

Date of Hearing: May 18, 2020

ASSEMBLY COMMITTEE ON HEALTH
Jim Wood, Chair
AB 2203 (Nazarian) – As Amended May 4, 2020

SUBJECT: Insulin cost-sharing cap.

SUMMARY: Establishes a copayment cap for insulin and prohibits a health care service plan (health plan) contract or a health insurance policy that is issued, amended, delivered, or renewed on or after January 1, 2021, from imposing cost sharing on a covered insulin prescription, except for a copayment not to exceed \$50 per 30-day supply of insulin, and no more than \$100 total per month, regardless of the amount or type of insulin. Specifically, **this bill:**

- 1) Prohibits, for every health plan contract or health insurance policy that is issued, amended, delivered, or renewed on or after January 1, 2021, the copayment for an insulin prescription covered from exceeding \$50 per 30-day supply, and no more \$100 total per month, regardless of the amount or type of insulin needed to fill the covered person's prescription or prescriptions
- 2) Prohibits a health plan contract or health insurance policy that is issued, amended, delivered, or renewed on or after January 1, 2021, from imposing a deductible, coinsurance, or other cost-sharing requirement on an insulin prescription, except for a copayment subject to 1) above.
- 3) Makes various findings and declarations, including that approximately 263,000 Californians are diagnosed with type 1 diabetes each year and approximately 4,037,000 Californian adults have diabetes and insulin prices have nearly tripled, creating financial hardships for people who rely on it to survive.

EXISTING LAW:

- 1) Establishes the Department of Managed Health Care (DMHC) to regulate health plans under the Knox-Keene Health Care Services Plan Act of 1975 and the California Department of Insurance (CDI) to regulate health insurers under the Insurance Code.
- 2) Requires health plans and health insurers providing health coverage in the individual and small group markets to cover, at a minimum, essential health benefits (EHBs), including the ten EHB benefit categories in the Patient Protection and Affordable Care Act, and consistent with California's EHB benchmark plan, the Kaiser Foundation Health Plan Small Group HMO 30 plan, as specified in state law.
- 3) Specifies EHBs in the following 10 categories: ambulatory patient services; emergency services; hospitalization; maternity and newborn care; mental health and substance use disorder services, including behavioral health treatment; prescription drugs; rehabilitative and habilitative services and devices; laboratory services; preventive and wellness services and chronic disease management; and, pediatric services, including oral and vision care.
- 4) Requires health plans to provide basic health care services, including: physician services; hospital inpatient and ambulatory care services; diagnostic laboratory and diagnostic and

therapeutic radiologic services; home health services; preventive health services; emergency health care services; and, hospice care.

- 5) Limits to \$250, the copayment and coinsurance for prescribed, orally administered anticancer medications used to kill or slow the growth of cancerous cells. Sunsets this provision on January 1, 2024.
- 6) Limits, with respect to an individual or group health plan contract or health insurance policy that covers EHBs, the copayment, coinsurance, or any other form of cost sharing for a covered outpatient prescription drug for an individual prescription for a supply of up to 30 days to \$250; for a product with an actuarial value at or equivalent to a bronze level, limits cost sharing to \$500 for a supply of up to 30 days; and for a high deductible health plan the \$250 or \$500 limits apply only after an enrollee's deductible is met. Sunsets these provisions on January 1, 2024.
- 7) Prohibits a health plan or health insurer from maintaining a drug formulary with more than four tiers.
- 8) Requires every health care service plan contract that covers hospital, medical, or surgical expenses to include coverage for specified equipment and supplies for the management and treatment of diabetes.
- 9) Requires a health insurance policy to include coverage for specified 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.

FISCAL EFFECT: This bill has not yet been analyzed by a fiscal committee.

