Date of Hearing: July 11, 2023

ASSEMBLY COMMITTEE ON HEALTH
Jim Wood, Chair
SB 873 (Bradford) – As Introduced February 17, 2023

SENATE VOTE: 28-2

SUBJECT: Prescription drugs: cost sharing.

SUMMARY: Requires an enrollee's or insured's defined cost sharing for each prescription drug to be calculated at the point of sale (POS) based on a price that is reduced by an amount equal to 90% of all rebates received, or to be received, in connection with the dispensing or administration of the drug, no later than January 1, 2025. Requires a health care service plan (health plan) or health insurer to, among other things, pass through to each enrollee or insured at the POS a good faith estimate of the enrollee's or insured's decrease in cost sharing. Requires the Department of Managed Health Care (DMHC) and the California Department of Insurance (CDI) Commissioner to submit an annual report on the impact of these provisions to the appropriate policy committees of the Legislature, as specified. Sunsets the provisions of this bill on January 1, 2027. Specifically, **this bill**:

POS Rebates

1) Requires an enrollee's or insured's defined cost sharing for each prescription drug to be calculated at the POS based on a price that is reduced by an amount equal to at least 90% of all rebates received, or to be received, in connection with the dispensing or administration of the drug, beginning no later than January 1, 2025.

2) Requires the health plan or insurer to pass through to each enrollee or insured at the POS a good faith estimate of the enrollee or insured's decrease in cost sharing required pursuant to this bill.

3) Requires the health plan or insurer to provide the enrollee or insured with an end-of-calendar-year reconciliation for any cost-sharing reductions owed to the enrollee or insured pursuant to this bill that were not passed on to the enrollee or insured through the estimated amount at the POS. Prohibits a health plan or insurer from recovering from an enrollee or insured any inaccurate estimate of cost-sharing reductions.

4) Requires each health plan or insurer to, either directly or indirectly through its agents, calculate the enrollee or insured's defined cost sharing and provide the dispensing pharmacy with the enrollee or insured's defined cost sharing for each prescription drug as required pursuant to 1) above.

5) Authorizes a health plan or insurer to decrease an enrollee or insured's defined cost sharing by an amount greater than that required pursuant to 1) above.

6) Adds a severability clause to address any conflict with federal requirements.

7) Requires cost sharing, including copayments, coinsurance, deductibles, and any other form of cost sharing to be consistent existing law on drug formularies and other provisions of this bill.

8) Defines the following:

   a) Defines cost sharing as a deductible payment or coinsurance amount imposed on an enrollee or insured for a covered prescription drug under the enrollee's health plan contract or insured's policy;
   b) Health plan, as defined as defined in Health & Safety Code (HSC) § 1345, and includes a specialized plan;
   c) Price protection rebates as a negotiated price concession that accrues directly or indirectly to a health plan or insurer, or other party on behalf of the health plan or insurer, in the event of an increase in the wholesale acquisition (WAC) cost of a drug above a specified threshold; and,
   d) Rebate as both of the following:
      i) Negotiated price concessions, including base price concessions, whether or not described as a "rebate," and reasonable, good faith estimates of price protection rebates and performance-based price concessions from a manufacturer, dispensing pharmacy, or other party in connection with the dispensing or administration of a prescription drug that may accrue directly or indirectly to the health care service plan, or other party on behalf of the health plan or insurer, including, but not limited to, health care service plan-owned pharmacy benefit managers (PBMs), during a calendar year; and,
      ii) Reasonable, good faith estimates of negotiated price concessions, fees, and other administrative costs that are passed through, or are reasonably anticipated to be passed through, to the health plan or insurer and serve to reduce the health plan or insurer's liabilities for a prescription drug.

9) Requires DMHC or CDI, on or before March 1 each year, to provide a report on this bill's impact on drug prices and health care premium rates to the appropriate policy committees of the Legislature.

10) Sunsets 1) to 9) above on January 1, 2027.

