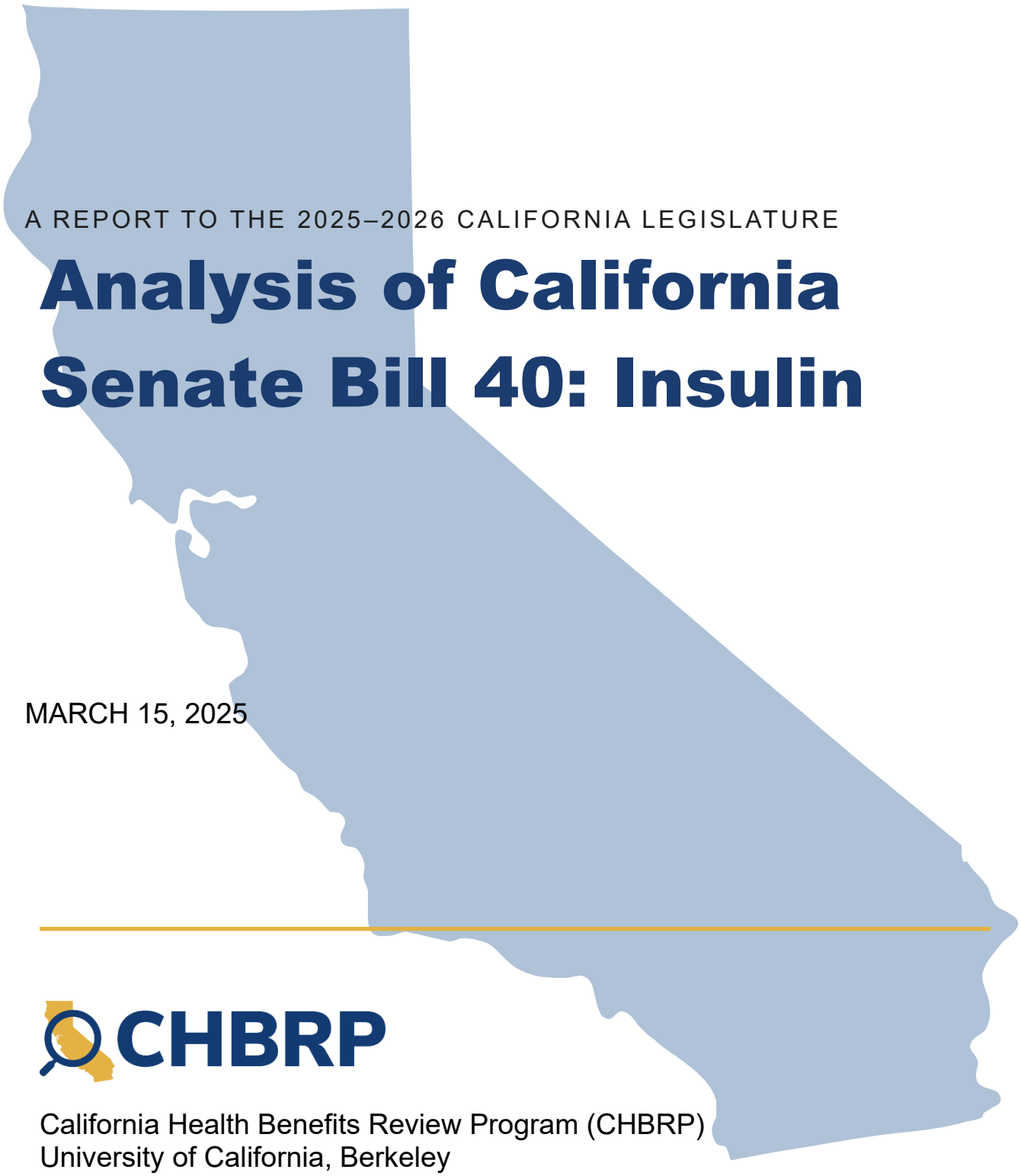
A REPORT TO THE 2025–2026 CALIFORNIA LEGISLATURE

Analysis of California Senate Bill 40: Insulin

MARCH 15, 2025



CHBRP

California Health Benefits Review Program (CHBRP)
University of California, Berkeley

chbrp.org

KEY FINDINGS

Analysis of California Senate Bill 40: Insulin

Summary to the 2025–2026 California State Legislature, March 15, 2025

CHBRP

Summary

The version of California Senate Bill (SB) 40 analyzed by California Health Benefits Review Program (CHBRP) would limit cost sharing for insulin to $35 for a 30-day supply and prohibit step therapy.

In 2026, of the 22.2 million Californians enrolled in state-regulated health insurance, 13.57 million of them would have insurance subject to SB 40.

Benefit Coverage

At baseline there are 92,636 enrollees who use insulin in commercial and California Public Employees' Retirement System (CalPERS) Department of Managed Health Care (DMHC)-regulated plans and California Department of Insurance (CDI)-regulated policies. CHBRP estimates 39,178 enrollees (42%) using insulin have cost sharing that exceeds the SB 40 cap. Postmandate, 100% of enrollees with cost sharing that exceeds the cap at baseline would have cost sharing below the cap. SB 40 would not exceed the definition of essential health benefits (EHBs) in California.

Medical Effectiveness

There is *strong evidence* that cost sharing affects insulin use and adherence in patients with diabetes; higher cost sharing reduces adherence, and lower cost sharing increases adherence. There is *some evidence* that reducing cost sharing is associated with decreased diabetes-related complications, emergency department visits, and hospitalizations.

There is *strong evidence* that step therapy is associated with a lower likelihood of initiating or continuing medications and with poorer adherence to medication, and *expert consensus* that step therapy protocols for insulin would be associated with lowered use and adherence.

Cost and Health Impacts

The 42% of enrollees with cost sharing that exceeds the cap at baseline would experience a 44% reduction in cost sharing, which would result in in a 4% increase in utilization of insulin postmandate for those enrollees. Average cost sharing for these enrollees would decrease from $52 per month to $29 per month.

In 2026, SB 40 would increase total net annual expenditures by $2,147,000 (0.001%) for enrollees with plans regulated by the DMHC and policies regulated by the CDI. This is due to an increase of $10,377,000 in total health insurance premiums paid by employers and enrollees, and a $8,230,000 decrease in enrollee expenses.

Step therapy is generally designed to require an enrollee to try a lower cost option before trying a higher cost option. Removal of step therapy could result in a portion of enrollees using more expensive insulins within the same therapeutic class, which would result in an increase in the average unit cost of insulin.

At the population level, SB 40 is unlikely to have a public health impact due to limited overall impacts. However, for the share of enrollees who would experience significant reductions in cost sharing, and therefore a clinically meaningful increase in utilization of insulin, SB 40 may result in a reduction in health care utilization, and potentially in reduced complications from diabetes over time.

Context

Diabetes mellitus (diabetes) is a chronic disease that prevents the proper production of and/or response to insulin, a hormone that facilitates the transfer of glucose

into cells to provide energy.[1] Three common types of diabetes are type 1 diabetes, type 2 diabetes, and gestational diabetes. Insulin is frequently used to treat all three types of diabetes. As of 2023, about 11.5% of the adult population in California has been diagnosed with diabetes. The incidence of diabetes is highest among adults aged 65 years and older.

The American Diabetes Association recommends different insulin regimens based on the patient's level of insulin deficiency, pattern of glucose levels, and individual patient characteristics. Insulin is necessary for the treatment of type 1 diabetes and is often needed for the treatment of type 2 diabetes and diabetes in pregnancy. Sometimes insulin is needed first line for type 2 diabetes for patients who have symptoms of acute insulin deficiency. However, most patients begin treatment with non-insulin medications for type 2 diabetes. Relatively new medications such as SGLT2 inhibitors and GLP-1 agonists are playing an increasingly important role in the management of type 2 diabetes because of their proven efficacy at improving long-term cardiovascular and renal outcomes compared to other medications (including insulin). As a result, the number of enrollees in California using insulin has decreased over time.

In general, insulin is expensive for individuals living with diabetes; therefore, cost may be a barrier to insulin use for some individuals.

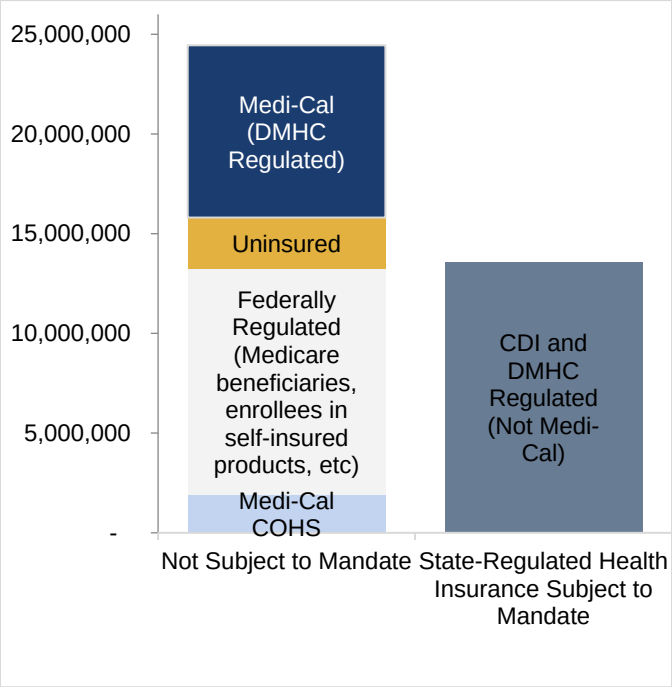
Bill Summary

Senate Bill (SB) 40 would limit cost sharing (copayments, coinsurance, and deductibles) for insulin to $35 for a 30-day supply and prohibit step therapy as a prerequisite to authorizing coverage of insulin. SB 40 states high deductible health plans (HDHPs) as defined under the definition set forth in Section 223(c)(2) of Title 26 of the United States Code would also be prohibited from imposing cost sharing exceeding $35, unless doing so would conflict with federal requirements for high deductible health plans.

For this analysis, CHBRP has assumed that mandates that reference plans and policies that cover prescription drugs are relevant to pharmacy benefit coverage.

Figure A notes how many Californians have health insurance that would be subject to SB 40.

Figure A. Health Insurance in CA and SB 40



Source: California Health Benefits Review Program, 2025.
Key: CDI = California Department of Insurance; COHS = County Organized Health System; DMHC = Department of Managed Health Care.

How does utilization impact premiums?

Health insurance, by design, distributes risk and expenditures across everyone enrolled in a plan or policy. It does so to help protect each enrollee from the full impact of health care costs that arise from that enrollee's use of prevention, diagnosis, and/or treatment of a covered medical condition, disease, or injury. Changes in utilization among any enrollees in a plan or policy can result in changes to premiums for all enrollees in that plan or policy.

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

Impacts

Benefit Coverage

About 61% of enrollees with health insurance subject to state benefit mandates have pharmacy benefits subject to SB 40. Other enrollees with a pharmacy benefit not regulated by DMHC or CDI or without a pharmacy benefit are considered to have compliant coverage at baseline. SB 40 would establish a cost-sharing cap of $35 for a 30-day supply of insulin, which affects just those enrollees who have cost sharing greater than the cap/limit at baseline.

At baseline, no enrollees have health insurance that requires step therapy of a non-insulin treatment before receiving coverage for insulin, but most enrollees have health insurance that includes at least one form of step therapy that requires use of one insulin before granting approval of another insulin of the same therapeutic class.

CHBRP estimates at baseline there are 92,636 enrollees who use insulin in commercial and California Public Employees' Retirement System (CalPERS) DMHC-regulated plans and CDI-regulated policies, where 53,458 enrollees using insulin have cost sharing that does not exceed the SB 40 cost-sharing cap (58%). CHBRP estimates 39,178 enrollees (42%) using insulin have cost sharing that exceeds the SB 40 cap. Postmandate, 100% of enrollees with cost sharing that exceeds the cap at baseline would have cost sharing below the cap.

Utilization

CHBRP estimates that for those enrollees whose claims exceeded the cap at baseline their average monthly cost sharing is $52/month; postmandate, the average monthly cost sharing for this group would go down to $29/month, which reflects a reduction of 44%.

To estimate the change in utilization postmandate for these enrollees for whom cost sharing is reduced, CHBRP applied an assumption of an increase in utilization of insulin of 4% based on literature and content expert input. Additionally, CHBRP assumes a 10% reduction in diabetes-related emergency department visits for this population.

Step therapy is generally designed to require an enrollee to try a lower cost option before trying a higher cost option. Removal of step therapy could result in a portion of enrollees using more expensive insulins within the same therapeutic class, which would result in an increase in the average unit cost of insulin.

Expenditures

In 2026, SB 40 would increase total net annual expenditures by $2,147,000 (0.001%) for enrollees with plans regulated by the California Department of Managed Health Care (DMHC) and policies regulated by the California Department of Insurance (CDI). This is due to an increase in $10,377,000 in total health insurance premiums paid by employers and enrollees, and a $8,230,000 decrease in enrollee expenses.

The changes in premiums as a result of SB 40 would be less than 0.03% for the different types of plans and policies by market segment and ranges from $0.04 per member per month (PMPM) for large-group DMHC-regulated plans and CDI-regulated policies to $0.19 PMPM for small group CDI-regulated policies.

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. Among the enrollees impacted by the cost-sharing cap, enrollees with out-of-pocket expenditures for insulin in the top 1% at baseline would have an annual savings of greater than $1,463. The annual savings for the top 5%, 10%, and 20% of enrollees based on cost-sharing expenditures for insulin would be greater than $446, $217, and $70, respectively.

Medi-Cal

The pharmacy benefit for beneficiaries in DMHC-regulated Medi-Cal managed care plans is administered by the Department of Health Care Services and therefore not impacted by SB 40.

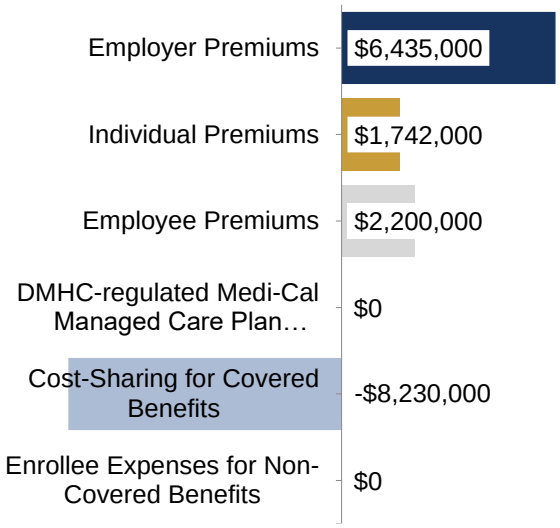
CalPERS

For enrollees associated with CalPERS in DMHC-regulated plans, there is no impact 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 40.

Figure B. Expenditure Impacts of SB 40



Source: California Health Benefits Review Program, 2025.

Medical Effectiveness

There is *strong evidence*[2] from seven observational 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.

There is *some evidence*[3] from four studies on the effect of cost sharing for insulin on diabetes-related health outcomes and utilization. These studies suggest that reduced cost sharing is associated with decreased diabetes-related complications, emergency department visits, and hospitalizations. The effect of cost sharing on additional health outcomes, such as glycemic control, is unknown.

There is *strong evidence* based on CHBRP's previous analysis of Assembly Bill (AB) 2144 that step therapy is associated with a lower likelihood of initiating or continuing medications and with poorer adherence to medication.

There is *expert consensus*,[4] consistent with the finding for prescription medications, that step therapy protocols for insulin are associated with lowered use and adherence. Additionally, there is clinical consensus that insulin is considered essential for effective treatment of diabetes and that delayed introduction of, or ineffective insulin therapy contributes to poor glycemic control and places patients at risk of complications.

There are several limitations that contributed to the gradings provided in this review, most notably the barriers to conducting rigorous randomized controlled trials of differential cost-sharing or utilization management strategies on insulin use, inherent differences between the types of diabetes, and the multifaceted nature of diabetes treatment, resulting in a literature base that is not as rigorous as ideal and thereby limiting the certainty of conclusions drawn from the evidence.

Public Health

In the first year postmandate, 39,178 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 4% increase in utilization of insulin. At the population level, SB 40 is unlikely to have a public health impact due to the relatively limited overall number of enrollees affected. However, for the share of enrollees who would experience significant reductions in cost sharing and therefore a clinically meaningful increase in utilization of insulin, SB 40 may result in a reduction in health care utilization, and potentially in reduced complications from diabetes over time.

Long-Term Impacts

CHBRP estimates annual insulin utilization per user after the initial 12 months from the enactment of SB 40 would likely stay similar to utilization estimates during the first 12 months postmandate. Health care utilization due to

[2] *Strong evidence* indicates that the majority of the studies reviewed are consistent in their findings that treatment is either effective or not effective. Conclusions could be altered with additional strong evidence.
[3] *Some evidence* indicates that a small number of studies have limited generalizability to the population of interest and/or the studies have a serious methodological concern in research design or implementation. Conclusions could be altered with additional evidence.

[4] *Expert consensus* indicates that the CHBRP identified content expert has experience that agrees with at least one published clinical practice guideline from a professional society or government agency, editorial from those in the field, or opinion/consensus statement from a professional society, but no published empiric evidence is available.

improved diabetes management may change in the long term, particularly with the continued increased use of GLP-1 medications. Reductions in significant complications or comorbidities may take years to be realized, but the benefits are potentially very substantial. With regard to the prohibition of step therapy for insulin, it is possible insurers may change their utilization management protocols in response. It is possible that if step therapy is prohibited altogether on all insulin products, insurers may shift toward other utilization management strategies, such as prior authorization or formulary restrictions, to control costs. Prior authorization could require additional documentation or clinical justification before approving certain insulin prescriptions, potentially delaying access. Insurers might also implement tighter formulary controls, limiting the range of covered insulin options or imposing quantity limits.

Essential Health Benefits and the Affordable Care Act

SB 40 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 40 would not exceed the definition of EHBs in California.

About CHBRP

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

The state funds CHBRP through an annual assessment on health plans and insurers in California.

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 chbrp.org.

Suggested citation

California Health Benefits Review Program (CHBRP). (2025). *Analysis of California Senate Bill 40 Insulin.* Berkeley, CA.