COMMENTS:

- 1) **PURPOSE OF THIS BILL.** According to the author, soaring prices have provided a wide range of concern about regulating the cost of prescription drugs. Diabetes affects millions of Californians a year. People with Type 1 diabetes and some with Type 2 diabetes must have insulin to live, but price increases for those whose coverage requires significant cost-sharing have made insulin unaffordable. This should not be the case. This bill implements much needed legislation that puts patients above profit. The author concludes that this bill is a concrete solution to the high-cost of insulin that is burdening people with diabetes across the state and an essential step to fulfilling our promise to all working families of California.
- 2) **BACKGROUND.** Maintaining a proper blood sugar (glucose) level is critical to maintaining good health and preventing complications for people with diabetes mellitus (DM). DM is a chronic disease with short- and long-term health effects that prevent the proper production of and/or response to insulin, a hormone that facilitates the transfer of glucose into cells to provide energy.
 - a) **CHBRP analysis.** AB 1996 (Thomson), Chapter 795, Statutes of 2002, requests the University of California to assess legislation proposing a mandated benefit or service and prepare a written analysis with relevant data on the medical, economic, and public health

impacts of proposed health plan and health insurance benefit mandate legislation. CHBRP was created in response to AB 1996. SB 125 (Hernandez), Chapter 9, Statutes of 2015, added an impact assessment on EHBs, and legislation that impacts health insurance benefit designs, cost sharing, premiums, and other health insurance topics.

CHBRP notes that there is substantial uncertainty regarding the impact of the COVID-19 pandemic on premium rates and health plan enrollment, including how the pandemic will impact healthcare costs in 2021. Since the variance of potential outcomes is significant, CHBRP does not take these effects into account as any projections at this point would be speculative, subject to federal and state decisions and guidance currently being developed and released. In addition, insurers', providers', and consumers' responses are uncertain and rapidly evolving to the public health emergency and market dynamic.

In its analysis of this bill, CHBRP states the following:

- i) **Enrollees covered.** CHBRP estimates that, in 2020, of the 21.7 million Californians enrolled in state regulated health insurance, 13.4 million of them will have insurance subject to this bill.
- ii) **Impact on expenditures.** CHBRP notes in its analysis that some health insurance benefit designs incorporate higher enrollee out-of-pocket expenses compared to the limits imposed under this bill in order to lower premiums. Reductions in allowed copayments, coinsurance, and/or deductibles can shift the cost to premium expenses. Based on claims data, the average cost of insulin per prescription per month is \$559 (as paid by insurers). For enrollees whose claims do not exceed the cost-sharing cap at baseline, the average cost sharing for insulin is \$18, and for those enrollees whose claims exceed the cost-sharing cap at baseline, the average cost sharing for insulin is \$74. Postmandate, cost sharing for enrollees who had claims exceeding the cap would experience a 51% reduction in cost sharing, resulting in an average cost share of \$36 per month. This bill would increase total net annual expenditures by \$2,581,000 or total net annual 0.002% for enrollees with DMHC-regulated plans and CDI-regulated policies. This is due to an increase in \$20,310,000 in total health insurance premiums paid by employers and enrollees for newly covered benefits, adjusted by a \$17,729,000 decrease in enrollee expenses for covered benefits. CHBRP estimates that total premiums for private employers purchasing group health insurance would increase by \$10,936,000, or 0.0202%. Total premiums for purchasers of individual market health insurance would increase by \$6,018,000, or 0.0384%. The greatest change in premiums as a result of this bill is for the small-group plans in the DMHC-regulated market (0.045% increase) and for the individual plans in the CDI-regulated market (0.047% increase). Based on the medical effectiveness review, which examined the literature on outcomes associated with better adherence to insulin, CHBRP assumed a 10% decrease in diabetes-related emergency department visits due to increased insulin utilization stemming from better adherence to insulin prescription regimens for those who underuse. Offsets stemming from this reduction in diabetes-related emergency department visits are estimated to result in \$1.1 million lower allowed costs postmandate in 2021. For baseline insulin users, this bill caps on cost sharing would only impact those enrollees who are above the cap at baseline. Overall, 38% of enrollees who use insulin at baseline would experience changes in cost sharing.