Prescription drug reporting requirements

11) Requires a health plan and insurer that reports rate information pursuant to existing law to also report the following:

   a) The 25 most frequently prescribed drugs with a POS rebate pursuant to 1) above; and, the 25 most costly drugs by total annual plan spending with a POS rebate pursuant to 1) above;
   b) For each plan with a prescription drug benefit that the health plan or insurer issued for delivery, renewed, amended, or continued during the immediately preceding calendar year, all of the following:
      i) The aggregate dollar amount of all rebates that the health plan or insurer or a designee of the health plan or insurer collected directly or indirectly from all pharmaceutical

manufacturers in connection with the design and administration of the plan, which are attributable to enrollee or insured drug utilization during that calendar year;
ii) The percentage of those rebates that the health care service plan made available to enrollees to reduce cost sharing for prescription drugs at the point of sale;
iii) The percentage of those rebates that the health care service plan utilized to reduce the portion of premiums allocated to each of prescription drug expenditures, hospital expenditures, medical expenditures, administrative costs, and other expenditures; and,
iv) The aggregate dollar amount of all health plan or insurer administrative service fees that the health plan or insurer or a designee of the health plan or insurer paid to a PBM or its designee in connection with the PBM's managing or administering the pharmacy benefit and administering, invoicing, allocating, and collecting rebates.

12) Prohibits DMHC and CDI, in their existing reporting requirement from revealing identity of a specific manufacturer, the prices charged for specific drugs or classes of drugs, or the amount of any rebates provided for specific drugs or classes of drugs, or otherwise have the potential to compromise the financial, competitive, or proprietary nature of any of that information.

13) Sunsets the POS rebate reporting provisions on January 1, 2027.

EXISTING LAW:

1) Establishes DMHC to regulate health plans under the Knox-Keene Health Care Service Plan Act of 1975 and the California Department of Insurance (CDI) to regulate health insurers. [HSC §1340, *et seq*., and Insurance Code (INS) §106, *et seq*.]

2) Establishes as California's Essential Health Benefits (EHBs) benchmark the Kaiser Small Group Health Maintenance Organization, existing California mandates, and ten Affordable Care Act (ACA) mandated benefits, including prescription drugs. [HSC §1367.005 and INS §10112.27]

3) Requires a health plan or health insurer that reports rate information, as specified, to report information no later than October 1 of each year that demonstrates the overall impact of drug costs on health care premiums. [HSC §1356.243 and INS §10123.205]

4) Requires health plans and insurers, for all covered prescription drugs, including generic drugs, brand name drugs, and specialty drugs dispensed at a plan pharmacy, network pharmacy, or mail order pharmacy for outpatient use, to report:
   a) The 25 most frequently prescribed drugs;
   b) The 25 most costly drugs by total annual plan spending; and,
   c) The 25 drugs with the highest year-over-year increase in total annual plan spending. [HSC §1356.243 and INS §10123.205]

5) Requires DMHC and CDI to compile the information from 4) above into a report for the public and Legislators where the data is aggregated and does not reveal information specific to individual plans. Requires the report to be published on DMHC's and CDI's website. [HSC §1356.243 and INS §10123.205]

6) Defines a PBM as a person, business, or other entity that, pursuant to a contract with a health plan, manages the prescription drug coverage provided by the health plan, including, but not limited to, the processing and payment of claims for prescription drugs, the performance of drug utilization review, the processing of drug prior authorization requests, the adjudication of appeals or grievances related to prescription drug coverage, contracting with network pharmacies, and controlling the cost of covered prescription drugs. [HSC §1385.001]

7) Requires a health plan that contracts with a PBM to require the PBM to comply with specified requirements including registration with DMHC and to exercise good faith and fair dealing in the performance of its duties. [HSC §1385.004 and §1385.005]

8) Requires the failure by a health plan to comply with PBM contractual requirements to constitute grounds for disciplinary action. Requires the DMHC Director, as appropriate, to investigate and take enforcement action against a health plan that fails to comply with these requirements and to periodically evaluate contracts between health plans and PBMs to determine if any audit, evaluation, or enforcement actions should be undertaken by DMHC. [HSC §1385.006]

9) Prohibits, 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 from exceeding $250; for a product with an actuarial value at or equivalent to a Bronze level, limits cost sharing to not more than $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. [HSC §1342.73 and INS §10123.1932]