Table of Contents

Lists of Tables and Figures

Acronyms and Abbreviations

AB – Assembly Bill
ACA – Affordable Care Act
CA – California
CalPERS – California Public Employees' Retirement System
CDC – Centers for Disease Control and Prevention
CDI – California Department of Insurance
CHBRP – California Health Benefits Review Program
COHS – County Organized Health System
DHCS – Department of Health Care Services
DKA – diabetes ketoacidosis
DMHC – Department of Managed Health Care
ED – emergency department
EHB – essential health benefits
HCGs – health cost guidelines
HDHP – high deductible health plans
HHS – hyperglycemic hyperosmotic syndrome
HMO – health maintenance organization
HSA – Health Savings Account
OAD – oral antidiabetic medication
PBM – pharmacy benefit manager
PMPM – per member per month
SB – Senate Bill

Introduction

The California Senate Committee on Health 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) 40, Insulin.

SB 40 Insulin Bill Language

SB 40 would prohibit state-regulated commercial and CalPERS plans or policies from imposing:

- a copayment exceeding $35 for a 30-day supply of insulin;
- other cost sharing including a deductible and coinsurance; and
- step therapy protocols as a prerequisite to authorizing coverage of insulin.

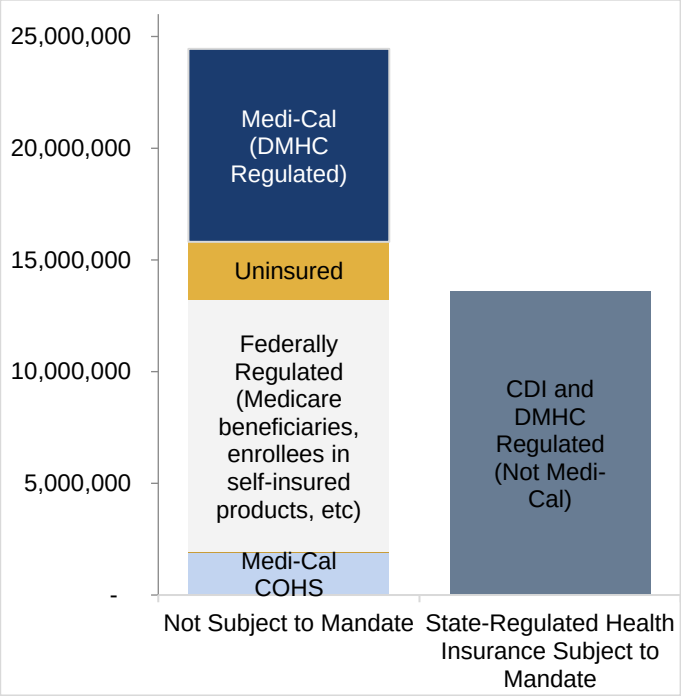
Additionally, SB 40 states the copayment limitation would apply to any insulin prescription product labeled or produced by California (see more information about CalRx in the *Policy Context* section).[6]

SB 40 states high deductible health plans (HDHPs) as defined under the definition set forth in Section 223(c)(2) of Title 26 of the United States Code would also be prohibited from imposing cost sharing exceeding $35, unless doing so would conflict with federal requirements for high deductible health plans (see more about Health Savings Account [HSA]-Qualified HDHPs in the *Policy Context* section).[7]

See the full text of SB 40 in Appendix A.

If enacted, SB 40 would apply to the health insurance of approximately 13,570,000 enrollees (36% of all Californians) (see Figure 1).

Figure 1. Health Insurance in CA and SB 40



Source: California Health Benefits Review Program, 2025.

- **Includes**: enrollees with a pharmacy benefit regulated by the Department of Managed Health Care (DMHC) and the California Department of Insurance (CDI), which includes enrollees in commercial or CalPERS health insurance.
- **Excludes**: Medi-Cal beneficiaries enrolled in DMHC-regulated plans or county organized health system (COHS) plans, whose pharmacy benefit is regulated by the Department of Health Care Services (DHCS).

[5] See CHBRP's authorizing statute.
[6] California launched CalRx Biosimilar Initiative, which aims to partner with a manufacturer to produce short- and long-acting insulin at reduced prices (DMHC, 2022).
[7] HDHPs under Sec 223(c)(2) of Title 26 of the United States Code 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. 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. Insulin is listed a treatment for chronic conditions, and therefore, the requirements of SB 40 would not interfere with an HDHP's qualification for an HSA.

See the following *Analytic Approach and Key Assumptions* section for additional information.

Terminology

SB 40 includes the following definitions:

- Insulin prescription drug – a prescription drug that contains insulin and is used to control blood glucose levels to treat diabetes mellitus.
- Step therapy protocol – a protocol or program that establishes the specific sequence in which prescription drugs for a specified condition, including self-administered drugs and physician-administered drugs, are medically appropriate for a particular enrollee and are covered under a plan or policy.

Relevant cost sharing definitions:

- Copayment – A form of cost sharing in which an enrollee pays a specific amount out-of-pocket at the time of receiving a health care service or when paying for a prescription, after any applicable deductible.
- Coinsurance – The percentage of covered health care costs, after any applicable deductible, for which an enrollee is responsible.
- Deductible – The amount an enrollee is required to pay out-of-pocket before the health plan or policy begins to reimburse providers for medically necessary use of covered benefits.

Appendix C provides an overview of cost sharing and step therapy, which are addressed by SB 40.

What Is Diabetes and When Is Insulin Used?

Diabetes is a chronic disease that prevents the proper production of and/or response to insulin, a hormone that facilitates the transfer of glucose into cells to provide energy (NIDDKD, 2017). Three common types of diabetes are type 1 diabetes, type 2 diabetes, and gestational diabetes. Insulin is frequently used to treat all three types of diabetes. Achieving stable, healthy blood glucose levels is challenging for individuals with diabetes. People with diabetes can experience swings between high blood glucose levels (*hyperglycemia)* and low blood glucose levels (*hypoglycemia).* Changes in stress, sleep, physical activity, diet, weight, illness, non-diabetes medications, and many other factors can contribute to hyper- and hypoglycemia, which can lead to both short- and long-term health effects.

The American Diabetes Association (ADA, 2025b) recommends different insulin regimens based on the patient's level of insulin deficiency, pattern of glucose levels, and individual patient characteristics. Insulin is necessary for the treatment of type 1 diabetes and often needed for the treatment of type 2 diabetes and diabetes in pregnancy. Relatively new medications such as SGLT2 inhibitors and GLP-1 agonists are playing an increasingly important role in the management of type 2 diabetes because of their proven efficacy at improving long-term cardiovascular and renal outcomes compared to other medications such as insulin. In addition, injectable GLP-1 medications are equally or more effective than insulin at improving glycemic levels for many type 2 diabetes patients. And unlike insulin, these medications do not cause hypoglycemia. For this reason, guidelines now recommend injectable GLP-1 agonists before insulin for patients whose glucose levels remain elevated despite oral therapy (which has led to fewer type 2 diabetes patients using insulin than in the past). As a result, the number of enrollees in California using insulin has decreased over time (see the *Benefit Coverage, Cost, and Utilization Impacts* section for more detail).

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Analytic Approach and Key Assumptions

CHBRP previously analyzed similar bills, AB 2203 Insulin Cost Sharing Caps in 2020, AB 97 Insulin Affordability in 2021, SB 473 Insulin Cost Sharing in 2021 and 2022, and SB 90 Insulin Affordability in 2023. Where applicable, this report builds on those analyses.

Prescription Drug Benefit

- Pharmacy benefits cover outpatient prescription drugs by covering prescriptions that are generally filled at a retail pharmacy, a mail-order pharmacy, or a specialty pharmacy. Drugs that are physician-ordered and administered under the supervision of a physician (generally in a hospital, a provider's office, infusion center, or similar medical facility), along with the hospital stay or office visit, are generally covered through a medical benefit. For this analysis, CHBRP has assumed that mandates that reference plans and policies that cover prescription drugs are relevant to pharmacy benefit coverage.

- As of January 1, 2022, outpatient prescription drugs are covered on a fee-for-service basis by DHCS for all Medi-Cal beneficiaries through the Medi-Cal Rx program.[8] Their pharmacy benefit is "carved out" of the coverage provided by Medi-Cal Managed Care plans, and so SB 40 does not impact their benefit coverage. However, insulins delivered in an in-patient setting would likely be billed to the medical benefit and would fall under the purview of SB 40. Therefore, SB 40 would apply to Medi-Cal managed care plans in these instances.[9]

Cost Sharing

- CHBRP assumes that SB 40 would require plans and policies to limit all cost sharing (copayment, coinsurance, and deductibles) to $35 or less for a 30-day supply of insulin. This applies to all insulins covered on-formulary as well as insulins off-formulary, should they be covered due to medical necessity.

- CHBRP assumes that all HSA-qualified HDHPs will elect to cover insulin predeductible according to federal law. More information about this assumption is included in the *Benefit Coverage, Utilization, and Cost Impacts* section.

Step Therapy

SB 40 would prohibit step therapy, including:

- step therapy requirements that would require an enrollee to use a non-insulin test, treatment, or service before receiving coverage for insulin.

- step therapy that requires use of one type of insulin before using another insulin of the same therapeutic class.[10]

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[8] For more on outpatient prescription drug coverage among Californians with state-regulated health insurance, see CHBRP's resource, *Pharmacy Benefit Coverage in State-Regulated Health Insurance*.
[9] Personal communication with DHCS, March 7, 2025.
[10] This interpretation is supported by the California Department of Insurance, which has stated this would also apply to insulins not listed on an insurer's formulary. Personal communication with CDI, February 19, 2025. The Department of Managed Health Care also interprets SB 40 to encompass this type of step therapy; personal communication with DMHC, March 7, 2025.

Policy Context

Health benefit mandates may interact and align with the following state and federal mandates, programs, and policies.

California Law and Regulations

Pharmacy benefits regulated by Department of Managed Health Care (DMHC) or California Department of Insurance (CDI) are required to provide coverage for insulin.[11]

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.[12] This provision is not specific to enrollees with a DMHC- or CDI-regulated pharmacy benefit.

Existing California law limits cost sharing for prescription drugs to up to $250 for a 30-day supply.[13] Separate pharmacy deductibles are limited to $500 for nongrandfathered individual and small-group plans and policies.

CalRx

The CalRx initiative aims to address insulin affordability by offering less expensive alternatives to existing products (Feldman, 2023). 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 Newsom Administration announced in March 2023 that Civica Rx, a nonprofit generic drug and pharmaceutical company, will develop and manufacture three types of insulin (CalRx, 2023). Civica has announced that the suggested retail price for a 10-mL vial of insulin will be no more than $30 and a 5-pack of 3-mL pens will be no more than $55, including the cost of distribution and pharmacy dispensing.[14] Once approved by the Food and Drug Administration, the intent is for these biosimilar insulins to be available through pharmacies for all Californians, regardless of insurance status. It is unclear what the timeline is for CalRx to begin manufacturing insulin (Kwang K, 2025).

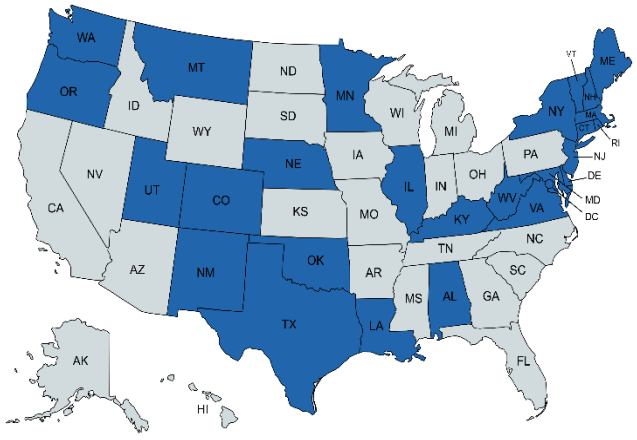
Previous California Legislation

Previous California legislation that would have limited cost sharing for insulin includes AB 2203 Insulin Cost-Sharing Cap in 2020, AB 97 Insulin Affordability in 2021, SB 473 Insulin Cost Sharing in 2021, and SB 90 Insulin Affordability in 2023. SB 90 was vetoed by Governor Newsom, and the other bills failed to pass out of the second chamber.

Similar Legislation in Other States

At least 26 states and Washington, DC, have passed laws that limit cost sharing (copayment, coinsurance, and deductibles)

Figure 2. Map of States With Laws Limiting Cost Sharing for Insulin, 2025



Source: California Health Benefits Review Program, 2025. Adapted from ADA, 2025.
Note: Blue color indicates a state law is in place.

[11] H&SC 1367.51; IC 10176.61.
[12] H&SC 1367.51; IC 10176.61.
[13] H&SC 1342.73; IC 10123.1932.
[14] More information about CalRx is available on their website.

for insulin, as of February 2025 (ADA, 2025a) (in blue, Figure 2).[15] Limits of cost sharing range between $100 per prescription to $25 per prescription.

Federal Policy Landscape

Due to the Inflation Reduction Act of 2022, all Medicare drug prescription plans (Medicare Part D) are required to comply with cost-sharing limits of $35 per 30-day insulin prescription (Medicare.gov, 2023). Additionally, this $35 cost-sharing limit also applies to insulin used in traditional insulin pumps, which are covered by Medicare Part B. Cost-sharing limits include coinsurance and copayments and prohibits insulin from being subject to the deductible.

High deductible health plans and health savings account-qualified HDHPs

High deductible health plans (HDHPs) are a type of health plan with requirements set by federal regulation.[16,17] As the name implies, these plans include a deductible – but they are not allowed to have separate medical and pharmacy deductibles. For the 2025 plan year, the Internal Revenue Service (IRS) defines an HDHP as any plan with a deductible of at least $1,650 for an individual and $3,300 for a family.[18] Annual out-of-pocket expenses for coverage of in-network tests, treatments, and services, which would result from cost sharing[19] applicable after the deductible is met, are not allowed to be more than $8,300 for an individual and $16,600 for a family.[20]

To be eligible to establish a HSA for taxable years beginning after December 31, 2003[21] (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 an 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.[22] 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.[23] Insulin is listed as a treatment for a chronic condition, and therefore, the requirements of SB 40 would not interfere with an HDHP's qualification for an HSA.

According to a 2021 survey of large employers, 76% of employers had added predeductible coverage according to the recently updated federal rules (Fronstin and Fendrick, 2021). Predeductible coverage was often added for health care services related to heart disease and diabetes. Two-thirds of employers added predeductible coverage for insulin or glucose-lowering agents.

[15] The Governor of Massachusetts signed S.3012 into law in January 2025.
[16] For enrollment estimates, see CHBRP's resource *Deductibles in State-Regulated Health Insurance*.
[17] HealthCare.gov, Glossary: High Deductible Health Plan (HDHP). Accessed March 5, 2021.
[18] IRS Revenue Procedure 2024-25.4.
[19] Such as copayments and coinsurance applicable to the covered test, treatment, or service.
[20] There is no annual out-of-pocket expenses limit for coverage of out-of-network tests, treatments, and services.
[21] 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.
[22] For more information on screening services, see Notice 2004-23, 2004-15 I.R.B. 725.
For additional guidance on preventive care, see Notice 2004-50, 2004-2 C.B. 196, Q&A 26 and 27; and Notice 2013-57, 2013-40 I.R.B. 293.
[23] For information on preventive care for chronic conditions, see Notice 2019-45, 2019-32 I.R.B. 593.

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 40 may interact with requirements of the ACA as presently exist in federal law, including the requirement for certain health insurance to cover essential health benefits (EHBs).[24,25]

For the 2025 plan year for nongrandfathered plans, the annual out-of-pocket maximums for an individual are $9,200 and $18,400 for a family.[26] 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.

Essential Health Benefits

In California, nongrandfathered[27] individual and small-group health insurance is generally required to cover essential health benefits (EHBs).[28] In 2026, approximately 11% of all Californians will be enrolled in a plan or policy that must cover EHBs.[29]

SB 40 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 40 does not exceed the definition of EHBs in California.

Other National Activity

Between 2007 and 2018, the average list price of brand-name insulin nearly tripled, increasing by 262% (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 increase in prices began to level out around 2016. In March 2023, several manufacturers of insulin announced changes to pricing of insulin products in the United States (Herper and Silverman, 2023; Lovelace, 2023; Luhby, 2023). Eli Lilly, the largest manufacturer of insulin, Novo Nordisk, and Sanofi have announced several changes to insulin prices and out-of-pocket costs. Eli Lilly and Sanofi will cap out-of-pocket costs of insulin to $35 for people who have health insurance, and all three companies will lower the list price of multiple insulin products. Since then, multiple health insurance companies have also implemented programs that either enable employers to elect lower cost sharing or predeductible coverage of insulin medications or have implemented lower cost sharing for all enrollees.[30]

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[24] The ACA requires nongrandfathered small-group and individual market health insurance – including, but not limited to, qualified health plans 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.
[25] 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.
[26] HealthCare.gov. Out-of-pocket maximum/limit. Accessed on February 5, 2025.
[27] A grandfathered health plan is "a group health plan that was created – or an individual health insurance policy that was purchased – on or before March 23, 2010. Plans or policies may lose their 'grandfathered' status if they make certain significant changes that reduce benefits or increase costs to consumers."
[28] For more detail, see CHBRP's issue brief, *Essential Health Benefits: An Overview of Benefits, Benchmark Plan Options, and EHBs in California*.
[29] See CHBRP's resource, *Sources of Health Insurance in California*.
[30] For example, Cigna's Patient Assurance Program limits cost sharing to $25 for select insulin products, and UnitedHealthcare includes access for certain preferred prescription drugs, including insulin, with no out-of-pocket costs for standard fully insured group plans.

Background on Diabetes and the Use of Insulin for Diabetes Management

This section provides background information about diabetes mellitus (diabetes), describes the demographics and prevalence of diabetes, and discusses the subject of Senate Bill (SB) 40, the use of insulin for diabetes management.

What Is Diabetes?