In addition, it is possible that some enrollees who had deferred insulin treatment due to cost could begin using insulin postmandate; thus, this group of enrollees would incur cost sharing postmandate where they did not have cost sharing at baseline. However, this group is estimated to be relatively small. Literature suggests approximately 2.5% of people who were prescribed insulin never started their prescription in the past year due to cost. Thus, for some enrollees, cost sharing may be the sole barrier to filling their insulin prescription. However, it is not known what the baseline cost sharing is for this group if they did fill their prescription (i.e., what proportion of non-users are above the cap), nor is it known what cost-sharing threshold would stimulate utilization among these enrollees. While CHBRP expects some demand response from this group when cost sharing is lowered postmandate, CHBRP expects it would be a relatively low utilization increase that would not substantially change the results of this analysis.

The enrollees most likely to experience the greatest out-of-pocket reductions postmandate are those who are enrolled in plans that require significant deductibles to be met before coinsurance or copayment is applied to the insulin purchase. Cost-sharing reductions due to this bill are the greatest for enrollees who have the highest out-of-pocket expense for insulin at baseline. Among the enrollees impacted by the cost-sharing cap, enrollees with out-of-pocket expenditures for insulin in the top 1% at baseline, have an annual savings of greater than \$2,806.

- (1) **Medi-Cal.** Although Medi-Cal managed care plans are subject to the Health and Safety Code, cost sharing for all Medi-Cal services is determined through the Welfare and Institutions Code. Therefore, because this bill does not amend Medi-Cal cost sharing, Medi-Cal managed care plans are not subject to the provisions of this bill.
 - (2) **The California Public Employees' Retirement System (CalPERS).** For CalPERS HMO enrollees, the impact on premiums is \$0 because there are no enrollees for whom cost sharing for insulin prescription is higher than the cap at baseline.
 - (3) **Number of Uninsured in California.** Since the change in average premiums does not exceed 1% for any market segment, CHBRP expects no measurable change in the number of uninsured persons due to this bill.
- iv) **EHBs.** This bill would not require coverage for a new state benefit mandate and instead modifies cost-sharing terms and conditions of an already covered medication.
- v) **Medical effectiveness.** Though there is a large body of literature on the effects of cost sharing and adherence to prescribed drug regimens, CHBRP found limited evidence from five cross-sectional and retrospective studies on cost-related insulin use/adherence that cost sharing affects insulin use and adherence in patients with diabetes. These studies provided limited evidence that higher cost sharing reduces adherence to insulin and lower cost sharing increases adherence to insulin. CHBRP found insufficient evidence on the associated effect of cost sharing for insulin on diabetes-related health outcomes, outpatient visits, emergency department visits, hospitalizations, long-term complications, and disability/absenteeism rates. Though the studies presented did report on these health and utilization outcomes, the findings

were not specific to the effect of insulin alone, but combined with use of other oral antidiabetic medications and testing supplies.