10) Establishes definitions for each tier of a health plan contract or health insurance policy for a nongrandfathered individual or small group product maintains a drug formulary grouped into tiers that includes a fourth tier:
    a) Tier one to consist of most generic drugs and low-cost preferred brand name drugs;
    b) Tier two to consist of nonpreferred generic drugs, preferred brand name drugs, and any other drugs recommended by the health plan or insurer's pharmacy and therapeutics committee based on safety, efficacy, and cost;
    c) Tier three to consist of nonpreferred brand name drugs or drugs that are recommended by the health plan or insurer's pharmacy and therapeutics committee based on safety, efficacy, and cost, or that generally have a preferred and often less costly therapeutic alternative at a lower tier; and,
    d) Tier four to consist of drugs that are biologics, drugs that the Food and Drug Administration (FDA) or the manufacturer requires to be distributed through a specialty pharmacy, drugs that require the enrollee to have special training or clinical monitoring for self-administration, or drugs that cost the health plan more than six hundred dollars ($600) net of rebates for a one-month supply.

    Permits health plans and health insurers to maintain a drug formulary with fewer than four tiers. Prevents the law from being construed to require a health plan or health insurer to impose cost sharing, or to require cost sharing for prescription drugs that state or federal law otherwise requires to be provided without cost sharing. [HSC §1342.71(b) and INS §10123.193(b)]

11) Prohibits a person who manufactures a prescription drug from offering in the state a discount, repayment, product voucher, or other reduction in an individual's out of pocket (OOP) expenses associated with their health insurance, health plan, or other health coverage, including, but not limited to, a copayment, coinsurance, or deductible, for a prescription drug if a lower cost generic drug is covered under the individual's health insurance, health plan, or other health coverage on a lower cost-sharing tier that is designated to be therapeutically equivalent as indicated by the FDA's "Approved Drug Products with Therapeutic Equivalence Evaluations." [HSC §132000]

FISCAL EFFECT: According to the Senate Appropriations Committee, unknown ongoing costs, likely hundreds of thousands (Managed Care Fund), for DMHC to administer the provisions. The CDI estimates costs of $269,000 in 2023-24, $325,000 in 2024-25, and $12,000 in 2025-56 and ongoing thereafter (Insurance Fund) to administer the provisions.

COMMENTS:

1) **PURPOSE OF THIS BILL**. According to the author, this bill will ensure patients are better able to afford their medications by reforming the state's prescription drug rebate system to ensure it benefits patients, not health care corporations. By including transparency provisions and requiring 90% of manufacturer rebates to be passed on at the pharmacy counter, patients will not only be able to better afford their medicines, they will also better adhere to their doctors' decisions by not rationing or skipping doses due to cost. The author concludes that since 2020, more than 100 similar measures have been introduced across the nation and in 2021 West Virginia passed a law (HB 2263) that requires 100% of rebates to first benefit the patient at the POS and then be used to lower premiums more broadly.

2) **BACKGROUND**.

   a) **Prescription Drug Spending and SB 17 DMHC Report.** SB 17 (Hernandez), Chapter 603, Statutes of 2017, requires health plans in the commercial market to annually report their prescription drug costs to the DMHC. This report looks at the impact of the cost of prescription drugs on health plan premiums and compares this data across the reporting years. The DMHC considers the total volume of prescription drugs prescribed by health plans and the total cost paid by health plans for these drugs, on both an aggregate spending level and a per member per month (PMPM) basis and compares the annualized data. The DMHC also analyzes how the 25 most frequently prescribed drugs, the 25 most costly drugs, and the 25 drugs with the highest year-over-year increase in total annual spending impacted health plan premiums over the course of the last four years. The most recent report notes the following key findings:

      i) Health plans paid about $10.8 billion for prescription drugs in 2021, an increase of almost $700 million or 6.6% from 2020. On a PMPM basis, health plans paid $71.46 in 2021, which is an increase of $4.56 PMPM from 2020. Since 2017, prescription drug costs paid by health plans increased by $2.1 billion or 22.2%. Unless otherwise specified, the prescription drug costs in this report are not adjusted for any manufacturer rebates. However, this report includes the total manufacturer drug rebates collected by health plans.

      ii) Prescription drugs accounted for 13.3% of total health plan premiums in 2021, an increase from 12.7% in 2020. Prescription drugs accounted for 12.8% and 12.7% of total health plan premiums in 2019 and 2018, respectively. The figures in this report

include only those prescription drugs dispensed through retail or mail order pharmacies, and do not include drugs that are provided in a hospital, administered in a doctor office, or otherwise paid for through capitated payments to delegated providers. Therefore, the 13.3% of premium in 2021 does not capture all costs of prescription drugs paid by health plans.

