terms (* indicates truncation of word stem)

- A1c
- Adherence
- Age
- Age Factors
- American
- Amputation
- Birth Injuries
- Birth Weight
- Birth/Newborn/Infant Hypoglycemia
- Birth/Newborn/Infant Size
- Bisexual
- Blindness
- Cardiovascular Diseases
- Cardiovascular Disorders
- Coinsurance
- Co-Insurance
- Coma
- Comorbidity
- Compliance
- Complications
- Copay
- Co-Pay
- Copayments (Insurance)
- Cost
- Cost Control
- Cost Effectiveness
- Cost Sharing
- Cost Shifting
- Cost Shifting in Employer-Based Health Insurance
- Costs and Cost Analysis
- Deductible
- Deductibles (Insurance)
- Diabetes
- Diabetes Complications
- Diabetes Management
- Diabetes Mellitus
- Diabetes Mellitus Complications
- Diabetic Angiopathies
- Diabetic Cardiomyopathies
- Diabetic Coma
- Diabetic Ketoacidosis
- Diabetic Neuropathies
- Diabetic Patients
- Disease Management
- Disparities
- Disparity
- Donohue Syndrome
- Drug Utilization
- Drug Utilization Review
- Dystocia
- Economics
- Emergency Service, Hospital
- Emergency Service, Hospital

- Emergency Services
- Emergency Visits/Admissions
- ESRD
- Ethnic
- Ethnic Groups
- Facilities and Services Utilization
- Fetal Outcome
- Gender
- Gender Equality
- Gender Equity
- Gender Gap
- Gender Specific Care
- Gestational diabetes
- Glycated Hemoglobin A
- Glycated Hemoglobin levels
- Glycemic Control
- Glycohemoglobin A levels
- HbA1c
- Health Insurance
- Health Status Disparities
- Healthcare Disparities
- Heart Attack
- Homosexual
- Hospital Admission
- Hospital Discharge
- Hospitalization
- Hospitalization
- Hypoglycemia
- Incidence
- Income
- Income (Economic)
- Income Level
- Infant, Low Birth Weight
- Infant, Premature
- Infant, Premature, Diseases
- Insulin
- Insurance Costs
- Ketoacidosis
- Kidney Diseases
- Kidney Failure
- Kidney Failure, Chronic
- Lesbian
- LGBTQ
- Medication Adherence
- Minorities
- Minority
- Minority Groups
- Minority Health
- Mortality, Premature
- Myocardial Infarction
- Newborn Respiratory Distress Syndrome
- Nonadherence
- Non-Compliance
- Office Visits
- Office Visits
- Outcome
- Outcome Assessment
- Out-Of-Pocket
- Patient Compliance
- Patient-Reported Outcomes
- Peripheral Neuropathy
- Pregnancy Complications
- Pregnancy in Diabetes
- Pregnancy Outcome
- Premature Death/Mortality
- Prevalence
- Race and Ethnic Discrimination
- Race Factors
- Racial
- Racial and Ethnic Attitudes
- Racial and Ethnic Differences
- Racial and Ethnic Groups
- Racial Disparities
- Renal Insufficiency, Chronic
- SDOH
- Sex Factors
- Sexual Behavior
- Sexual Orientation
- Sexuality
- Social Determinants
- Social Determinants of Health
- Stroke
- Transgender
- Transsexual
- Treatment Outcomes
- Treatment Refusal
- Type 2 Diabetes
- U.S.
- United States
- US
- Usage
- Utilization
- Utilization Review

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

The cost analysis in this report was prepared by the members of the cost team, which consists of CHBRP task force members and contributors from the University of California, Los Angeles, and the University of California, Davis, as well as the contracted actuarial firm, Milliman, Inc.[56]

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.[57]

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

Analysis-Specific Caveats and Assumptions

This subsection discusses the caveats and assumptions relevant specifically to an analysis of SB 473.

- National Drug Codes (NDCs) for insulin were identified using the MediSpan® Master Drug Data Base v2.5.
- Once identified, these NDCs for insulin were used to extract data from Milliman's 2019 Consolidated Health Cost Guidelines Sources Database (CHSD). CHBRP limited its data pull to California only. These data were used to develop prevalence, utilization, baseline allowed cost, and enrollee cost-sharing information by commercial market segment for insulin users. In addition, CHBRP developed this information separately for two distinct groups of insulin users:
  - Enrollees who did not have any claims that exceeded the mandated cost-sharing cap; and
  - Enrollees who had at least one claim that exceeded the mandated cost-sharing cap.
- 2019 allowed cost for insulin was trended 1.5% per year from 2019 to 2022 based on recent and projected annual increases in net insulin prices.
- Cost-sharing data was adjusted to take into account estimated changes in copay levels between 2019 and 2022 and the effect of enrollees who reach their out-of-pocket limits.
- Utilization was converted to monthly equivalent using standard insurance industry definitions.
- Milliman's 2019 CHSD data was used to estimate utilization, allowed cost, and enrollee cost-sharing offsets for the reduction in diabetes-related ER visits due to increased insulin utilization. The 2019 unit cost for ER visits was trended to 2022 at 7.0% per year based on outpatient facility trend estimates.

Determining Public Demand for the Proposed Mandate

This subsection discusses public demand for the benefits SB 473 would mandate. Considering the criteria specified by CHBRP's authorizing statute, CHBRP reviews public demand for benefits relevant to a proposed mandate in two ways. CHBRP:

- Considers the bargaining history of organized labor; and

[56] CHBRP's authorizing statute, available at http://chbrp.com/CHBRP_authorizing_statute_2018_FINAL.pdf, requires that CHBRP use a certified actuary or "other person with relevant knowledge and expertise" to determine financial impact.
[57] See method documents posted at http://chbrp.com/analysis_methodology/cost_impact_analysis.php; in particular, see *2019 Cost Analyses: Data Sources, Caveats, and Assumptions*.

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

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

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

In 2020, CVS Health, a pharmacy benefit manager, began offering a plan design with zero out-of-pocket costs for diabetes medications and supplies.[58] This indicates there is a demand from employers and other purchasers of pharmacy benefits for plan designs with no or low cost-sharing for insulin prescriptions.

Second Year Impacts on Benefit Coverage, Utilization, and Cost

CHBRP has considered whether continued implementation during the second year of the benefit coverage requirements of SB 473 would have a substantially different impact on utilization of either the tests, treatments, or services for which coverage was directly addressed, the utilization of any indirectly affected utilization, or both. CHBRP reviewed the literature and consulted content experts about the possibility of varied second year impacts and determined the second year's impacts of SB 473 would be substantially the same as the impacts in the first year (see Table 1). Minor changes to utilization and expenditures are due to population changes between the first year postmandate and the second year postmandate.

[58] CVS Health, A prescription for better diabetes management: RxZERO plan design eliminates member out-of-pocket costs. January 2020.

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

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

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

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