- iv) **Benefit coverage.** CHBRP estimates at baseline there are 121,442 enrollees who use insulin in plans regulated by DMHC and policies regulated by CDI, where 75,059 enrollees using insulin have cost sharing that does not exceed this bill's cost-sharing cap. CHBRP estimates 46,383 enrollees using insulin have cost sharing that exceeds this bill's cap. Postmandate, 100% of enrollees with cost sharing that exceeds the cap at baseline would have cost sharing below the cap of \$50 or \$100.
- v) **Utilization.** Postmandate, the group whose claims exceeded the cost-sharing cap at baseline would experience an increase in utilization because this group would experience a decrease in cost sharing due to this bill. Utilization among enrollees who exceeded the cap at baseline is higher than those under the cap, which reflects the greater need for insulin in this group of enrollees. To estimate changes in utilization postmandate, CHBRP applied an estimate of price elasticity of demand to enrollees exceeding the cap at baseline. CHBRP assumes that for every 10% reduction in cost sharing, insulin utilization increases by 2.57%. Based on this assumption, CHBRP estimates a 51% reduction in cost sharing for those enrollees who have cost sharing exceeding the cost-sharing cap at baseline, and therefore estimates a 13% increase in utilization of insulin postmandate for those enrollees.
- iv) **Public health.** In the first year postmandate, 46,383 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 13% increase in utilization of insulin. CHBRP found limited evidence that cost sharing for insulin is effective in improving adherence to insulin in patients with diabetes, and insufficient evidence on the effect of cost sharing for diabetes-related health outcomes. Therefore, this bill may result in improved glycemic control, a reduction in healthcare utilization, a reduction in long-term complications attributable to DM, and improved quality of life for enrollees that experience a decrease in cost sharing and improved insulin adherence, or begin using insulin due to reduced costs
- iv) **Long-term impacts.** CHBRP estimates annual insulin utilization after the initial 12 months from the enactment of this bill would likely stay similar to utilization estimates during the first 12 months postmandate. Health care utilization due to improved diabetes management may change in the long term. Reductions in significant complications or comorbidities may take years to develop, but are not trivial. Similarly, reductions in significant complications or comorbidities may take years to develop, as would significant differences in disability and absenteeism. This bill is unlikely to impact these public health outcomes statewide, but at a person-level it could make a substantial difference in long-term healthcare spending, morbidity, and mortality. CHBRP estimates that this bill would improve disparities related to income for some enrollees who have cost-related barriers to insulin use. CHBRP is unable to estimate reductions in existing disparities. However, because the prevalence of diabetes is higher for African Americans than for whites, and there is evidence that cost-related medication non-adherence is also more associated with African Americans, it is possible that this disparity may be reduced for the population this bill impacts. The impact of this bill on premature mortality is unknown due to the lack of

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

- b) **Other states.** According to CHBRP, at least eight states have passed laws that limit cost sharing (copayment, coinsurance, or deductibles) for insulin, as of April 2020. Colorado, Illinois, New York, Washington, and West Virginia currently limit cost sharing for an insulin prescription to \$100 per 30-day supply, regardless of the amount or type of insulin. Maine limits cost sharing for insulin to \$35 for a 30-day supply, regardless of the amount. New Mexico limits cost sharing for a 30-day supply of preferred formulary insulin or the medically necessary equivalent to \$25.¹⁶ Utah limits cost sharing for a 30-day supply of at least one insulin in each “therapy category” to \$30 and prohibits insulin from being subject to the deductible. Similar legislation has been introduced in at least 30 other states. Some states would limit cost sharing for insulin prescriptions to \$25 for a 30-day supply, while others would limit cost sharing for insulin prescriptions to \$100 for a 30-day supply. Virginia also recently passed legislation that limit cost-sharing to \$50.
- c) **Federal proposals.** On March 11, 2020, the Centers for Medicare & Medicaid Services announced the Part D Senior Savings Model, a voluntary model that enables participating Part D enhanced plans to lower Medicare beneficiaries’ out-of-pocket costs for insulin to a maximum \$35 copay per 30-day supply throughout the benefit year. The program will be in effect for the next plan year, beginning January 1, 2021. Two current federal pieces of legislation would impact cost sharing for prescription drugs in general and would potentially result in a reduction in cost sharing for insulin. One of the federal bills would limit total annual out-of-pocket expenses for prescription drugs for those enrolled in Medicare Part D. The other federal bill would limit annual out-of-pocket expenses to \$2,000 and S. 2543 would limit annual out-of-pocket expenses to \$3,100.
- d) **Insulin cost increases.** According to CHBRP, the average list price of brand-name insulin nearly tripled between 2007 and 2018, increasing by 262%. While the average net price also increased, the increase was smaller (51%) and was offset by discounts such as those paid by manufacturers. The price increases were higher between 2012 and 2015, but began to level out in 2016. The reasons insulin prices are increasing are not entirely clear but are due in part to the complexity of drug pricing in general and of insulin pricing in particular. As the price of insulin has increased, so too have patient out-of-pocket costs. Between 2006 and 2013, average out-of-pocket costs per insulin user among Medicare Part D enrollees increased by 10% per year for all insulin types. The increases in list price, net price, and out-of-pocket costs are substantially higher than increases due to inflation. Overall inflation between 2006 and 2013 was 2.2%, medical care service costs increased by 3.8%, and spending for all prescription drugs increased by an average of 2.8%.