Diabetes is a chronic disease that prevents the proper production of and/or response to insulin, a hormone that facilitates the transfer of glucose into cells to provide energy (NIDDKD, 2017). There are three common types of diabetes, and insulin is frequently used to treat all three types:

- **Type 1 diabetes** is an autoimmune condition that attacks and destroys the insulin-producing cells in the pancreas. Treatment requires lifetime use of daily insulin injections and/or an insulin pump to replace the patient's inability to produce insulin.
- **Type 2 diabetes** is a condition that prevents the body from properly responding to insulin (known as insulin resistance). In many situations, people with type 2 diabetes also have impaired insulin production. Treatments for type 2 diabetes include lifestyle modifications, oral medications, non–insulin-injected medications, and/or insulin.
- **Gestational diabetes** is the diagnosis of diabetes during the second or third trimester of pregnancy. People who develop gestational diabetes mellitus remain at higher risk for diabetes throughout their life. Treatments of gestational diabetes include lifestyle modification, oral medication, and/or insulin.

Achieving stable, healthy blood glucose levels is challenging for individuals with diabetes. People with diabetes can experience swings between high blood glucose levels (*hyperglycemia)* and low blood glucose levels (*hypoglycemia).* Changes in stress, sleep, physical activity, diet, weight, illness, non-diabetes medications, and many other factors can contribute to hyper- and hypoglycemia with can lead to both short- and long-term health effects.

Short-Term Health Effects

In the short term, hyperglycemia can cause thirst, increase urination, nausea, vomiting, dehydration, headache, fatigue, confusion, poor wound healing, and hyperglycemic crisis (including diabetes ketoacidosis [DKA] and hyperglycemic hyperosmotic syndrome [HHS]), which can lead to coma or death (Burgess et al., 2021; Umpierrez et al., 2024). Hyperglycemia also leads to increased risk of infections (such as COVID-19) and increased risk of severe illness from infections (ADA, 2021; CDC, 2021; Holt et al., 2024).

Hypoglycemia can cause anxiety, speech problems, palpitations, headaches, blurry vision, dizziness, fatigue, tremors, confusion, cognitive dysfunction, falls, accidents, seizures, coma, and death (Lee et al., 2020; Nakhleh and Shehedah, 2021; Saunders et al., 2023). Some patients (between 20% and 40% of type 1 diabetes patients and 10% of type 2 diabetes patients) have *hypoglycemia unawareness*, a condition in which individuals are unable to sense low blood sugar, which puts them at high risk for severe hypoglycemic events requiring hospitalization (Martín-Timón and Cañizo-Gómez, 2015).

For pregnant people, diabetes may lead to health effects during pregnancy including pregnancy loss, birth defects, stillbirths, preterm birth, abnormal fetal growth, preeclampsia, and possible early and/or more invasive delivery methods including cesarean sections. Infants of people with diabetes can suffer complications during and directly after birth, including hypoglycemia, respiratory distress, and hyperbilirubinemia (jaundice) (ADA, 2025b).

Long-Term Effects

The frequency and severity of hyper- and hypoglycemia over time are associated with serious morbidity and mortality outcomes due to the effects of diabetes on the blood vessels and nerves throughout the body (ADA, 2025b). Complications of diabetes affect nearly all major organs of the body. Damage to the vessels of the eyes leads to deterioration of vision and blindness. Damage to the blood vessels of the kidney lead to proteinuria, loss of renal function, kidney failure, and need for dialysis. Damage to the nerves and vessels in the arms and legs leads to severe pain, numbness, muscle atrophy, claudication, and ulcer formation, which can lead to severe infections and amputations. Damage to the vessels of the heart and brain lead to high blood pressure, ischemic heart disease, heart attacks, heart failure, and strokes. The effect of diabetes also leads to periodontal disease, bone diseases such as osteoporosis and fractures, cognitive impairment and dementia, disabilities, mental health disorders, gastrointestinal disorders, urinary and sexual dysfunction, sleep disorders, liver disease and liver failure, cancer risk, pancreatitis, and increase rates of and risks from infections.

In the United States, diabetes has a major effect on the health of the public. It 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, 2017). Although people with diabetes may not avoid all associated complications, managing blood glucose levels over time helps prevent, delay, or ameliorate its morbidity, mortality, and comorbidities.

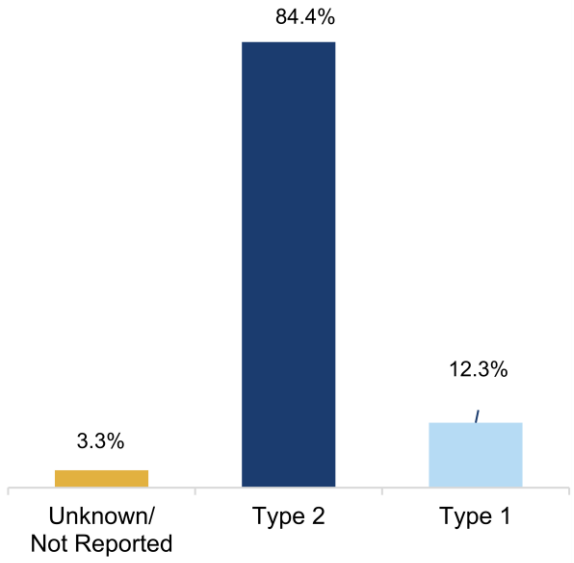
Diabetes Prevalence in California

Diabetes is one of the most common chronic conditions in California and the United States. According to the 2023 Behavioral Risk Factor Surveillance System, 11.5% of the adult population in California has been diagnosed with any type of diabetes (America's Health Rankings, 2024). Approximately 2.9% of adults in California aged 18 to 44 years, 16.4% of adults aged 45 to 64 years, and 23.5% of adults aged over 65 years have diabetes (America's Health Rankings, 2024).

The following are the most recent prevalence estimates for the privately insured subset of the population[31] by type of diabetes for adults, pregnant people, and youth:

- *Adults*: Of the estimated 6.5% (968,000) privately insured adult (aged 18–64 years) enrollees with diabetes, about 12.3% have type 1 diabetes and about 84.2% have type 2 diabetes (Figure 3) (CHIS, 2022b).
- *Pregnant people*: Between 5% and 9% of pregnancies are affected by gestational diabetes (CDC, 2024b). According to the CDC, approximately 50% of women with gestational diabetes develop type 2 diabetes (CDC, 2025).
- *Youth*: CHIS does not report diabetes in those under age 18 years after 2007; however, national data published by the CDC estimates that in 2019, 0.35% of youth under age 20 years are diagnosed with type 1 diabetes (~86%) and type 2 diabetes (~14%) (CDC, 2024a).

Figure 3. Prevalence of Type 1 and Type 2 Diabetes Among Privately Insured Californians Aged 18-64 Years Diagnosed With Diabetes, 2022



Source: California Health Benefits Review Program, 2025. Based on 2022 data from the California Health Interview Survey (CHIS). Note: CHIS reports "Unknown or Not Reported" 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.

[31] As discussed in the Policy Context section, Medi-Cal managed care plans are not subject to SB 40.

Disparities[32] in Diabetes Prevalence

Disparities are noticeable and preventable or modifiable differences between groups of people. Health insurance benefit mandates or related legislation may impact disparities.

CHBRP found literature identifying disparities by race/ethnicity, age, level of education and income in diabetes prevalence. The prevalence of diabetes is similar between men and women. More information about disparities in prevalence of DM is included in Appendix D.

- **Race or Ethnicity:** In California and nationally, prevalence of diabetes is highest among American Indians/Alaska Natives, people of Hispanic origin, Black people, and Asian/Pacific Islanders, as compared with White people (CDC, 2025; CHIS, 2022a).
- **Age:** Prevalence of diabetes increases with age, with adults over age 65 years experiencing the highest rates of type 2 diabetes (CDC, 2025; CHIS, 2022a).
- **Income:** Prevalence of diabetes is higher among persons with lower incomes, and multiple studies have found an increased risk of persons with lower socioeconomic status developing type 2 diabetes (Agardh et al., 2011; America's Health Rankings, 2024; Beckles and Chou, 2016; Liu et al., 2023).
- **Education:** The prevalence of diabetes is more than twice as high for Californians without a high-school diploma as compared with adults aged over 25 years with a college degree (28.7% vs. 9.3%) (America's Health Rankings, 2024).

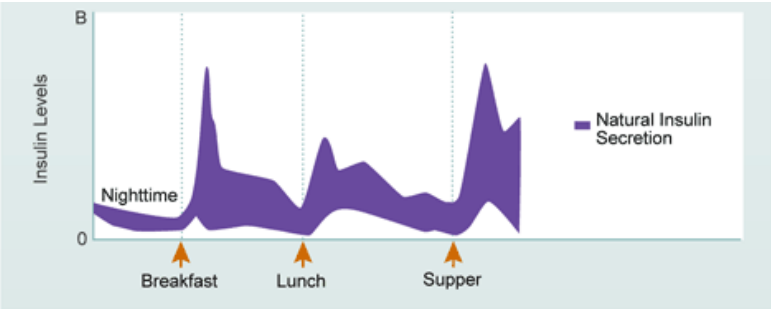
Diabetes Management Using Insulin

As described earlier in this section, the hallmark difference between type 1 diabetes and type 2 diabetes is the body's ability to create or utilize insulin to regulate blood sugar levels. This section summarizes the types of insulin products available and mechanisms of delivery, as well as clinical practice recommendations for diabetes management.

Insulin Secretion

Insulin supplementation in people with diabetes serves to mimic the normal insulin levels and fluctuations seen in people without diabetes (UCSF, 2025). Normal insulin levels are maintained in a low and steady range overnight and between meals, with spikes occurring at mealtimes, which help the body with absorption of sugars. The body maintains a constant release of insulin and responds to food intake automatically as can be seen in Figure 4 (UCSF, 2025).

Figure 4. Normal (Non-Diabetic) Insulin Fluctuations Throughout the Day



Source: UCSF Diabetes Teaching Center. Insulin Basics - Type 2 Diabetes. 2025. Available at: https://diabetesteachingcenter.ucsf.edu/about-diabetes/type-2-diabetes/insulin-basics-type-2-diabetes. Accessed February 4, 2025.

Types of insulin and Delivery Mechanisms

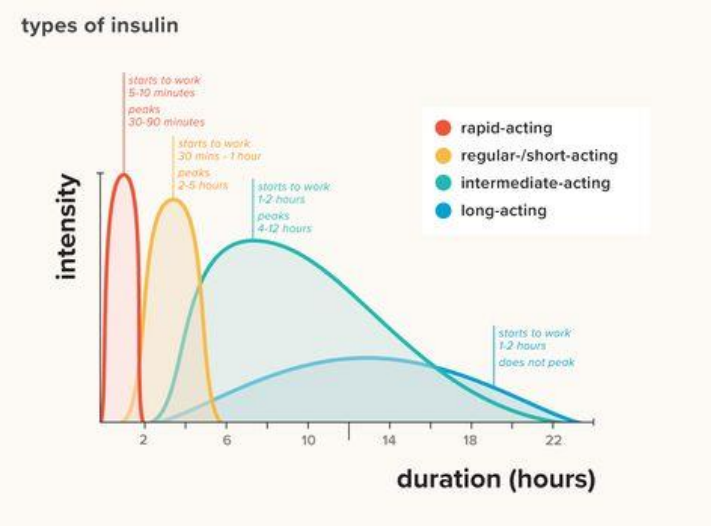
Insulin is used as a medication for people with diabetes to help lower blood glucose levels. There are multiple types of insulin medication. They are classified by the rate at which they act in the body. The differences between types of insulin include onset, peak, duration, concentration, and delivery method. Figure 5 and Table 1 summarize types of insulin products. Short- or rapid-acting insulin is used to control blood glucose levels related to meals (called bolus or prandial

[32] 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).

insulin), as it is absorbed quickly from the bloodstream. Intermediate- or long-acting insulin is used to control blood glucose levels during sleep and between meals (called basal insulin) as it absorbed at a slower, more stable rate (Shah et al., 2016). Mixed insulin is used for those who need to limit the number of injections they take per day as it includes a combination of both long-acting and short-acting characteristics (ADA, 2025b). Insulin falls into two categories. Human insulin is an older insulin that closely mimics the insulin that is made in the human body. Analog insulins are newer insulins that are genetically altered from human insulin to have better patterns of absorption and cause less risk of hypoglycemia.

There are various delivery methods of insulin, such as subcutaneous injections with a vial and syringe, injection with prefilled pen, or continuous infusion with an insulin pump. Insulin pumps best mimic the function of the pancreas by delivering small steady doses of insulin (HHN, 2018). A non-injection insulin product available since 2015 is an inhaled insulin (ADA, 2025b). This delivery method is used as a rapid-acting insulin before meals (ADA, 2025b). 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, 2025b; Shah et al., 2016). Developments to oral routes of administration are currently under investigation, as are buccal, peritoneal, and transdermal (Shah et al., 2016).

Figure 5. Types of Insulin Products



Source: Healthline. "Insulin Chart: What You Need to Know About Insulin Types and Timing". Heather Grey. Page last reviewed: May 10, 2022. Available at: https://www.healthline.com/health/type-2-diabetes/insulin-chart Accessed February 5, 2025.

Table 1. Types of Insulin Products

Type of Insulin	Category	Delivery	Onset	Peak Time	Duration
Rapid-acting insulin	Analog	Vial, pen, cartridge, or inhaler	15-30 minutes	1-2 hours	2-4 hours
Regular or short-acting insulin	Human	Vial or pen	30 minutes	2-3 hours	3-6 hours
Intermediate-acting	Human	Vial or pen	2-4 hours	4-12 hours	12-18 hours
Long-acting	Analog	Vial, pen, or cartridge	2 hours	Does not peak	Up to 24 hours
Ultra long-acting	Analog	Vial or pen	6 hours	Does not peak	36+ hours
Premixed insulin products	Human or Analog	Vial or pen	5-60 minutes	Varies	10 to 16 hours

Source: California Health Benefits Review Program, 2025, based on CDC, 2024c; Donner and Sarkar, 2023.

Clinical Practice Guidelines for Insulin Use in Diabetes

The American Diabetes Association (ADA, 2025b) recommends different insulin regimens based on the patient's level of insulin deficiency, patters of glucose levels, and individual patient characteristics. Insulin is necessary for the treatment of type 1 diabetes and is often needed for the treatment of type 2 diabetes and diabetes in pregnancy.

Patients with type 1 diabetes use insulin in two patterns, basal (background) insulin and bolus (prandial or mealtime) insulin. This is achieved by using four or more injections of insulin per day (a long-acting insulin analog once or twice a day and a rapid-acting insulin analog with meals) or by using an insulin pump (a rapid-acting insulin delivering a continuous infusion to provide both basal and bolus insulin). Insulin doses are self-adjusted by an individual based on glucose levels, diet, exercise, and multiple other factors, or automatically adjusted using an automated insulin delivery system.

Patients with type 2 diabetes receive treatment with a wide variety of medications, and insulin is often required as one of the treatment components (ADA, 2025b). The initial pharmacologic agent for the treatment of hyperglycemia in type 2 diabetes depends on patient-specific factors (e.g., level of hyperglycemia, evidence of insulin deficiency, risk of side effects, presence of comorbidities such cardiovascular disease, heart failure, chronic kidney disease, obesity, and liver disease, etc.). Sometimes insulin is needed first line for type 2 diabetes for patients who have symptoms of acute insulin deficiency. However, most patients begin treatment with non-insulin medications for type 2 diabetes. In particular, the relatively new medications such as SGLT2 inhibitors and GLP-1 agonists are playing an increasingly important role in the management of type 2 diabetes because of their proven efficacy at improving long-term cardiovascular and renal outcomes compared to other medications (including insulin). Furthermore, injectable GLP-1 agonist medications are equally or more effective than insulin at improving glycemic levels for patients with type 2 diabetes. And unlike insulin, these medications do not cause hypoglycemia. For this reason, guidelines now recommend injectable GLP-1 agonists before insulin for patients whose glucose levels remain elevated despite oral therapy. This has led to fewer patients with type 2 diabetes using insulin than in the past. Insulin therapy is generally used when glucose levels are elevated despite optimization of the non-insulin medications. Once insulin does need to be added to type 2 diabetes, typically a long-acting analog insulin is added to the non-insulin medication regimen as a daily injection. A rapid-acting insulin may also need to be added at mealtimes. Insulin doses for type 2 diabetes are often self-adjusted based on glucose levels, diet, exercise, and other factors, just as they are for type 1 diabetes.

Treatment of diabetes in pregnancy may require insulin therapy depending on glucose levels and patient-specific factors (ADA, 2025b). Glucose targets are substantially lower in people who are pregnant than those we are not, and pharmacologic treatment is initiated if glucose levels are above those targets. Since few medications other than insulin are considered safe in pregnancy, insulin is often the primary treatment for hyperglycemia. Similar as for type 1 diabetes, both basal and bolus insulin are often required, necessitating multiple injections per day or the use of an insulin pump. Insulin doses are self-adjusted based on glucose levels, diet, exercise, and other factors.

Cost-Related Barriers of Insulin Use

In general, insulin is expensive for individuals living with diabetes (Bakkila et al., 2022; Borden et al., 2025). 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 impacts insulin use and adherence.

Additional cost barriers related to insulin include the cost of blood glucose monitors, testing strips and lancets, and/or continuous glucose monitors. These devices are necessary in order to effectively use and adjust insulin. In addition, many patients with type 1 diabetes use automated insulin delivery systems, which are systems that automatically adjust insulin pump infusion rates based on real-time blood glucose levels. These additional prescriptions and supplies may contribute to or exacerbate an enrollee's difficulty in paying for their diabetes care. It was reported that for patients with lower incomes, nearly two-thirds experienced challenges with affording diabetes equipment (Herkert et al., 2019).

Differences in the Use and Adherence of Insulin

The prevalence of insulin use among individuals with type 1 diabetes is 100%. Approximately one-third (34.1%) of patients with diabetes used insulin in 2022 and among adults aged 20 and older, 12.39% started using insulin within a year of their diagnosis of diabetes (CDC, 2025). Insulin adherence refers to whether a patient is using insulin as per an agreed upon shared decision plan with their provider.

- **Race/Ethnicity:** Evidence is mixed regarding significant racial or ethnic differences in utilization of diabetes medication, including insulin (Brod et al., 2012; Golden et al., 2012). However, Kang et al. (2018) report significant racial/ethnic disparities for cost-related medication[33] nonadherence for non-Hispanic Black people compared to non-Hispanic White people.