iii) Total prescription drug costs increased by 6.6% in 2021, whereas total medical expenses increased by 9.2%. Overall, total health plan premiums increased by 2.2% from 2020 to 2021.

iv) On a PMPM basis, health plans' prescription drug costs increased by 6.8%, medical expenses increased by 9.4% and health plan premiums increased by 2.4% from 2020 to 2021.

v) Manufacturer drug rebates totaled approximately $1.674 billion, up from $1.437 billion in 2020 and $1.205 billion in 2019. This represents about 15.5% of the $10.8 billion spent on prescription drugs in 2021. On a PMPM basis, manufacturer drug rebates equaled $11.10 PMPM, up from $9.51 PMPM in 2020. This also equates to 15.5% of the $71.46 PMPM health plans paid for prescription drugs in 2021. Health plans provided the total manufacturer drug rebate information for all drugs. The manufacturer drug rebate was not provided for the top 25 most frequently prescribed drugs, the top 25 most costly drugs or top 25 drugs with highest year-over-year increase in total annual spending.

vi) While specialty drugs accounted for only 1.6% of all prescription drugs dispensed, they accounted for 62.9% of total annual spending on prescription drugs. "Specialty Drug" is a drug with a negotiated monthly cost that exceeds the threshold for a specialty drug under the Medicare Part D program.

vii) Generic drugs accounted for 88.2% of all prescribed drugs but only 16.3% of the total annual spending on prescription drugs.

viii) Brand name drugs accounted for 10.2% of prescriptions and constituted 20.8% of the total annual spending on prescription drugs.

ix) The 25 most frequently prescribed drugs represented 49.2% of all drugs prescribed and approximately 42.5% of the total annual spending on prescription drugs.

x) For the 25 most frequently prescribed drugs, enrollees paid 3.3% of the cost of specialty drugs, 9.2% of the cost of brand name drugs, and 62.4% of the cost of generics.

xi) Of the 13.3% of total health plan premium that was spent on prescription drugs, the 25 most costly drugs accounted for 6.8%.

xii) Overall, health plans paid 92.6% of the cost of the 25 most costly prescribed drugs across all three categories (generic, brand name and specialty).

xiii) For the first time, the Pfizer and Moderna COVID-19 vaccines were amongst the 25 most frequently prescribed drugs, 25 most costly drugs and 25 drugs with the highest year-over year increase in total spending. While the cost of the COVID-19 vaccines was covered by the federal government, health plans were responsible for the cost of administration of a significant number of vaccines in 2021.

b) Brand Name Drug Pricing. In November 2021, as part of its Controlling Health Care Costs series, the Commonwealth Fund presented findings from a number of studies on prescription drug costs and spending in the United States with other high-income countries to review that the main culprit is high United States prices for brand-name drugs and that high drug prices are a financial strain for patients, employers, and state and federal governments. Another 2019 Commonwealth Fund article entitled, "Perverse

Incentives: Why Brand-Name Drugs Can Cost Less Than Generics For Medicare Beneficiaries," noted that generic drugs, lower-cost alternatives to brand-name drugs, are a popular tool for curbing pharmaceutical spending. Since they lower costs to payers (and in the case of Medicare, taxpayers), patients typically face lower cost-sharing for these products. However, the article notes that's not always the case for Medicare beneficiaries with Part D outpatient drug coverage. Some people enrolled in a Medicare Part D drug plan spend more filling generic drug prescriptions than their peers spend on brand-name equivalents. One reason is that Medicare patients using brand-name drugs reap a cost reduction that users of generics do not, a manufacturer discount that counts toward their OOP spending. Adopted as part of the ACA, the discount means that beneficiaries who use higher-cost branded drugs sometimes end up spending less of their own money than those taking a lower-cost generic. The Bipartisan Budget Act (BBA) of 2018 modified the Part D benefit to ensure that beneficiaries would not pay more for biosimilars (generic versions of large-molecule drugs, or biologics) than their brand-name counterparts. However, this protection does not extend to generic drugs. A Commonwealth Fund supported study looked at nine brand-name products with generic or biosimilar equivalents to see how the current Part D benefit design affects OOP spending.