Additionally, the American Diabetes Association states that as the price of insulin continues to rise, individuals with diabetes are often forced to choose between purchasing the medications or paying for other necessities, exposing them to serious short- and long-term health consequences. To find solutions to the issue of insulin affordability, there

must be a better understanding of the transactions throughout the insulin supply chain, the impact each stakeholder has on what people with diabetes pay for insulin, and the relative efficacy of therapeutic options.

- e) **State proposals.** At the beginning of this year, the Governor outlined a list of prescription drug proposals. At this time, it is unclear whether the Governor will move forward with these proposals. These proposals included the following:
- iv) **Generic Drug Manufacturing and Labelling:** California will be the first state to create its own generic drug label and make generic prescription drugs available for sale to all Californians: The Administration will negotiate partnerships to establish the state's own generic drug label. The state would contract with one or more generic drug manufacturers to manufacture select generic drugs on behalf of the state and participating entities. According to the Governor's proposed budget, this proposal would increase competition in the generic market, resulting in lower generic drug prices for all purchasers.
 - v) **Golden State Drug Pricing Schedule:** The Administration proposes to establish a single market for drug pricing within the state. This proposal would enable all purchasers—Medi-Cal, California Public Employees' Retirement System, Covered California, private insurers, self-insured employers, and others, to combine their purchasing power. Drug manufacturers would have to bid to sell their drugs, at a uniform price, in the California market. California would invoke a most-favored-nation clause in the manufacturer price bid, which would require manufacturers to offer prices at or below the price offered to any other state, nation, or global purchaser if they wish to sell their products in California.
 - vi) **Medi-Cal Best Price:** Current law authorizes the Department of Health Care Services (DHCS) to negotiate state supplemental rebates based, in part, on the best prices that manufacturers provide to other purchasers within the United States. The Budget proposes to expand the DHCS's authority to consider the best prices offered by manufacturers internationally when conducting negotiations for state supplemental rebates.
 - vii) **Rebates for Non-Medi-Cal Purchases:** The Budget proposes to leverage the purchasing power of the Medi-Cal program to negotiate supplemental rebates on behalf of target populations outside the Medi-Cal program.
- 3) **SUPPORT.** According to the American Diabetes Association, sponsor of this bill, this bill is part of a movement that is sweeping the nation to protect people living with diabetes who need insulin to survive. Over 35 states have introduced similar legislation to limit out-of-pocket costs for insulin. To date, three states have approved this legislation and five more legislatures have passed legislation that is now awaiting gubernatorial action. As our nation grapples with the economic uncertainty amid our COVID-19 pandemic, this bill is more important than ever to protect people living with diabetes who need affordable access to insulin. The California Academy of Family Physicians writes that making insulin more affordable will help keep patients who use this lifesaving drug healthy and out of health care settings where they can be exposed to the virus which poses increased risks for people with diabetes.