- **Gender:** 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 eating disorders (Peyrot et al., 2010).

- **Age:** Davies et al. (2013) noted that for studies within the review (one study of patients with type 1 diabetes, two studies of patients with type 2 diabetes, one study of both type 1 and type 2 diabetes, and one with type of diabetes not reported), older age was a predictor for nonadherence to insulin therapy; however, two other studies indicated older patients were more adherent, whereas one showed that younger patients were more adherent. Peyrot et al. (2010) found no association between age and intentional insulin omission among patients with type 1 diabetes, and it was proposed that perhaps patients "aged out" of the behavior as they get older. Conversely, when including cost as a factor, a person of younger age (<55 years) was at significantly greater risk for cost-related medication nonadherence for diabetes when compared to older adults aged 75 years and over (Kang et al., 2018).

- **Income:** Peyrot and colleagues (2010) also found that respondents with higher household income were less likely to skip insulin injections as prescribed. In addition, individuals with higher socioeconomic status have lower cost-related medication nonadherence for diabetes (Herkert et al., 2019; Kang et al., 2018). The rate of cost-related medication nonadherence decreased as the 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).

Societal Impact of Diabetes in California

The presence of diabetes in California has direct and indirect economic and societal costs. In dollar terms, the societal impact can be indirect (e.g., lost wages) as well as direct (e.g., medical care). According to the American Diabetes Association, total direct medical expenses in California were estimated to be $27 billion in 2017 for diagnosed diabetes ($34.76 billion in 2025 dollars) (ADA, 2023). An additional $12.5 billion was spent on indirect costs due to lost productivity ($16.09 billion in 2025 dollars). Indirect costs have also been reported as high as $32.6 billion (in 2013) when including morbidity and premature mortality costs ($44.17 billion in 2025 dollars) (Shrestha et al., 2018). Please note, the societal impact discussed here is relevant to a broader population than SB 40 impacts, which would affect the health insurance of a subset of Californians (see the *Introduction* section). See the *Benefit Coverage, Utilization, and Cost Impacts* section for estimates of direct cost impacts for the specific population targeted by SB 40.

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[33] Medications included insulin. Kang et al. (2018) did not report differences in adherence by type of medication.

Medical Effectiveness

As discussed in the *Introduction* section, SB 40 would limit cost sharing (copayment, coinsurance, or deductible) for insulin to $35 for a 30-day supply and prohibit step therapy. Additional information on the management of diabetes mellitus and insulin cost sharing is included in the *Background* section. The medical effectiveness review summarizes findings from evidence[34] on the effects of cost sharing and step therapy for insulin on use and adherence for patients with diabetes (type 1 diabetes, type 2 diabetes, and gestational diabetes) and how insulin treatment adherence related to cost affects the management of diabetes.

Research Approach and Methods

The search for cost sharing was limited to studies published from 2022 to the present because CHBRP had previously conducted thorough literature searches on these topics in 2023 for SB 90.[35] The search for step therapy for insulin included studies published from 2015 to the present.

A total of two new studies were included in the medical effectiveness review for this report as well as seven studies that were included in the previous reviews for SB 90. The other articles were eliminated because they did not focus on cost-related insulin adherence, were from outside the United States, or were narrative and 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 CHBRP's Medical Effectiveness Analysis and Research Approach document.

The conclusions below are based on the best available evidence from peer-reviewed and grey literature.[36] 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 type 1, type 2, or gestational diabetes?
2. What are the associated effects of cost sharing for insulin on health outcomes and utilization?
3. What are the effects of step therapy on insulin use/adherence for patients with type 1, type 2, or gestational diabetes?

Methodological Considerations

The primary focus of this review and analysis is on insulin use and adherence related to cost sharing and step therapy. Thus, it does not review adherence for overall diabetes management, for which there are multiple components. Additionally, this bill would apply to patients with a diabetes diagnosis, of which there are three common types: type 1 diabetes, type 2 diabetes, or gestational diabetes. 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 or utilization management strategies on insulin use (i.e., ethical considerations, medical necessity of insulin for treatment of type 1 diabetes, and multifaceted treatment regimens required to effectively treat diabetes), resulting in a literature base that is not as rigorous as ideal and thereby limiting the certainty of conclusions

34 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 in the Medical Effectiveness Analysis and Research Approach document, 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.
35 Studies of the effects of cost sharing and step therapy on insulin use and adherence for patients with diabetes were identified through searches of PubMed and Embase. Websites maintained by the following organization was also searched: American Diabetes Association. The search was limited to abstracts of studies published in English and within the United States.
36 Grey literature consists of material that is not published commercially or indexed systematically in bibliographic databases. See CHBRP's website for more information.

drawn from the evidence. Although the importance of real-world evidence should not be underestimated, RCTs remain the gold standard for evaluating effectiveness.

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 Diabetes Association (ADA) treatment guidelines as referenced in the "Clinical Practice Guidelines for Diabetes Mellitus" section in the *Background* section. Based on these guidelines, this analysis assumes that insulin is effective for diabetes management.

Outcomes Assessed

The primary outcome of interest for the effect of cost sharing and step therapy 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), health care utilization (e.g., emergency department visits, hospitalizations), productivity (disability, absenteeism), and diabetes-related complications or comorbidities (e.g., amputations, ulcers, blindness, heart attack, stroke).

Study Findings

This following section summarizes CHBRP's findings regarding the strength of evidence for the effects of cost sharing and step therapy 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 are included in the box below.

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

Very strong evidence indicates that there are multiple studies of a treatment and the large majority of studies are of high quality and consistently find that the treatment is either effective or not effective. Conclusions are unlikely to be altered by additional evidence.

Strong evidence indicates that the majority of the studies reviewed are consistent in their findings that treatment is either effective or not effective. Conclusions could be altered with additional strong evidence.

Some evidence indicates that a small number of studies have limited generalizability to the population of interest and/or the studies have a serious methodological concern in research design or implementation. Conclusions could be altered with additional evidence.

Conflicting evidence indicates that a similar number of studies of equal quality suggest the treatment is effective as suggest the treatment is not effective.

Not enough research indicates that there are no studies of the treatment or the available studies are not of high quality, meaning there is not enough evidence available to know whether or not a treatment is effective. It does not indicate that a treatment is not effective.

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

As discussed in the *Policy Context* section, 26 states plus Washington, DC have passed laws that limit cost sharing for insulin. In recent years, some evaluations of the impact of these state insulin cost-sharing limits have been published. Colorado was one of the first states to cap out-of-pocket costs for insulin and, as such, is the most extensively evaluated to date. CHBRP identified one new study as well as seven previously identified studies that examined the effects of cost

sharing on insulin use for diabetes treatment (summarized below). For a full description of the studies previously identified by CHBRP, see CHBRP's analysis of SB 90 (2023). Other recent evaluations of insulin cost-sharing caps were excluded from this analysis due to lack of relevant comparison groups, small sample sizes, or confounding variables that limit CHBRP's ability to draw conclusions from the results.

A cohort study examined adherence to insulin in individuals with type 1 diabetes after the implementation of a state-level insulin cost-sharing cap (Giannouchos et al., 2024). The cohort included 1,629 individuals with a diagnosis of type 1 diabetes enrolled in state-regulated health insurance plans subject to Colorado's $100 copayment cap legislation. Adherence was measured using the proportion of days covered between prescriptions filled and was measured separately for basal and bolus insulins. **The study found that the cost-sharing cap was associated with increases in adherence to insulin therapy (both basal and bolus insulin).** Subgroup analyses were conducted based on pre-policy spending and compared individuals who never paid more than $100 out-of-pocket (low-spending group) to those who had paid $100 or more at least once (high-spending group). The high-spending group included about 25% of the study population. **This analysis indicated that the overall observed increase in insulin adherence was entirely attributed to insulin users in the high-spending group.** Changes in adherence for both types of insulin were not found to be significant in the low-spending group. These results suggest that state insulin cap policies may improve adherence to insulin for those individuals spending more than the cost-sharing cap pre-policy implementation.

A systematic review by Davies et al. (2013) identified studies reporting factors associated with adherence to insulin therapy in adults with type 1 or type 2 diabetes. Seventeen studies were identified, and two of these studies examined the effects of financial burden on adherence. These studies by Nair et al. (2009) and Chang et al. (2010) showed that reducing or eliminating copayments using a value-based insurance design resulted in increased insulin adherence in patients with type 1 and type 2 diabetes as well as increased insulin initiation rates for type 2 diabetes patients. It is important to note that these value-based insurance designs involved placing all diabetic drugs and testing supplies on the lowest copay tier.

A 2016 systematic review by Capoccia et al. synthesized the evidence on general medication adherence with prescribed glucose-lowering agents (including insulin and oral antidiabetic agents). 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. One was another study examining the effects of value-based insurance by Nair et al. (2010) for individuals with type 1 and type 2 diabetes in a different employer group. Differences in mean insulin adherence rates were again found to be significant. The second study by Gibson et al. (2010) assessed the relationship between cost sharing and adherence to medications in patients with type 2 diabetes. This study combined insulin and oral antidiabetic medications (OADs) in their examination of adherence rates to prescribed regimens and did not analyze results by insulin alone. They reported that doubling patient cost sharing (an increase from $10 to $20 in the cost-sharing index) resulted in a reduction in adherence.

A retrospective paired sample study of patients with type 2 diabetes sought to measure the impact of differences in out-of-pocket costs for type 2 diabetes patients on adherence to a prescribed combination drug therapy regimen (Nelson et al., 2021). The analysis included longitudinal pharmacy data from the Medical Expenditure Panel Survey on 1,189 patients with type 2 diabetes. There was a significant negative correlation observed between the differences in out-of-pocket costs from the most to least costly medication in the regimen and adherence. This indicated that the greater the cost difference between the most and least costly of two prescribed medications, the more likely patients were only adherent to the less costly medication. A reduction in adherence to the more costly medication in the regimen was observed when the difference in out-of-pocket costs was greater than $33 per month. However, in an additional analysis of contributing factors, the type of medication – specifically insulin – was found to significantly influence adherence behavior. If the more costly medication in the combination therapy regimen was insulin, patients were more likely to be adherent to only the more costly medication. This suggests that although patients may prioritize adherence to their insulin prescription, overall cost may impact adherence to other prescribed medications in their treatment plan.

Two studies specifically examined the effects of cost sharing and insulin adherence among Medicare Part D beneficiaries. Using predictive modeling strategies based on changes in percent coverage from Medicare's drug benefit structure, Chandra et al. (2021) estimated changes in prescriptions filled for specific drug classes. They found an estimated 3% decrease in adherence to insulin and other OADs for every 10% increase in cost sharing. Trish et al. (2021) examined the association between out-of-pocket spending and insulin adherence among Medicare Part D beneficiaries. They found that higher out-of-pocket insulin costs were associated with lower adherence, with reduced insulin use in high-cost phases of Medicare plans.

A retrospective cohort study by McAdam-Marx et al. (2022) examined the effects of patient out-of-pocket costs for insulin on medication adherence. The study included 21,085 individuals with type 1 diabetes and 75,512 individuals with type 2 diabetes with commercial health insurance. Average insulin out-of-pocket costs per 30-day supply were categorized into four groups ($0-$20, >$20-$35, >$35-$50, and >$50). Overall, patients with average out-of-pocket costs greater than $50 were more likely to have a gap in insulin prescription refills of 60 or more continuous days compared to those with out-of-pocket costs in the $0-$20 category. For those with type 2 diabetes specifically, patients with average out-of-pocket costs greater than $35 were also more likely to have a gap in insulin prescription refills compared to those with out-of-pocket costs in the $0-$20 category. This comparison was not significant for those with type 1 diabetes. These results suggest that cost sharing of less than $50 may improve insulin adherence, and that adherence for those with type 2 diabetes is more sensitive to cost-sharing limits.

Summary of findings regarding cost sharing on insulin use and adherence: There is *strong evidence*[37] from seven observational 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.

Figure 6. Evidence of Effectiveness of Cost Sharing on Insulin Use and Adherence

Effect of Cost Sharing for Insulin on Health Outcomes and Utilization

CHBRP identified 1 new study that examined the effects of cost sharing for insulin on diabetes-related health outcomes and utilization. CHBRP previously identified 3 studies that reported on health outcomes and utilization results; however, these findings were not specific to insulin alone, and included the effect of cost sharing for insulin, other OADs, and diabetic testing supplies. For a full description of the results, see CHBRP's analysis of SB 90 (2023).

The cohort study of insulin users with type 1 diabetes in Colorado found declines in the mean number of medical claims per person per month for diabetes-related complications in the high-spending group only (those who spent more than the copayment cap in the pre-policy period) (Giannouchos et al., 2024).

The Nair et al. (2009, 2010) studies on the impact of value-based insurance designs reported decreases in diabetes-related emergency department visits and hospitalizations. However, these effects include the entire sample of patients with diabetes, not only those on insulin, and the associated effects of the lowered cost of diabetic testing supplies and other diabetic drugs.

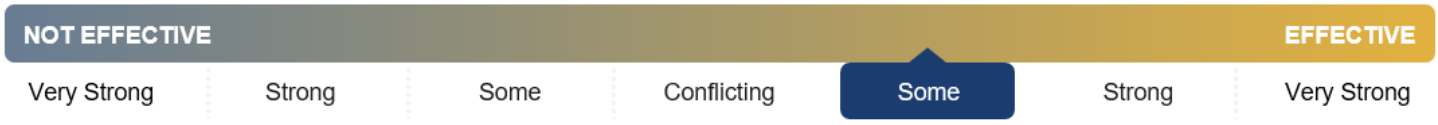
The Gibson et al. (2010) retrospective cross-sectional study examined the relationship between improved adherence to the prescribed diabetes treatment regimen for patients with type 2 diabetes (OADs with and without insulin) and health outcomes and found significant reductions in long-term complications, emergency department (ED) visits and hospitalizations. In addition, the number of physician visits (non-ED visits) was higher among adherent patients. They also

[37] CHBRP's analysis of SB 90 includes CHBRP's previous evidence grading terminology of *preponderance of evidence*.

found that the number of short-term disability days were reduced for adherent patients, but found no difference in absenteeism.

Summary of findings regarding cost sharing for insulin on health outcomes and utilization: There is *some evidence* from four studies on the effect of cost sharing for insulin on diabetes-related health outcomes and utilization. These studies suggest that reduced cost sharing is associated with decreased diabetes-related complications, emergency department visits, and hospitalizations. The effect of cost sharing on additional health outcomes, such as glycemic control, is unknown. This does not mean that there is no effect, but rather that there are limitations to measuring long-term health effects that may take many years to develop.

Figure 7. Effect of Cost Sharing for Insulin on Diabetes-Related Complications, ED Visits, and Hospitalizations

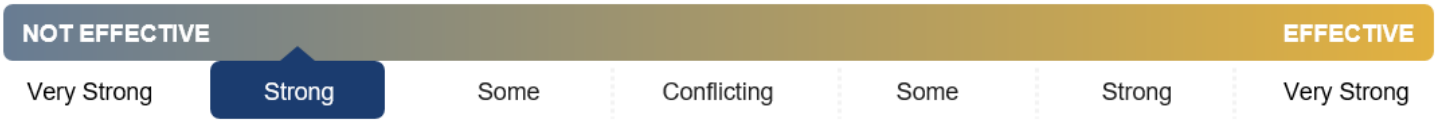


Effect of Step Therapy on Insulin Use and Adherence for Diabetes Mellitus

CHBRP did not identify any studies specifically on the impact of step therapy for insulin on use and adherence for diabetes treatment. CHBRP previously analyzed the effect of step therapy for prescription medications (AB 2144 in 2020) and found *strong evidence* to suggest that step therapy reduces use of any medication for a condition (CHBRP, AB 2144, 2020). The results were consistent across multiple conditions that step therapy is associated with a lower likelihood of initiating or continuing medications and with poorer adherence to medication. A decrease in medication use may be harmful if medication is essential for effective treatment of the condition. For diabetes treatment, there is clinical consensus that delayed introduction of, or ineffective, insulin therapy contributes to poor glycemic control and places patients at risk of complications (ADA, 2025b).[38]

Summary of findings regarding step therapy for initiation, continuation, and adherence to prescription medications: There is *strong evidence*[39] based on CHBRP's previous analysis of AB 2144 that step therapy is associated with a lower likelihood of initiating or continuing medications and with poorer adherence to medication.

Figure 8. Effect of Step Therapy for Initiation, Continuation, and Adherence to Prescription Medications



Summary of findings regarding step therapy for insulin use and adherence: There is *expert consensus*,[40] consistent with the finding for prescription medications, that step therapy protocols for insulin would be associated with lowered use and adherence. Additionally, there is clinical consensus that insulin is considered essential for effective treatment of diabetes and that delayed introduction of, or ineffective, insulin therapy contributes to poor glycemic control and places patients at risk of complications (ADA, 2025b).

[38] This consensus is additionally supported by Dr. Kimberly Buss of UCSF, CHBRP's content expert for the analysis of SB 40.
[39] CHBRP's analysis of AB 2144 includes CHBRP's previous evidence grading terminology of *preponderance of evidence*.
[40] *Expert consensus* indicates that the CHBRP-identified content expert has experience that agrees with at least one published clinical practice guideline from a professional society or government agency, editorial from those in the field, or opinion/consensus statement from a professional society, but no published empiric evidence is available.

Figure 9. Effect of Step Therapy for Insulin Use and Adherence

Summary of Findings

CHBRP found *strong evidence* from nine observational studies on cost-related insulin use/adherence that cost sharing affects insulin use and adherence in patients with diabetes. These studies provided strong *evidence* that higher cost sharing reduces adherence to insulin and lower cost sharing increases adherence to insulin. CHBRP found *some evidence from three observational studies* on the associated effect of cost sharing for insulin on diabetes-related health outcomes, emergency department visits, and hospitalizations. These studies suggest that reduced cost sharing is associated with decreased diabetes-related complications, emergency department visits, and hospitalizations. However, the results from two of these studies combine the effect of lowered cost for insulin and other diabetes drugs and testing supplies. The effect of cost sharing on additional health outcomes, such as glycemic control and long-term comorbidities, is unknown. This does not mean that there is no effect, but rather that there are limitations to measuring long-term health effects that may take many years to develop. Any effect resulting in better glycemic control or reducing long-term comorbidities would have significant impacts on health outcomes for diabetes that are not reflected in this analysis.

CHBRP previously analyzed the effect of step therapy for prescription medications (AB 2144) and found *strong evidence* to suggest that step therapy reduces use of any medication for a condition (CHBRP, AB 2144, 2020). The results were consistent across multiple conditions that step therapy is associated with a lower likelihood of initiating or continuing medications and with poorer adherence to medication. CHBRP determined that there is *expert consensus*, consistent with the finding for prescription medications, that step therapy protocols for insulin would be associated with lowered use and adherence. Additionally, there is clinical consensus that insulin is considered essential for effective treatment of diabetes and that delayed introduction of, or ineffective, insulin therapy contributes to poor glycemic control and places patients at risk of complications (ADA, 2025b).

There were several limitations that contributed to the gradings provided in this review, most notably the barriers to conducting rigorous RCTs of differential cost sharing or utilization management strategies on insulin use, inherent differences between the types of diabetes, and the multifaceted nature of diabetes treatment, resulting in a literature base that is not as rigorous as ideal and thereby limiting the certainty of conclusions drawn from the evidence.

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Benefit Coverage, Utilization, and Cost Impacts

As discussed in the *Introduction* section, SB 40 would limit cost sharing for insulin to $35 for a 30-day supply and prohibit step therapy for insulin among state-regulated commercial and CalPERS plans and policies.This section reports the potential incremental impacts of SB 40 on estimated baseline benefit coverage, utilization, and overall cost.

Analytic Approach and Key Assumptions

As outlined in the *Policy Context* section, Department of Managed Health Care (DMHC)-regulated plans and California Department of Insurance (CDI)-regulated policies with a pharmacy benefit must cover insulin, and all plans and policies must cover diabetes management supplies and equipment as medically necessary.

Almost all – 96.2% – commercial/California Public Employees' Retirement System (CalPERS) enrollees in 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.[41] Of the remaining commercial/ CalPERS enrollees, 1.2% do not have a pharmacy benefit, and 2.6% have a pharmacy benefit that is not regulated by DMHC or CDI. For Medi-Cal beneficiaries in DMHC-regulated managed care plans, the pharmacy benefit is separate and administered by the Department of Health Care Services (DHCS) under the Medi-Cal Rx program; therefore, it is not subject to DMHC regulation. Because SB 40 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 assumed to be compliant.

This section reports the potential incremental impacts of SB 40 on estimated baseline benefit coverage, utilization, and overall cost. This analysis uses the following methodologic approach and key assumptions:

- CHBRP used Milliman's 2023-2024 Consolidated Health Cost Guidelines Sources Database (CHSD) California data to determine insulin utilization, baseline allowed cost, and enrollee cost-sharing by commercial market segment for insulin users. 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 at baseline; and
    - Enrollees who had at least one claim that exceeded the mandated cost-sharing cap at baseline.
- CHBRP assumes that enrollees whose claims exceeded the cost-sharing cap at baseline will increase their insulin utilization due to reduced cost sharing postmandate. This assumption is strongly supported by evidence described above in the *Medical Effectiveness* section. CHBRP's projected increase in utilization (4% among enrollees who exceeded the cost-sharing cap at baseline) is based largely on findings from studies analyzing the impact of Colorado's insulin cost-sharing cap and content expert input.[42] Details regarding this assumption are provided in the section entitled "Baseline and Postmandate Utilization and Unit Cost" and in Appendix B.
- CHBRP assumes the reduction in cost sharing postmandate results in increased utilization of insulin as prescribed, which translates to improved health outcomes that occur in a 1-year postmandate timeframe. As with CHBRP's utilization assumption, this assumption regarding outcomes (also referred to as offsets) is supported by evidence from Colorado's cost-sharing cap on insulin and other evidence that suggests reduced cost sharing is associated with decreased diabetes-related health complications (see the *Medical Effectiveness* section). CHBRP assumes a 10% reduction in diabetes-related emergency department (ED) visits associated with increased utilization of insulin among enrollees who experience a reduction in cost sharing and subsequent increased

[41] For more detail, see CHBRP's resource *Pharmacy Benefit Coverage in State-Regulated Health Insurance*.
[42] Communication with Dr. Kimberly Buss, February 2025.

utilization postmandate. More details on this assumption are provided in the section entitled "Baseline and Postmandate Utilization and Unit Cost" and in Appendix B.

- CHBRP assumes SB 40 would prohibit step therapy, including (1) step therapy requirements that would require an enrollee to use a non-insulin test, treatment, or service before receiving coverage for insulin, and (2) step therapy that requires use of one type of insulin before using another insulin of the same therapeutic class.[43] CHBRP provides a hypothetical example to demonstrate how step therapy requirements could potentially impact insulin utilization patterns and costs. This is based on the assumption that enrollees who use insulin might switch between different insulin types (such as from biosimilars to other insulins) if step therapy is prohibited postmandate. These changes in product type would influence average unit costs of insulin. This approach was chosen because actual behavioral changes are difficult to predict with certainty, making an illustrative example more appropriate than definitive predictions for showing potential step therapy impacts.

CHBRP previously analyzed similar bills: AB 2203 Insulin Cost-Sharing Cap in 2020, AB 97 Insulin Affordability in 2021, SB 473 Insulin Cost Sharing in 2021 and 2022, and SB 90 Insulin Affordability in 2023. CHBRP notes there are a number of ways in which the analysis of SB 40 is different from the previous analyses:

1. There is new literature on the impacts of cost-sharing caps in other states, summarized in the *Medical Effectiveness* section. Insulin cost-sharing caps have been most extensively studied in Colorado, which implemented a $100 cap per 30-day supply of prescription insulin in 2020 for enrollees in state-regulated commercial health insurance plans. CHBRP used evidence from these studies to inform assumptions about changes in utilization and health outcomes resulting from cost-sharing caps. More details can be found in the "Baseline and Postmandate Utilization and Unit Cost" section.

2. Additionally, it is important to note that unit costs for insulin have changed, with some major manufacturers reducing the list price of insulin and reducing cost sharing (Nagel et al., 2024). In January 2024, many insulin manufacturers reduced list prices in response to the removal of the Average Manufacturer Price (AMP) cap under the American Rescue Plan Act. This policy change effectively decreased the financial incentives for manufacturers to maintain high list prices and rebates. As a result, the industry responded by lowering both list prices and rebates. Consequently, plan sponsors are receiving less rebate revenue for insulin in 2024 compared to recent prior years. The reduction in insulin list prices between CHBRP's prior and current analyses is largely offset by a reduction in insulin rebate revenue.

3. Increased use of GLP-1 receptor agonists to manage diabetes have also reduced the overall need for insulin treatment, thus the prevalence of insulin users has dropped over time (Rogers and Dewey, 2024). With the decline in costs and the decline in number of insulin users, the analysis of SB 40 has resulted in a notably lower expenditure impact compared to previous CHBRP reports.

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

Baseline and Postmandate Benefit Coverage

As discussed in the *Introduction* section, SB 40 would apply to DMHC and CDI state-regulated health insurance, including commercial enrollees and enrollees with insurance through CalPERS. It should be noted that DMHC regulates the plans and policies of approximately 74% of enrollees associated with CalPERS.[44]

Table 2 provides estimates of how many Californians have health insurance subject to state benefit mandates (22,207,000) and how many have health insurance with a pharmacy benefit subject to SB 40 (12,947,784). About 58% of

[43] This interpretation is supported by the California Department of Insurance, which has stated this would also apply to insulins not listed on an insurer's formulary. Personal communication with CDI, February 19, 2025.
[44] For more detail, see CHBRP's resource, *Sources of Health Insurance in California*.

enrollees with health insurance subject to state benefit mandates have pharmacy benefits subject to SB 40. Other enrollees with a pharmacy benefit not regulated by DMHC or CDI or without a pharmacy benefit are considered to have compliant coverage at baseline. SB 40 would establish a cost-sharing cap of $35 for a 30-day supply of insulin, which affects just those enrollees who have cost sharing greater than the cap/limit at baseline. The estimated number of enrollees who are impacted is shown in a subsequent Table 3 below.

At baseline, no enrollees have health insurance that requires step therapy of a non-insulin treatment before receiving coverage for insulin, but many enrollees have health insurance that includes at least one form of step therapy that requires use of one insulin before granting approval of another insulin of the same therapeutic class (e.g., preferred and non-preferred insulins, on-formulary and off-formulary insulins).

Table 2. Enrollees in Health Insurance With State-Regulated Pharmacy Benefits That Would Be Impacted by SB 40, 2026

	Population
Total enrollees with health insurance subject to state benefit mandates (a)	22,207,000
Total enrollees with a state-regulated pharmacy benefit subject to SB 40 (b)	12,947,784
Enrollees with pharmacy benefit subject to SB 40 (% of total)	58%

Source: California Health Benefits Review Program, 2025.
Notes: (a) Enrollees in plans and policies regulated by DMHC or CDI. Includes those associated with Covered California, CalPERS, or Medi-Cal.[1]
(b) Does not include enrollees in DMHC-regulated plans or CDI-regulated policies with a pharmacy benefit not state-regulated or without a pharmacy benefit; the pharmacy benefit for beneficiaries in DMHC-regulated Medi-Cal Managed Care plans is administered by the Department of Health Care Services and therefore not impacted by SB 40.
Key: CalPERS = California Public Employees' Retirement System; CDI = California Department of Insurance; DMHC = Department of Managed Health Care.

Baseline and Postmandate Utilization and Unit Cost

SB 40 would establish a cost-sharing cap of $35 for a 30-day supply of insulin. This change affects just those enrollees in DMHC and CDI state-regulated health insurance plans facing cost sharing greater than the cap/limit such that postmandate their cost-sharing expenses would be reduced to no longer exceed the cap.

CHBRP estimates at baseline there are 92,636 enrollees who use insulin in commercial and CalPERS DMHC-regulated plans and CDI-regulated policies, where 53,458 enrollees using insulin have cost sharing that *does not exceed* the SB 40 cost-sharing cap (58%). CHBRP estimates 39,178 enrollees (42%) using insulin have cost sharing *that exceeds* the SB 40 cap. Postmandate, 100% of enrollees with cost sharing that exceeds the cap at baseline would have cost sharing below the cap. This means, postmandate, 39,178 enrollees would no longer have cost sharing that exceeds the cap. This translates to a 73% increase in the number of enrollees whose cost sharing is below the cap postmandate.

CHBRP calculated insulin 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 4. Utilization (measured as number of 30-day supply insulin prescriptions per month per user) is 0.80 for enrollees whose claims did not exceed the cost-sharing cap at baseline and is 0.90 for enrollees whose claims did exceed the cost-sharing cap. (This paradoxical higher utilization in the high cost-sharing group is likely due to underlying differences in characteristics of these two populations.) 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. CHBRP estimates that for those enrollees whose claims exceeded the cap at baseline their average monthly cost sharing is $52/month; postmandate, the average monthly cost sharing for this group would go down to $29/month, which reflects a reduction of 44%.

To estimate the change in utilization postmandate for these enrollees for whom cost sharing is reduced, CHBRP applied an assumption of an increase in utilization of insulin of 4% based on literature and content expert input. The literature includes two evaluation studies that have assessed the impact of cost sharing caps implemented in Colorado. Ukert et al. (2024) found that insulin utilization increased by 4% across all insulin users following the cap's enactment. Giannouchos et al. (2024) focused specifically on individuals with type 1 diabetes, finding that adherence among this population increased by approximately 6%, whereas diabetes-related complications declined by about 13% when out-of-pocket costs

for insulin declined by about 27% overall, based on CHBRP's calculations. Because the Giannouchos et al. study was limited to type 1 diabetes patients, CHBRP considered these findings alongside those from Ukert et al. (2024), which examined all insulin users (not just type 1). Because the cap in California ($35/month) would be lower than the cap in Colorado ($100/month), the impact on utilization may be more modest, given those enrollees who were spending just above the cap at baseline may not increase postmandate utilization as much because their cost savings are more modest. The Colorado studies showed that utilization change postmandate is driven largely by the highest spenders. These studies from Colorado reinforce the well-documented price sensitivity of insulin utilization (see the *Medical Effectiveness* section on cost sharing) and align with Myerson et al. (2023), which evaluated the impact of the Medicare Part D $35 monthly insulin copay cap. The Medicare study similarly found a 4% increase in insulin utilization post-cap, further supporting the expectation that reductions in out-of-pocket costs drive increased adherence, albeit modestly.

Given this body of evidence, CHBRP assumes that SB 40's insulin cost cap would lower out-of-pocket costs for enrollees who previously exceeded the cap, leading to increased utilization among those benefiting from cost reductions. After consulting with CHBRP's content expert[45] and using estimates from the Colorado studies, CHBRP assumes a 4% postmandate increase in insulin utilization among enrollees whose costs exceeded the cap at baseline. Additionally, CHBRP assumes a 10% reduction in diabetes-related emergency department (ED) visits for this population. CHBRP's determination to include this offset is based on clinical evidence demonstrating that inadequate insulin adherence increases the risk of severe complications, such as diabetic ketoacidosis, which frequently result in emergency department visits. CHBRP's assumed reduction in diabetes-related ED visits is based on results from Colorado (Giannouchos et al., 2024) wherein they found a 20% reduction in diabetes-related complications after the enactment of the cost sharing cap. CHBRP dampened this estimate by a factor of one-half, given the study's narrower study population and inclusion of both long- and short-term diabetes-related complications in their assessment of outcomes. The application of this assumption reflects offsets that impact subsequent premium and expenditure estimates provided in this section. The value of these offsets, as calculated in the model, is $1,685,000 total.

The average cost of insulin per prescription per month is $249 (Table 4). As noted earlier, this cost is substantially lower than the average unit cost previously cited in CHBRP analyses due to recent trends that have lowered unit costs for insulin. Note that the claims data used in this analysis reflects the gross cost of insulin, defined as the price paid at the pharmacy, without adjustments for rebates or other manufacturer pricing concessions that may later be returned to pharmacy benefit managers (PBMs) and plan sponsors. The claims data captures amounts paid by the plan and the plan's estimated view of the member's out-of-pocket cost, but it does not account for the use of manufacturer coupons that some enrollees may use to lower their cost sharing. Due to lack of data, CHBRP is unable to estimate the number of enrollees who use such coupons. Some enrollees may have already been paying $35 or less per month for insulin and would not experience additional cost-sharing reductions under SB 40.

As explained earlier, with regard to the step therapy component of SB 40, CHBRP provides a hypothetical example to demonstrate how step therapy requirements could potentially impact insulin utilization patterns and costs (Table 3). This is based on the assumption that enrollees who use insulin might switch between different insulin types within the same therapeutic class (such as from biosimilars to other insulins) if step therapy is prohibited postmandate. These changes in product type would influence average unit costs of insulin. This approach was chosen because actual behavioral changes are difficult to predict with certainty, making an illustrative example more appropriate than definitive predictions for showing potential step therapy impacts. Step therapy is generally designed to require an enrollee to try a lower cost option before trying a higher cost option. In its survey of insurers in California, CHBRP found none require step therapy of a non-insulin drug before starting insulin, but they often require step therapy of one insulin before starting another insulin. For example, among long-acting insulins Tresiba, Lantus, and Basaglar, step therapy may require an enrollee to try Lantus before Basaglar or Tresiba. This step therapy has the effect of maintaining higher utilization of Lantus. Removing the step therapy would move some of the utilization from Lantus to Basaglar or Tresiba. This movement impacts the average unit cost of insulin. When such adjustment is made, the unit cost of insulin may go up slightly. The hypothetical example

[45] Dr. Kimberly Buss, 2/24/2025

below shows what that could look like as an illustration. This shift in use of different brands of insulin could modestly increase CHBRP's estimated expenditures.

Table 3. Hypothetical Example to Illustrate a Possible Effect of Prohibition of Step Therapy Due to SB 40 on Distribution and Utilization and Average Unit Cost

Product	2024 Unit Cost per 30-Day Supply	2024 Utilization (Days Supply) Distribution	Hypothetical 2024 Utilization Distribution With Step Therapy Requirements Removed
Tresiba	$448.31	15%	20%
Basaglar	$249.76	15%	20%
Novolog	$134.85	10%	10%
Lantus	$73.92	9%	5%
All other insulins	$242.60	50%	45%
Average insulin unit cost		**$249.46**	**$ 265.97**

Source: California Health Benefits Review Program, 2025.

Because CHBRP's 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).

Table 4 provides estimates of the impacts of SB 40 on utilization, cost sharing, and unit cost of insulin.

Table 4. Impacts of SB 40 on Utilization and Unit Cost of Insulin, 2026

	Baseline	Postmandate	Increase/Decrease	Percentage Change
Number of enrollees using insulin	92,636	92,636	–	0%
Enrollees whose claims do not exceed the cost-sharing cap	53,458	92,636	39,178	73.29%
Enrollees whose claims exceed the cost-sharing cap	39,178	–	(39,178)	−100%
Utilization per insulin user (# of 30-day supply insulin prescriptions per month)	0.84	0.86	0.02	1.82%
Utilization for enrollees whose claims did not exceed the cost-sharing cap at baseline	0.80	0.80	–	0%
Utilization for enrollees whose claims exceeded the cost-sharing cap at baseline	0.90	0.94	0.04	4.00%

Average monthly cost sharing for insulin per insulin user	$30	$21	−$9	−28.93%
Average monthly cost sharing for enrollees whose claims did not exceed the cost-sharing cap at baseline	$14	$15	$2	12.43%
Average monthly cost sharing for enrollees whose claims exceeded the cost-sharing cap at baseline	$52	$29	−$23	−43.96%
Average cost of insulin per prescription per month	$249	$249	$0	0%

Source: California Health Benefits Review Program, 2025.

Baseline and Postmandate Expenditures

For DMHC-regulated plans and CDI-regulated policies, SB 40 would increase total premiums paid by employers and enrollees for newly covered benefits. Enrollee cost sharing would decrease. This would result in an increase in total net annual expenditures of $2,147,00 (0.001%) for enrollees with DMHC- and CDI-regulated pharmacy benefits.

Below, Table 5 provides estimates of the impacts of SB 40 on expenditures, which include premiums, enrollee cost sharing, and enrollee expenses for noncovered benefits.