- 4) **SUPPORT IF AMENDED.** Health Access California, in support if amended, requests an amendment indicating that the co-pay cap apply to the state generic of insulin or the lowest-cost therapeutic equivalent.
- 5) **OPPOSITION.** America's Health Insurance Plans contends that this legislation is potentially unworkable and does nothing to prevent drug manufacturers, the source of high insulin prices, from continuing to increase prescription drug prices. The Association of California Life and Health Insurance Companies and the California Association of Health Plans contend that the prescription drug copay cap in existing law was carefully and thoughtfully negotiated to protect all consumers from the high cost of specialty drugs while ensuring that the cost of healthcare remained affordable. Unfortunately, this bill directly interferes with that goal, as it sets a precedent that treats one class of drugs differently as it creates a special category for insulin. This inevitably will increase the cost of premiums for all insureds and enrollees by inappropriately socializing the cost of these drugs against all rate payers
- 6) **RELATED LEGISLATION.** AB 1943 (Grayson) state the intent of the Legislature to enact legislation that would help ensure that insulin is available and affordable to all Californians. AB 1943 is pending in Assembly Rules Committee.
- 7) **PREVIOUS LEGISLATION.**
 - a) SB 1021 (Weiner), Chapter 787, Statutes of 2018, provides that the copayment, coinsurance, or any other form of cost sharing for a covered outpatient prescription drug for an individual prescription shall not exceed \$250 for a supply of up to 30 days, except as specified and requires a non-grandfathered individual or small group plan contract or policy to use specified definitions for each tier of a drug formulary. Sunsets provisions of this bill on January 1, 2024.
 - b) AB 1860 (Limon), Chapter 427, Statutes of 2018, prohibits, until January 1, 2019, an individual or group health plan contract or health insurance policy, that provides coverage for prescribed, orally administered anticancer medications used to kill or slow the growth of cancerous cells from requiring an enrollee or insured to pay, notwithstanding any deductible, a total amount of copayments and coinsurance that exceeds \$250 for an individual prescription of up to a 30-day supply of a prescribed orally administered anticancer medication, as specified. Sunsets provisions of this bill on January 1, 2024.
 - c) SB 17 (Hernandez), Chapter 603, Statutes of 2017, requires health plans and insurers that report rate information through the existing large and small group rate review process to also report specified information related to prescription drug pricing to DMHC and CDI. Requires DMHC and CDI to compile specified information into a consumer-friendly report that demonstrates the overall impact of drug costs on health care premiums. Requires drug manufacturers to notify specified purchasers, in writing at least 90 days prior to the planned effective date, if it is increasing the wholesale acquisition cost of a prescription drug by specified amounts. Requires drug manufacturers to notify Office of Statewide Health Planning and Development (OSHPD) three days after FDA approval when introducing a new drug to market, as specified. Requires drug manufacturers to provide specified information to OSHPD related to the drug's price.

8) POLICY COMMENTS.

- a) Attorney General (AG) role. As stated above, it is unclear why insulin prices are increasing and states that have passed legislation have included a provision regarding the role of the AG in compiling and analyzing information as it relates to insulin pricing. The author may wish to add a similar mechanism to allow the State AG to evaluate and analyze increasing drug costs.
- b) Sunset. The author may wish to amend this bill to include a sunset similar to the copay caps as described in existing law above to evaluate the potential impacts to health care premiums.

REGISTERED SUPPORT / OPPOSITION:**Support**

American Diabetes Association (sponsor)
 The Health Trust
 American Academy of Pediatrics California
 American Congress of Obstetricians & Gynecologists – District IX
 Association of Diabetes Care & Education Specialists
 Beyond Type 1
 Biocom
 California Academy of Family Physicians
 California Academy of Physician Assistants
 California Chronic Care Coalition
 California Podiatric Medical Association
 Carb DM
 Children with Diabetes
 Diabetes Political Action Committee
 The diaTribe Foundation
 The Health Trust
 Latino Coalition for a Healthy California
 National Diabetes Volunteer Leadership Council
 National Psoriasis Foundation

Opposition

America's Health Insurance Plans
 Association of California Life & Health Insurance Companies
 California Association of Health Plans
 California Chamber of Commerce

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