Table 5. Impacts of SB 40 on Expenditures, 2026

	Baseline	Postmandate	Increase/Decrease	Percentage Change
Premiums				
Employer-sponsored (a)	$68,752,638,000	$68,759,073,000	$6,435,000	0.009%
CalPERS employer (b)	$7,881,873,000	$7,881,873,000	$0	0%
Medi-Cal (excludes COHS) (c)	$31,818,731,000	$31,818,731,000	$0	0%
Enrollee premiums				
Enrollees, individually purchased insurance	$21,757,790,000	$21,759,532,000	$1,742,000	0.008%
Outside Covered California	$6,011,399,000	$6,011,893,000	$494,000	0.008%
Through Covered California	$15,746,391,000	$15,747,639,000	$1,248,000	0.008%
Enrollees, group insurance (d)	$21,712,866,000	$21,715,066,000	$2,200,000	0.010%
Enrollee out-of-pocket expenses				
Cost sharing for covered benefits (deductibles, copays, etc.)	$18,992,422,000	$18,984,192,000	−$8,230,000	−0.043%
Expenses for noncovered benefits (e) (f)	$0	$0	$0	0%
Total expenditures	$170,916,320,000	$170,918,467,000	$2,147,000	0.001%

Source: California Health Benefits Review Program, 2025.
Notes: (a) In some cases, a union or other organization. Excludes CalPERS.
(b) Includes only CalPERS enrollees in DMHC-regulated plans. Approximately 54.0% 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) Includes only Medi-Cal beneficiaries enrolled in DMHC-regulated plans.
(d) Enrollee premium expenditures include contributions by enrollees to employer (or union or other organization)-sponsored health insurance, health insurance purchased through Covered California, and any contributions to enrollment through Medi-Cal to a DMHC-regulated plan.
(e) 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.
(f) For covered benefits, such expenses would be eliminated, although enrollees with newly compliant benefit coverage might pay some expenses if benefit coverage is denied (through utilization management review).
Key: CalPERS = California Public Employees' Retirement System; CDI = California Department of Insurance; COHS = County Organized Health Systems; DMHC = Department of Managed Health Care

Premiums

At the end of this section, Table 8 and Table 9 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).

Changes in premiums as a result of SB 40 would vary by market segment. Note that such changes are related to the number of enrollees (see Table 2, Table 8, and Table 9), with health insurance that would be subject to SB 40.

Commercial

The changes in premiums as a result of SB 40 would be less than 0.05% for the different types of plans by market segment and ranges from $0.04 for large-group DMHC-regulated plans and CDI-regulated policies to $0.19 for small-group CDI-regulated policies.

CalPERS

For enrollees associated with CalPERS in DMHC-regulated plans, there is no impact because there are no enrollees for whom cost sharing for insulin prescription is higher than the cap at baseline.

Medi-Cal

The pharmacy benefit for beneficiaries in DMHC-regulated Medi-Cal Managed Care plans is administered by the Department of Health Care Services and therefore not impacted by SB 40.

Enrollee Expenses

SB 40–related changes in cost sharing for covered benefits (deductibles, copays, etc.) and out-of-pocket expenses for noncovered benefits would vary by market segment. Note that such changes are related to the number of enrollees (see Table 2, Table 8, and Table 9) with health insurance that would be subject to SB 40 expected to use insulin during the year after enactment.

Average enrollee out-of-pocket expenses per user

For baseline insulin users, the SB 40 cap on cost sharing would only impact those enrollees who are above the cap at baseline. Overall, 42% 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 $14. For enrollees whose claims exceed the cost-sharing cap at baseline, the average monthly cost sharing for insulin is $52 at baseline and would decrease by 44% to $29 per month postmandate (Table 4).

Table 6 shows impact of SB 40 by market segment. Enrollees in small-group plans would have the greatest reduction in annual out-of-pocket expenses postmandate ($380).

Table 6. Impact of SB 40 on Average Annual Enrollee Out-of-Pocket Expenses Per User, by Market Segment, 2026

	Large Group	Small Group	Individual	CalPERS	Medi-Cal (b)
% of Enrollees with out-of-pocket expenses impact due to SB 40 (a)	31.35%	56.57%	54.94%	N/A	N/A
Avg. annual out-of-pocket expenses reductions for enrollees (b)	$238	$380	$89	N/A	N/A

Source: California Health Benefits Review Program, 2025.
Notes: Average enrollee out-of-pocket expenses include expenses for both covered and noncovered benefits.
(a) Not including impacts on premiums.
(b) Benefit coverage for Medi-Cal beneficiaries does not generally include any cost sharing.
Key: CalPERS = California Public Employees' Retirement System.

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 estimates indicate that for enrollees subject to SB 40, approximately 18% of large-group, 47% of small-group, and 55% of individual market enrollees are in plans or policies with prescription drug deductibles, where deductibles may have a material impact on insulin cost sharing.[46] Of these enrollees, 7% of large-group, 10% of small-group, and 8% of individual market enrollees are enrolled in HSA-qualified HDHPs. The estimates of cost-sharing reductions presented include the total impact on cost-sharing incurred by the enrollee, including deductibles, coinsurance, and copays.

Cost-sharing reductions due to SB 40 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 would have an annual savings of greater than $1,463 (Table 7). The annual savings for the top 5%, 10%, and 20% of enrollees based on cost-sharing expenditures for insulin would be greater than $446, $217, and $70, respectively. The estimates of cost-sharing reductions presented below include the total impact on cost-sharing incurred by the enrollee, including deductibles, coinsurance, and copays.

Table 7. Impact of SB 40 on Average Annual Enrollee Out-of-Pocket Expenses Per User, by Enrollee Baseline Out-of-Pocket Costs, 2026

Out-of-Pocket Expenses	Baseline (Uncapped Annual Cost)	Postmandate (Capped Annual Cost)	Annual Savings
Top 1% of enrollees have cost/savings greater than	$1,918	$770	$1,463
Top 5% of enrollees have cost/savings greater than	$870	$525	$446
Top 10% of enrollees have cost/savings greater than	$600	$420	$217
Top 20% of enrollees have cost/savings greater than	$390	$310	$70

[46] More information about the share of enrollees in state-regulated plans with deductibles is available in CHBRP's resource *Deductibles in State-Regulated Health Insurance*.

Source: California Health Benefits Review Program, 2025.
Note: The value at each percentile shown is relative to the distribution for that column only. 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.

Postmandate Administrative and Other Expenses

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

Other Considerations for Policymakers

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

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 40.

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 40 would have on the number of enrollees who use these programs.

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Table 8. Baseline Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2026

	DMHC-Regulated						CDI-Regulated			
	Commercial Plans (by Market) (a)			Publicly Funded Plans			Commercial Policies (by Market) (a)			
	Large Group	*Small Group*	*Individual*	*CalPERS (b)*	*Medi-Cal (Excludes COHS) (c)*		*Large Group*	*Small Group*	*Individual*	Total
					Under 65	*65+*				
Enrollee counts										
Total enrollees in plans/policies subject to state mandates (d)	8,034,000	2,076,000	2,181,000	914,000	7,787,000	850,000	264,000	65,000	36,000	22,207,000
Total enrollees in plans/policies subject to SB 40	8,034,000	2,076,000	2,181,000	914,000	0	0	264,000	65,000	36,000	13,570,000
Premiums										
Average portion of premium paid by employer (e)	$557.33	$507.76	$0.00	$718.62	$276.79	$583.72	$609.11	$567.83	$0.00	$108,453,242,000
Average portion of premium paid by enrollee	$145.58	$212.63	$818.51	$139.09	$0.00	$0.00	$224.25	$185.49	$777.47	$43,470,656,000
Total premium	**$702.91**	**$720.39**	**$818.51**	**$857.71**	**$276.79**	**$583.72**	**$833.35**	**$753.32**	**$777.47**	**$151,923,898,000**
Enrollee expenses										
Cost sharing for covered benefits (deductibles, copays, etc.)	$64.42	$164.36	$272.54	$81.59	$0.00	$0.00	$122.99	$249.30	$173.93	$18,992,422,000
Expenses for noncovered benefits (f)	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0
Total expenditures	**$767.33**	**$884.75**	**$1,091.05**	**$939.30**	**$276.79**	**$583.72**	**$956.34**	**$1,002.63**	**$951.40**	**$170,916,320,000**

Source: California Health Benefits Review Program, 2025.
Notes: (a) Includes enrollees with grandfathered and nongrandfathered health insurance acquired outside or through Covered California (the state's health insurance marketplace).
(b) Includes only CalPERS enrollees in DMHC-regulated plans. Approximately 51.6% are state retirees, state employees, or their dependents. About one in five of these enrollees has a pharmacy benefit not subject to DMHC.[47] 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) Includes only Medi-Cal beneficiaries enrolled in DMHC-regulated plans. Includes those who are also Medicare beneficiaries.
(d) Enrollees in plans and policies regulated by DMHC or CDI. Includes those associated with Covered California, CalPERS, or Medi-Cal.[48]
(e) In some cases, a union or other organization – or Medi-Cal for its beneficiaries.
(f) Includes only those expenses that are paid directly by enrollees (or other sources) to providers for services related to the mandated benefit that are not covered by insurance at baseline. This only includes those expenses that will be newly covered, postmandate. Other components of expenditures in this table include all health care services covered by insurance.
Key: CalPERS = California Public Employees' Retirement System; CDI = California Department of Insurance; COHS = County Organized Health Systems; DMHC = Department of Managed Health Care.

[47] For more detail, see CHBRP's resource *Pharmacy Benefit Coverage in State-Regulated Health Insurance.*
[48] For more detail, see CHBRP's resource *Sources of Health Insurance in California*.

Table 9. Postmandate Change in Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2026

	DMHC-Regulated						CDI-Regulated			
	Commercial Plans (by Market) (a)			Publicly Funded Plans			Commercial Policies (by Market) (a)			
	Large Group	*Small Group*	*Individual*	*CalPERS (b)*	*Medi-Cal (Excludes COHS) (c)*		*Large Group*	*Small Group*	*Individual*	Total
					Under 65	*65+*				
Enrollee counts										
Total enrollees in plans/policies subject to state mandates (d)	8,034,000	2,076,000	2,181,000	914,000	7,787,000	850,000	264,000	65,000	36,000	22,207,000
Total enrollees in plans/policies subject to SB 40	8,034,000	2,076,000	2,181,000	914,000	0	0	264,000	65,000	36,000	13,570,000
Premiums										
Average portion of premium paid by employer (e)	$0.0316	$0.1277	$0.0000	$0.0000	$0.0000	$0.0000	$0.0292	$0.1466	$0.0000	$6,435,000
Average portion of premium paid by enrollee	$0.0083	$0.0535	$0.0653	$0.0000	$0.0000	$0.0000	$0.0107	$0.0479	$0.0755	$3,941,000
Total premium	$0.0399	$0.1812	$0.0653	$0.0000	$0.0000	$0.0000	$0.0399	$0.1945	$0.0755	**$10,376,000**
Enrollee expenses										
Cost sharing for covered benefits (deductibles, copays, etc.)	−$0.0314	−$0.1418	−$0.0552	$0.0000	$0.0000	$0.0000	−$0.0302	−$0.1418	−$0.0530	−$8,230,000
Expenses for noncovered benefits (f)	$0.0000	$0.0000	$0.0000	$0.0000	$0.0000	$0.0000	$0.0000	$0.0000	$0.0000	$0
Total expenditures	$0.0085	$0.0394	$0.0101	$0.0000	$0.0000	$0.0000	$0.0097	$0.0527	$0.0225	**$2,146,000**
Percent change										
Premiums	0.0057%	0.0252%	0.0080%	0.0000%	0.0000%	0.0000%	0.0048%	0.0258%	0.0097%	0.0068%
Total expenditures	0.0011%	0.0045%	0.0009%	0.0000%	0.0000%	0.0000%	0.0010%	0.0053%	0.0024%	0.0013%

Source: California Health Benefits Review Program, 2025.
Notes: (a) Includes enrollees with grandfathered and nongrandfathered health insurance acquired outside or through Covered California (the state's health insurance marketplace).
(b) Includes only CalPERS enrollees in DMHC-regulated plans. Approximately 51.6% are state retirees, state employees, or their dependents. About one in five of these enrollees has a pharmacy benefit not subject to DMHC.[49] 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) Includes only Medi-Cal beneficiaries enrolled in DMHC-regulated plans. Includes those who are also Medicare beneficiaries.
(d) Enrollees in plans and policies regulated by DMHC or CDI. Includes those associated with Covered California, CalPERS, or Medi-Cal.[50]
(e) In some cases, a union or other organization, or Medi-Cal for its beneficiaries.
(f) Includes only those expenses that are paid directly by enrollees (or other sources) to providers for services related to the mandated benefit that are not covered by insurance at baseline. This only includes those expenses that will be newly covered, postmandate. Other components of expenditures in this table include all health care services covered by insurance.
Key: CalPERS = California Public Employees' Retirement System; CDI = California Department of Insurance; COHS = County Organized Health Systems; DMHC = Department of Managed Health Care.

[49] For more detail, see CHBRP's resource *Pharmacy Benefit Coverage in State-Regulated Health Insurance*.
[50] For more detail, see CHBRP's resource *Sources of Health Insurance in California*.

Public Health Impacts

As discussed in the *Introduction* section, SB 40 would limit cost sharing of insulin to $35 per 30-day supply and prohibit step therapy for insulin for enrollees with state-regulated commercial or California Public Employees' Retirement System (CalPERS) coverage. Additional information on diabetes and insulin is included in the *Background* section.

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). This section estimates the short-term impact[51] of SB 40. See the *Long-Term Impacts* section for discussion of premature death, economic loss, and disparities.

Estimated Public Health Outcomes

Measurable health outcomes relevant to SB 40 included utilization of insulin and the associated effects of insulin adherence on health as measured by health care 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, *strong evidence* that cost sharing affects insulin use and adherence in patients with diabetes, and *some evidence* that lower cost sharing for insulin results in decreased diabetes-related complications, emergency department visits, and hospitalizations. The effect of cost sharing on additional health outcomes, such as glycemic control, is unknown.

As presented in the *Benefit Coverage, Utilization, and Cost Impacts* section, 39,178 enrollees who have claims that exceed the cost-sharing cap at baseline would experience an average of a 44% reduction in cost sharing, reducing average monthly cost sharing from $52 to $29. 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 40 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 that may have higher cost sharing (Cefalu et al., 2018). Enrollees with type 2 diabetes are more likely than those with type 1 diabetes to increase utilization owing to the inability of patients with type 1 diabetes to limit insulin intake without adverse effects on their health. The limited impact at the population level is supported by two recent studies that examined the impact of cost sharing caps on insulin utilization and health outcomes for all insulin users (Anderson et al., 2024; Garabedian et al., 2024). Both studies did not identify a significant change in insulin utilization or health outcomes for the full population as a result of reductions in cost sharing.

In the first year postmandate, 39,178 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 4% increase in utilization of insulin. At the population level, SB 40 is unlikely to have a noticeable affect across the health of the public due to limit of this impact only on the subset of patients using insulin with high out of pocket costs at baseline. However, these enrollees with significant reductions in cost sharing may experience a decrease burden of their illness and a reduction in complications.

Glycemic Control

For the population that would experience significant reductions in out-of-pocket costs due to SB 40, achieving stable blood glucose levels 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 (Martín-Timón and Cañizo-Gómez, 2015). Therefore, achievement of

[51] CHBRP defines short-term impacts as changes occurring within 12 months of bill implementation.

more stable glucose levels due to improved utilization of insulin may help avoid these serious health consequences associated with diabetes.

Health Care Utilization

For the population that would experience significant reductions in out-of-pocket costs due to SB 40, impacts to health care utilization may include reduced emergency services and hospitalizations. This would reduce costly emergency services and also have direct impacts on the patient.

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 40. For example, Hajós and colleagues (2012) found improvements in quality-of-life scores with improved HbA1c levels due to optimized insulin therapy for those with type 2 diabetes who had suboptimal glycemic control (Hajós et al., 2012). Note that quality of life in patients with diabetes is affected more by the presence of complications than by the diagnosis itself (Venkataraman et al., 2013).

Impact on Disparities[52]

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 prevalence exist by race/ethnicity, age, education, and income. CHBRP did not find evidence in the literature it evaluated showing differential affect of insulin caps on different demographic subgroups; therefore, it is not projected that SB 40 would directly impact diabetes disparities (for a discussion of potential impacts beyond the first 12 months of implementation, see the *Long-Term Impacts* section). That said, SB 40 would likely preferentially improve outcomes for those people with the most difficulty paying for high cost of insulins.

Despite SB 40 applying only to commercial and CalPERS enrollees, SB 40 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.

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[52] 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 40, 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 40 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 may change in the long term, particularly with the continued increased use of GLP-1 medications. Reductions in significant complications or comorbidities may take years to develop but have profound impacts on population health.

With regard to the prohibition of step therapy for insulin, it is possible insurers may change their utilization management protocols in response. Although insurers do not require step therapy of a non-insulin drug before starting insulin, several require step therapy of one insulin before using another. If step therapy were prohibited, it is possible that insurers may use other utilization management strategies for insulin, potentially limiting the range of covered insulin options on formulary or imposing quantity limits.

Cost Impacts

CHBRP estimates cost after the initial 12 months from the enactment of SB 40 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 disparities, premature death, and economic loss.

Long-Term Complications

Time spent in hyperglycemia and the frequency and severity of hyper- and hypoglycemia over time 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 40 can help enrollees taking insulin afford their prescribed dose, it is possible that rates of these comorbid conditions attributable to diabetes would be reduced over time.

Impacts on Disparities[53]

In the case of SB 40, evidence shows that variances in education and income exist for the population with diabetes and contribute to differences in insulin adherence. It is possible that a reduction in cost sharing for insulin therapy would reduce variation in insulin use due to income and socioeconomic status.

In the long term, CHBRP estimates that SB 40 would reduce disparities in diabetes care related to income for enrollees who have cost-related barriers to insulin use. Additionally, because the prevalence of diabetes is higher and there is evidence that cost-related medication nonadherence is more common for Black people, it is possible that SB 40 may also reduce racial disparities in diabetes care.

Impacts on Premature Death and Economic Loss

Premature death is often defined as death occurring before the age of 75 years (NCI, 2019).[54]

Diabetes contributes significantly to premature death and economic loss in California. In addition to complications from diabetes, hypoglycemia 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 (Conroy et al., 2014).

As discussed in the *Background* section, total direct medical expenses for diabetes in California were estimated to be $27 billion. An additional $12.5 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 40 on premature mortality is unknown. However, well-managed glucose levels result in fewer complications of diabetes (e.g., blindness, amputations, kidney disease). Preventing diabetes complications through improved use of insulin could help prevent premature death.

Although the impact of SB 40 on economic loss cannot be quantified, prevention of complications due to improved glucose management would likely reduce economic loss.

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

Appendix A. Text of Bill Analyzed

On January 14, 2025, the California Senate Committee on Health requested that CHBRP analyze SB 40, as introduced on December 3, 2024.

Below is the bill language, as it was introduced on December 3, 2024.

CALIFORNIA LEGISLATURE— 2025–2026 REGULAR SESSION

SENATE BILL **NO. 40**

Introduced by Senator Wiener
(Principal coauthor: Senator Rubio)
(Coauthors: Assembly Members Arambula and Bains)

December 03, 2024

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.

SB 40, as introduced, Wiener. Health care coverage: insulin.

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 disability insurance policy issued, amended, delivered, or renewed on or after January 1, 2000, that covers prescription benefits to include coverage for insulin if it is determined to be medically necessary.

This bill would generally prohibit a health care service plan contract or disability insurance policy issued, amended, delivered, or renewed on or after January 1, 2026, from imposing a copayment of more than $35 for a 30-day supply of an insulin prescription drug or imposing a deductible, coinsurance, or any other cost sharing on an insulin prescription drug, except as specified. On and after January 1, 2026, the bill would prohibit a health care service plan or disability insurer from imposing step therapy protocols as a prerequisite to authorizing coverage of insulin. 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.

DIGEST KEY

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

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BILL TEXT

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

SECTION 1.

(a) The Legislature finds and declares all of the following:

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

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

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

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

(5) Imposing a deductible on insulin, and requiring individuals to meet that deductible, creates a financial burden that presents a barrier to accessing insulin.

(6) Diabetes is the seventh leading cause of death, and it is 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.

(7) Studies have shown that managing diabetes can prevent complications and medical emergencies associated with diabetes that result in emergency room visits, hospitalizations, and costly treatments.

(b) Therefore, it is the intent of the Legislature to enact legislation on important policies to reduce the costs for Californians with diabetes to obtain lifesaving 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), a health care service plan contract that is issued, amended, or renewed on or after January 1, 2026, shall not impose a copayment on an insulin prescription drug that exceeds thirty-five dollars ($35) for a 30-day supply, and shall not impose a deductible, coinsurance, or any other cost sharing on an insulin prescription drug.

(2) Notwithstanding paragraph (1), if a health care service plan contract is a high deductible health plan, as defined in Section 223(c)(2) of Title 26 of the United States Code, the contract shall not impose a deductible, coinsurance, or any other cost sharing on an insulin prescription drug, unless not applying the deductible, coinsurance, or other cost sharing to an insulin prescription drug would conflict with federal requirements for high deductible health plans.

(3) When the state has the capacity to label or produce an insulin prescription drug, the deductible and copayment limitations in paragraph (1) shall also apply to an insulin prescription drug, or any therapeutic equivalent insulin prescription drug, that is labeled or produced by the state.

(4) For purposes of this subdivision, "insulin prescription drug" means a prescription drug that contains insulin and is used to control blood glucose levels to treat diabetes.

(e) Consistent with this section, on and after January 1, 2026, a health care service plan shall not impose step therapy protocols as a prerequisite to authorizing coverage of insulin. For purposes of this section, "step therapy protocol" means a protocol or program that establishes the specific sequence in which prescription drugs for a specified condition, including self-administered drugs and physician-administered drugs, are medically appropriate for a particular enrollee and are covered under a health care service plan contract.

~~(d)Every~~

(f) 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.

~~(e)~~ *(g)* The diabetes outpatient self-management training, education, and medical nutrition therapy services identified in subdivision ~~(d)~~ *(f)* 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.

~~(f)~~ *(h)* The copayments for the benefits specified in subdivision ~~(d)~~ *(f)* shall not exceed those established for physician office visits by the plan.

~~(g)Every~~ *(i) 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.

~~(h)~~ *(j)* A health care service plan ~~may~~ *shall* not reduce or eliminate coverage as a result of ~~the requirements of~~ this section.

~~(i)Nothing in this section shall be construed to~~ *(k) This section does not* deny or restrict in any way the department's authority to ensure plan compliance with this chapter ~~when~~ *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~~ *An* insurer issuing, amending, delivering, or renewing a disability insurance policy 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~~ *An* insurer issuing, amending, delivering, or renewing a disability insurance policy 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), a disability insurance policy that is issued, amended, or renewed on or after January 1, 2026, shall not impose a copayment on an insulin prescription drug that exceeds thirty-five dollars ($35) for a 30-day supply, and shall not impose a deductible, coinsurance, or any other cost sharing on an insulin prescription drug.

(2) Notwithstanding paragraph (1), if a disability insurance policy is a high deductible health plan, as defined in Section 223(c)(2) of Title 26 of the United States Code, the policy shall not impose a deductible, coinsurance, or any other cost sharing on an insulin prescription drug, unless not applying the deductible, coinsurance, or other cost sharing to an insulin prescription drug would conflict with federal requirements for high deductible health plans.

(3) When the state has the capacity to label or produce an insulin prescription drug, the deductible and copayment limitations in paragraph (1) shall also apply to an insulin prescription drug, or any therapeutic equivalent insulin prescription drug, that is labeled or produced by the state.

(4) For purposes of this subdivision, "insulin prescription drug" means a prescription drug that contains insulin and is used to control blood glucose levels to treat diabetes.

(e) Consistent with this section, on and after January 1, 2026, a disability insurer shall not impose step therapy protocols as a prerequisite to authorizing coverage of insulin. For purposes of this section, "step therapy protocol" means a protocol or program that establishes the specific sequence in which prescription drugs for a specified condition, including self-administered drugs and physician-administered drugs, are medically appropriate for a particular insured and are covered under a disability insurance policy.

~~(d)Every~~

(f) An 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)~~ *(g)* The diabetes outpatient self-management training, education, and medical nutrition therapy services identified in subdivision ~~(d)~~ *(f)* 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)~~ *(h)* The coinsurances and deductibles for the benefits specified in subdivision ~~(d)~~ *(f)* shall not exceed those established for physician office visits by the insurer.

~~(g)~~ *(i)* Every disability 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)~~ *(j)* An insurer ~~may~~ *shall* not reduce or eliminate coverage as a result of ~~the requirements of~~ this section.

~~(i)~~ *(k)* 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. Cost Impact Analysis: Data Sources, Caveats, and Assumptions

With the assistance of CHBRP's contracted actuarial firm, Milliman, Inc., the cost analysis presented in this report was prepared by the faculty and researchers connected to CHBRP's Task Force with expertise in health economics.[55] 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 on CHBRP's website.[56]

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

Analysis-Specific Data Sources

Baseline insulin cost sharing and step therapy for commercial enrollees was determined by a survey of the largest (by enrollment) providers of health insurance in California. Responses to this survey represent 75% of commercial enrollees with health insurance that can be subject to state benefit mandates. As necessary, CHBRP extrapolated from responses of similarly situated plans/policies.

- CHBRP identified National Drug Codes (NDCs) for insulin from the MediSpan® Master Drug Data Base v2.5 were used to extract data from Milliman's 2023-2024 CHSD, focusing on California, to develop utilization, baseline allowed cost, and enrollee cost-sharing information for insulin users by commercial market segment.

- CHBRP assumes the insulin products available in Milliman's 2024 Consolidated Health Cost Guidelines Sources Database (CHSD), which was used for this analysis, will continue to be available in 2026. CHBRP is unable to predict the number, type, or price of new insulin products that may come to the market in 2026, nor how new products might affect the price and cost sharing for existing products.

    - 2024 allowed cost for insulin was trended 5% per year from 2024 to 2026.

- The claims data used in the analysis reflects the gross cost of the drug (the price paid at the pharmacy) without any offsets for rebates or other manufacturer pricing concessions returned to PBMs and plan sponsors. The majority of the change in the unit cost of insulin between prior CHBRP analyses and this current analysis is due to a reduction in the gross cost, but in practice, this is mostly offset by a reduction in rebates. The claims data used in this analysis captures plan paid and the plan's view of member paid. Members may have used manufacturer coupons to reduce their cost sharing. This is not reflected in the claims data. It is possible that some members were already using a coupon to reduce their cost sharing to $35 or lower per fill and so would not see a cost sharing reduction as a result of SB 40. As a result, there may be a premium increase without a corresponding decrease in member cost sharing.

- Utilization, allowed cost, and enrollee cost sharing offsets for the reduction in diabetes-related ED visits due to increased insulin utilization were estimated using Milliman's 2023 CHSD data. The 2023 unit cost for ED visits was trended to 2026 at 7% per year based on outpatient facility trend estimates.

Health Cost Guidelines

The health cost guidelines (HCGs) are a health care pricing tool used by actuaries in many of the major health plans in the United States. The guidelines provide a flexible but consistent basis for estimating health care costs for a wide variety

[55] CHBRP's authorizing statute requires that CHBRP use a certified actuary or "other person with relevant knowledge and expertise" to determine financial impact.
[56] See CHBRP's Cost Impact Analysis landing page; in particular, see *Cost Impact Analyses: Data Sources, Caveats, and Assumptions*.

of commercial health insurance plans. It is likely that these organizations use the HCGs, among other tools, to determine the initial premium impact of any new mandate. Thus, in addition to producing accurate estimates of the costs of a mandate, we believe the HCG-based values are also good estimates of the premium impact as estimated by the HMOs and insurance companies.

The highlights of the commercial HCGs include:

- Specific major medical, managed care, and prescription drug rating sections and guidance with step-by-step rating instructions.
- Other helpful analysis resources, such as inpatient length of stay distribution tables, Medicare Severity-Adjusted Diagnosis Related Group (MS-DRG) models, and supplementary sections addressing EHBs and mandated benefits, experience rating, and individual and small group rating considerations.
- Presentation of loosely and well-managed nationwide utilization and cost information by Milliman benefit-aligned service categories used throughout the Rating Structures – inpatient hospital services for both loosely and well-managed are also supported by DRG level utilization and cost benchmarks.
- Annual updates address emerging regulatory considerations such as health care reform and mental health parity requirements.
- Annually updated benefit descriptions used in the HCG service categories.
- Annually updated medical trend assumptions and considerations.
- Presentation of two sets of nationwide area factors to facilitate development of area-specific claim costs, including separate utilization and charge level factors by type of benefit, state and Metropolitan Statistical Area for first-dollar coverage, and composite factors by deductible amount.
- Claim Probability Distributions (CPDs) by type of coverage that contain distributions of claim severity patterns for unique combinations of benefits and member types (adult, child, composite member).
- The Prescription Drug Rating Model (RXRM), an automated rating tool that provides a detailed analysis of prescription drug costs and benefits.

Consolidated Health Cost Guidelines Sources Database

Milliman maintains benchmarking and analytic databases that include health care claims data for nearly 60 million commercial lives and over 3 million lives of Medicaid managed care data. This dataset is routinely used to evaluate program impacts on cost and other outcomes.

Detailed Cost Notes Regarding Analysis-Specific Caveats and Assumptions

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

Determining Public Demand for the Proposed Mandate

CHBRP reviews public demand for benefits by comparing 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 have the largest number of enrollees. The CalPERS PPOs currently provide benefit coverage similar to what is available through group health insurance plans and policies that would be subject to the mandate.

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

Second-Year Impacts on Benefit Coverage, Utilization, and Cost

CHBRP has considered whether continued implementation during the second year of the benefit coverage requirements of SB 40 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 40 would be substantially the same as the impacts in the first year (see Tables 2, 4, and 5). Minor changes to utilization and expenditures are due to population changes between the first year postmandate and the second year postmandate.

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Appendix C. Cost Sharing and Utilization Management

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

Cost Sharing

Payment for use of covered health insurance benefits is shared between the payer (e.g., health plan/insurer or employer) and the enrollee. Common cost-sharing mechanisms include copayments, coinsurance, and/or deductibles (but do not include premium expenses[57]). There are a variety of cost-sharing mechanisms that can be applicable to covered benefits (Figure 9). 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.[58]

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

An enrollee using insulin may experience multiple forms of out-of-pocket expenses. 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 out-of-pocket expenses meet the annual out-of-pocket maximum, the enrollee would no longer be responsible for cost-sharing responsibilities.

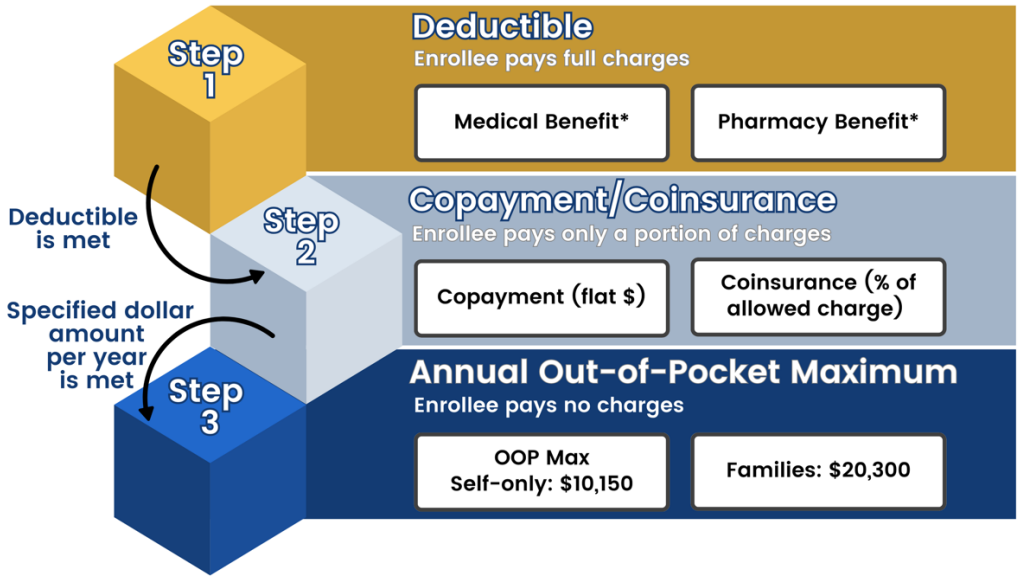
SB 40 would instead require that an enrollee only pay the cost sharing of up to $35 for a 30-day supply of insulin, regardless of whether they have met their deductible.

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, 2022). 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.

[57] Premiums are paid by most enrollees, regardless of their use of any tests, treatments, or services. Some enrollees may not pay premiums because their employers cover the full premium, they receive premium subsidies through the Covered California, or they receive benefits through Medi-Cal.
[58] Plans and policies sold within Covered California are required by federal law to meet specified actuarial values. The actuarial value is required to fall within specified ranges and dictates the average percent of health care costs a plan or policy covers. If a required reduction in cost sharing impacts the actuarial value, some number of these plans or policies might have to alter other cost-sharing components of the plan and/or premiums in order to keep the overall benefit design within the required actuarial value limits.

Figure 10. Overview of the Intersection of Cost-Sharing Methods Used in Health Insurance



Source: California Health Benefits Review Program, 2025; CMS, 2024.
Notes: 1) Steps 1 and 2 are not mutually exclusive. Under certain circumstances (i.e., preventive screenings or therapies), enrollees may pay coinsurance or copayments prior to their deductible being met; also copayments and coinsurance may be applied against the deductible in some circumstances. The figure assumes that the enrollee is in a plan with a deductible. If no deductible, then enrollee pays a coinsurance and/or a copayment beginning with the first dollar spent (Step 2). The annual out-of-pocket maximums listed in Step 3 increase each year according to methods detailed in CMS' Notice of Benefit and Payment Parameters (CMS, 2024).
2) There is variation in the type and source of the pharmacy benefit among commercial and CalPERS enrollees in DMHC-regulated plans and CDI-regulated policies. While most enrollees have a pharmacy benefit that is regulated by DMHC or CDI, a small share of enrollees in the individual market have a pharmacy benefit that covers only generic medications, do not have a pharmacy benefit at all, or have a pharmacy benefit not subject to DMHC or CDI regulation. Thus, the deductible paid by enrollees will vary depending on whether they have a medical and/or pharmacy benefit included in their plan or policy.
Key: CalPERS = California Public Employees' Retirement System; CDI = California Department of Insurance; DMHC = Department of Managed Health Care; OOP Max = annual out-of-pocket maximum.

Step Therapy

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

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Appendix D. Disparities in Prevalence of Diabetes

Race or Ethnicity

In California, Hispanic people (10.3%), Black people (10.5%), and Asian/Pacific Islanders (10.7%) have higher prevalence of type 2 diabetes than non-Hispanic White people (7.3%) (CHIS, 2022a).This is consistent with racial/ethnic differences found nationally: prevalence of diagnosed diabetes was highest among American Indians/Alaska Natives (16.0%), people of Hispanic origin (10.3%), and non-Hispanic Black people (12.5%), followed by non-Hispanic Asian people (9.2%) and non-Hispanic White people (8.5%) (CDC, 2025). However, White people are more likely to develop type 1 diabetes than Black people and Hispanic/Latino people (CDC, 2019).

Sex or Gender[59]

The prevalence of diabetes is similar between men (12.8%) and women (10.3%) in California (America's Health Rankings, 2024). This trend is consistent with national prevalence rates: approximately 12.6% of men in the United States have diabetes, while 11.6% of women do (America's Health Rankings, 2024).

Age

Across all age groups, the prevalence of type 1 diabetes is low in California (<2%) (CHIS, 2022b, Conroy et al., 2014). However, differences exist across age groups in the state regarding the prevalence of type 2 diabetes: the prevalence of type 2 diabetes is less than 3% for adults aged 44 years and under but rises sharply to 11.2% for those aged 45 to 64 years and to >17% for those aged 65 years and older (CHIS, 2022b, Conroy et al., 2014). Similarly, in the United States, the prevalence of adults with diagnosed diabetes (type 1 or type 2 diabetes) increases with age, though national rates report reaching 24.4% among those aged 65 years and older (CDC, 2025).

Income

The percentage of adults in California with diagnosed type 1 diabetes or type 2 diabetes is more than double for those with family incomes below $25,000 and for families with incomes between $25,000 and $50,000 as compared to those whose income is $100,000 or more (18.6% and 16.7% vs. 8.1%, respectively) (America's Health Rankings, 2024). In 2011, a systematic review and meta-analysis of 23 studies, along with more recent largescale analyses across 10 thousand people, lower socioeconomic status was strongly associated with an increased risk of type 2 diabetes (Agardh et al., 2011; Beckles and Chou, 2016; Liu et al., 2023).

Education

As of 2023, the prevalence of diabetes is more than twice as high for Californians without a high-school diploma as compared with adults aged over 25 with a college degree (28.7% vs. 9.3%) (America's Health Rankings, 2024).

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[59] CHBRP uses the National Institutes of Health (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).

References

Agardh E, Allebeck P, Hallqvist J, Moradi T, Sidorchuk A. Type 2 diabetes incidence and socio-economic position: a systematic review and meta-analysis. *International Journal of Epidemiology*. 2011;40(3):804-818.

America's Health Rankings. Annual Report, Diabetes, California, United States. 2024 edition. Available at: https://www.americashealthrankings.org/explore/measures/Diabetes/CA. Accessed on February 1, 2025.

American Diabetes Association (ADA). Diabetes and Coronavirus (COVID-19). 2021. Available at: https://www.diabetes.org/coronavirus-covid-19. Accessed March 16, 2021.

American Diabetes Association (ADA). State Insulin Copay Caps. 2025a. Available at: https://diabetes.org/tools-resources/affordable-insulin/state-insulin-copay-caps. Accessed February 5, 2025.

American Diabetes Association (ADA). The Burden of Diabetes in California. 2023. Available at: https://diabetes.org/sites/default/files/2023-09/ADV_2023_State_Fact_sheets_all_rev_California.pdf. Accessed February 5, 2025.

American Diabetes Association (ADA) Professional Practice Committee. Summary of Revisions: Standards of Care in Diabetes—2025. *Diabetes Care*. 2025b;48(Supplement_1):S6-S13.

Anderson KE, Chaiyakunapruk N, Gutierrez EJ, et al. State out-of-pocket caps on insulin costs: no significant increase in claims or utilization. *Health Affairs (Millwood)*. 2024;43(8):1137-1146.

Bakkila BF, Basu S, Lipska KJ. Catastrophic spending on insulin in the United States, 2017-18. *Health Affairs (Millwood)*. 2022 Jul;41(7):1053-1060.

Beckles GL, Chou CF. Disparities in the prevalence of diagnosed diabetes - United States, 1999-2002 and 2011-2014. *MMWR: Morbid Mortality Weekly Report*. 2016;65(45):1265-1269..

Borden CG, Bakkila BF, Nally LM, Lipska KJ. The association between cost-related insulin rationing and health care utilization in U.S. adults with diabetes. *Diabetes Care*. 2025;48(3):400-404.

Brod M, Rana A, Barnett AH. Adherence patterns in patients with type 2 diabetes on basal insulin analogues: missed, mistimed and reduced doses. *Current Medical Research and Opinion*. 2012;28(12):1933-1946.

Burgess JL, Wyant WA, Abdo Abujamra B, Kirsner RS, Jozic I. Diabetic wound-healing science. *Medicina (Kaunas, Lithuania)*. 2021;57(10):1072.

California Health Information Survey (CHIS). Ever Diagnosed With Diabetes Compared by Type of Current Health Insurance Coverage: 2022. 2022a. Available at: http://ask.chis.ucla.edu. Accessed January 29, 2025.

California Health Information Survey (CHIS). Type of Diabetes - Type I or Type II Compared by Type of Current Health Insurance Coverage: 2022. 2022b. Available at: http://ask.chis.ucla.edu. Accessed January 29, 2025.

CalRx. Making Prescription Drugs More Affordable for Californians: Fact Sheet. 2023. Available at: https://calrx.ca.gov//uploads/2023/03/CalRx-Fact-Sheet.pdf. Accessed March 20, 2023.

Capoccia K, Odegard PS, Letassy N. Medication adherence with diabetes medication: a systematic review of the literature. *Diabetes Educator*. 2016;42(1):34-71.

Cefalu WT, Dawes DE, Gavlak G, et al. Insulin Access and Affordability Working Group: conclusions and recommendations. *Diabetes Care*. 2018:41(6):1299-1311.

Center on Budget and Policy Priorities. Key Facts: Cost-Sharing Charges. 2022. Available at: www.healthreformbeyondthebasics.org/cost-sharing-charges-in-marketplace-health-insurance-plans-answers-to-frequently-asked-questions/. Accessed January 9, 2023.

Centers for Disease Control and Prevention (CDC). COVID-19: People With Certain Medical Conditions. January 29, 2021. Available at: https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html. Accessed March 16, 2021.

Centers for Disease Control and Prevention (CDC). Diabetes in Young People Is on the Rise. 2024a. Available at: https://www.cdc.gov/diabetes/data-research/research/young-people-diabetes-on-rise.html. Accessed January 30, 2025

Centers for Disease Control and Prevention (CDC). Diabetes: Who's at Risk? August 28, 2019. Available at: https://www.cdc.gov/diabetes/basics/risk-factors.html. Accessed March 20, 2020.

Centers for Disease Control and Prevention (CDC). Gestational Diabetes. May 15, 2024. 2024b. Available at: https://www.cdc.gov/diabetes/about/gestational-diabetes.html. Accessed January 30, 2025.

Centers for Disease Control and Prevention (CDC). National Diabetes Statistics Report, 2024. Atlanta, GA: Centers for Disease Control and Prevention, U.S. Dept of Health and Human Services; 2025. Available at: https://www.cdc.gov/diabetes/php/data-research/index.html. Accessed January 30, 2025.

Centers for Disease Control and Prevention (CDC). Types of Insulin. 2024c. Available at: www.cdc.gov/diabetes/about/how-to-use-insulin.html. Accessed February 5, 2025.

Centers for Medicare & Medicaid Services (CMS). Premium Adjustment Percentage, Maximum Annual Limitation on Cost Sharing, Reduced Maximum Annual Limitation on Cost Sharing, and Required Contribution Percentage for the 2026 Benefit Year. 2024. Available at: https://www.cms.gov/files/document/2026-papi-parameters-guidance-2024-10-08.pdf. Accessed October 17, 2024.

Chandra A, Flack E, Obermeyer Z. *The Health Costs of Cost-Sharing*. NBER Working Paper Series. No. 28439. Cambridge, MA: National Bureau of Economic Research; 2021.

Chang A, Liberman JN, Coulen C, Berger JE, Brennan TA. Value-based insurance design and antidiabetic medication adherence. *American Journal of Pharmacy Benefits.* 2010;2(1):39-44.

Conroy SM, Lee AK, Pendleton L, Bates JH. *Burden of Diabetes in California*. Sacramento, CA: Chronic Disease Control Branch, California Department of Public Health; 2014.

Davies MJ, Gagliardino JJ, Gray LJ, Khunti K, Mohan V, Hughes R. Real-world factors affecting adherence to insulin therapy in patients with type 1 or type 2 diabetes mellitus: a systematic review. *Diabetic Medicine*. 2013;30(5):512-524.

Department of Managed Health Care (DMHC). DMHC Report Shows Prescription Drug Costs Increased by $2.1 Billion Over Five Years. 2022. Available at: https://www.dmhc.ca.gov/AbouttheDMHC/Newsroom/December27,2022.aspx. Accessed March 1, 2023.

Donner T, Sarkar S. Insulin – pharmacology, therapeutic regimens, and principles of intensive insulin therapy. [Updated 2019 Feb 23]. In: Feingold KR, Anawalt B, Blackman MR, et al., editors. Endotext [Internet]. South Dartmouth, MA: MDText.com, Inc.; 2000-. Table 2. Available at: https://www.ncbi.nlm.nih.gov/books/NBK278938/table/insulin-pharmacology.T.insulins_commerci/. Accessed February 20, 2023.

Feldman R. CalRx biosimilar insulin: California's initiative to enter the insulin market. *JAMA Internal Medicine*. 2023;183(10):1043-1044.

Fronstin P, Fendrick AM. Employer Uptake of Pre-Deductible Coverage for Preventive Services in HSA-Eligible Health Plans. Employee Benefit Research Institute. 2021. Available at: https://www.ebri.org/docs/default-source/ebri-issue-brief/ebri_ib_542_hsaemployersur-14oct21.pdf. Accessed March 2, 2023.

Garabedian LF, Ross-Degnan D, Costa R, Argetsinger S, Zhang F, Wharam JF. The impact of insulin out-of-pocket caps among commercially insured diabetes patients. *Diabetes.* 2023;72(Supplement 1):15-OR.

Gardner JW, Sanborn JS. Years of potential life lost (YPLL)—what does it measure? *Epidemiology (Cambridge, Mass.)*. 1990;1(4):322-329.

Giannouchos TV, Ukert B, Buchmueller T. Health outcome changes in individuals with type 1 diabetes after a state-level insulin copayment cap. *JAMA Network Open*. 2024;7(8):e2425280.

Gibson TB, Song X, Alemayehu B, et al. Cost sharing, adherence, and health outcomes in patients with diabetes. *American Journal of Managed Care.* 2010;16(8):589-600.

Gillani SW, Ansari IA, Zaghloul HA, et al. Predictors of health-related quality of life among patients with type II diabetes mellitus who are insulin users: a multidimensional model. *Current Therapeutic Research*. 2019;90:53-60.

Golden SH, Brown A, Cauley JA, et al. Health disparities in endocrine disorders: biological, clinical, and nonclinical factors—an Endocrine Society scientific statement. *Journal of Clinical Endocrinology & Metabolism*. 2012;97(9):E1579-E1639.

Hajós TR, Pouwer F, De Grooth R, et al. The longitudinal association between glycaemic control and health-related quality of life following insulin therapy optimisation in type 2 diabetes patients. A prospective observational study in secondary care. *Quality of Life Research*. 2012;21(8):1359-1365.

Herkert D, Vijayakumar P, Luo J, et al. Cost-related insulin underuse among patients with diabetes. *JAMA Internal Medicine*. 2019;179(1):112-114.

Hernandez I, San-Juan-Rodriguez A, Good CB, Gellad WF. Changes in list prices, net prices, and discounts for branded drugs in the US, 2007- 2018. *JAMA*. 2020;323(9):854-862.

Herper M, Silverman E. Eli Lilly Cuts Prices for Some Insulin Products, but Some Are Wary. STAT News. 2023. Available at: https://www.statnews.com/pharmalot/2023/03/01/eli-lilly-cuts-prices-for-some-insulin-products-but-experts-and-critics-are-skeptical/. Accessed March 3, 2023.

Holt RIG, Cockram CS, Ma RCW, Luk AOY. Diabetes and infection: review of the epidemiology, mechanisms and principles of treatment. *Diabetologia*. 2024;67(7):1168-1180.

Hormone Health Network (HHN). Insulin Pump | Endocrine Society. Hormone.org, Endocrine Society, 2018. Available at: https://www.hormone.org/diseases-and-conditions/diabetes/diabetes-technology/insulin-pump. Accessed March 24, 2020.

Kang H, Lobo JM, Kim S, Sohn MW. Cost-related medication non-adherence among US adults with diabetes. *Diabetes Research and Clinical Practice*. 2018;143:24-33.

Kwang H. California Made a Big Bet on Producing Its Own Insulin. There's No 'Date Certain' for Delivery. CalMatters. March 3, 2025. Available at: https://calmatters.org/health/2025/03/california-insulin-production-delay/. Accessed March 4, 2025.

Lee AK, Juraschek SP, Windham BG, et al. Severe hypoglycemia and risk of falls in type 2 diabetes: the Atherosclerosis Risk in Communities (ARIC) study. *Diabetes Care*. 2020;43(9):2060-2065. doi:10.2337/dc20-0316

Liu C, He L, Li Y, Yang A, Zhang K, Luo B. Diabetes risk among US adults with different socioeconomic status and behavioral lifestyles: evidence from the National Health and Nutrition Examination Survey. *Frontiers in Public Health*. 2023;11:1197947.

Lovelace B. Sanofi Announces Insulin Price Cap After Actions by Eli Lilly and Novo Nordisk. NBC News. Available at: https://www.nbcnews.com/health/health-news/sanofi-insulin-price-cap-rcna75346. Accessed March 20, 2023.

Luhby T. Novo Nordisk becomes latest to announce it is cutting insulin prices by up to 75%. CNN Health. 2023. Available at: https://www.cnn.com/2023/03/14/health/novo-nordisk-insulin-prices/index.html. Accessed March 20, 2023.

Martín-Timón I, del Cañizo-Gómez FJ. Mechanisms of hypoglycemia unawareness and implications in diabetic patients. *World Journal of Diabetes*. 2015;6(7):912-926.

McAdam-Marx C, Ruiz-Negron N, Sullivan JM, Tucker JM. The effects of patient out-of-pocket costs for insulin on medication adherence and health care utilization in patients with commercial insurance; 2007-2018. *Journal of Managed Care & Specialty Pharmacy.* 2022;28(5):494-506.

McCoy RG, Van Houten HK, Ziegenfuss JY, Shah ND, Wermers RA, Smith SA. Increased mortality of patients with diabetes reporting severe hypoglycemia. *Diabetes Care*. 2012;35(9):1897-1901.

Medicare.gov. Insulin. Available at: https://www.medicare.gov/coverage/insulin. Accessed March 8, 2023.

Myerson R, Qato DM, Goldman DP, Romley JA. Insulin fills by Medicare enrollees and out-of-pocket caps under the Inflation Reduction Act. *JAMA*. 2023;330(7):660-662.

Nagel KE, Ramachandran R, Lipska KJ. Lessons from insulin: policy prescriptions for affordable diabetes and obesity medications. *Diabetes Care*. 2024;47(8):1246-1256.

Nair KV, Miller K, Park J, Allen RR, Saseen JJ, Biddle V. Prescription co-pay reduction program for diabetic employees. *Population Health Management*. 2010;13(5):235-245.

Nair KV, Miller K, Saseen J, Wolfe P, Allen RR, Park J. Prescription copay reduction program for diabetic employees: impact on medication compliance and healthcare costs and utilization. *American Health & Drug Benefits*. 2009;2(1):14.

Nakhleh A, Shehadeh N. Hypoglycemia in diabetes: an update on pathophysiology, treatment, and prevention. *World Journal of Diabetes*. 2021;12(12):2036-2049.

National Cancer Institute (NCI). NCI Dictionary of Cancer Terms: Premature Death. 2019. Available at: www.cancer.gov/publications/dictionaries/cancer-terms/def/premature-death. Accessed August 29, 2019.

National Institute of Diabetes and Digestive and Kidney Diseases (NIDDKD). What Is Diabetes? 2017. Available at: https://www.niddk.nih.gov/health-information/diabetes/overview/what-is-diabetes. Accessed March 4, 2020.

National Institutes of Health (NIH), Office of Research on Women's Health. Sex and Gender. 2019.

Nelson DR, Heaton P, Hincapie A, Ghodke S, Chen J. Differential cost-sharing undermines treatment adherence to combination therapy: evidence from diabetes treatment. *Diabetes Therapy*. 2021;12(8):2149-2164.

Peyrot M, Rubin RR, Kruger DF, Travis LB. Correlates of insulin injection omission. *Diabetes Care.* 2010;33(2):240-245.

Pharmacy Benefits Management Institute (PBMI). *2014-2015 Prescription Drug Benefit Cost and Plan Design Report*. Plano, TX: PBMI; 2015.

Pharmacy Benefits Management Institute (PBMI). *2018 Trends in Specialty Drug Benefits Report*. Plano, TX: PBMI; 2018.

Rogers J, Dewey B. Understanding the Cost Dynamics of Antidiabetic Medications: A Trend Analysis (2016-2024). Milliman. 2024. Available at: https://edge.sitecorecloud.io/millimaninc5660-milliman6442-prod27d5-0001/media/Milliman/PDFs/2024-Articles/12-19-24_Antidiabetic-Rx-report.pdf. Accessed February 12, 2025.

Saunders AL, Bodine C, Snell-Bergeon J, Forlenza GP, Shah VN. Higher prevalence of hypoglycemia and unsafe driving practices in adults with type 1 diabetes. *Diabetes Care*. 2023;46(4):e92-e93.

Shah RB, Patel M, Maahs DM, Shah VN. Insulin delivery methods: past, present and future. *International Journal of Pharmaceutical Investigation.* 2016;6(1):1-9.

Shrestha SS, Honeycutt AA, Yang W, et al. Economic costs attributable to diabetes in each US state. *Diabetes Care*. 2018;41(12):2526-2534.

Trish E, Kaiser K, Joyce G. Association of out-of-pocket spending with insulin adherence in Medicare Part D. *JAMA Network Open*. 2021;4(1):e2033988.

Ukert BD, Giannouchos TV, Buchmueller TC. Colorado insulin copay cap: lower out-of-pocket payments, increased prescription volume and days' supply. *Health Affairs (Millwood)*. 2024;43(8):1147-1155.

Umpierrez GE, Davis GM, ElSayed NA, et al. Hyperglycemic crises in adults with diabetes: a consensus report. *Diabetes Care*. 2024;47(8):1257-1275.

University of California (UCSF) Diabetes Teaching Center. Insulin Basics - Type 2 Diabetes. 2025. Available at: https://diabetesteachingcenter.ucsf.edu/about-diabetes/type-2-diabetes/insulin-basics-type-2-diabetes. Accessed February 4, 2025.

Venkataraman K, Wee HL, Leow MK, et al. Associations between complications and health-related quality of life in individuals with diabetes. *Clinical Endocrinology*. 2013;78(6):865-873.

Wyatt R, Laderman M, Botwinick L, Mate K, Whittington J. Achieving Health Equity: A Guide for Health Care Organizations. IHI White Paper. Cambridge, MA: Institute for Healthcare Improvement; 2016.

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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 chbrp.org.

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