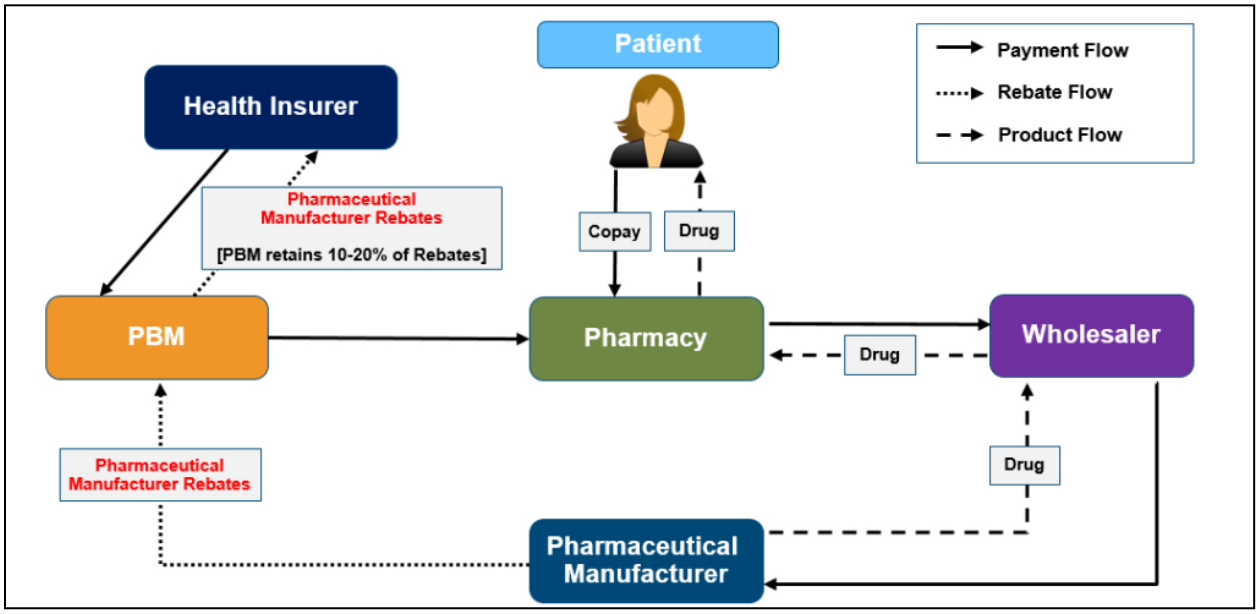
According to the study, lowering patients' OOP spending for biosimilars but not for generic drugs, and by increasing discounts on brand-name products, the BBA perpetuated incentives for doctors and patients to opt for higher-cost brand-name drugs. This raises several concerns. Incentives to use brand-name products may decrease the market share for generics or even discourage manufacturers from developing more of them. Moreover, patients may not have the option in their Part D plans to switch between brand-name and generic drugs, as plans may not offer both. To address the problem, the authors suggest eliminating manufacturer discounts from OOP spending calculations or extending to generics the discounts currently available for brand-name drugs and biosimilars. By lowering patients' OOP spending for biosimilars but not for generic drugs, and by increasing discounts on brand-name products, the study's author states that the BBA perpetuated incentives for doctors and patients to opt for higher-cost brand-name drugs.

c) Prescription Drug Rebates. According to the California Health Benefit Review Program (CHBRP), almost all Californians enrolled in plans regulated by the DMHC and policies regulated by the CDI have coverage for outpatient prescription drugs through a pharmacy benefit that is part of the plan or policy. In this arrangement, the health insurer may use an in-house PBM of their own or subcontract with a PBM. This bill addresses the flow of outpatient prescription drug rebates between manufacturers and PBMs and plan sponsors.

According to a 2018 Milliman White Paper (White Paper), for brand-name prescription drugs in competitive therapeutic classes, rebates are often the deciding factor when health insurers choose how to cover a drug, and how much a patient should pay for it. Many patients interact only with their doctors and pharmacies to obtain their prescription drugs. However, the prescription drug distribution chain is complex and involves several stakeholders. These stakeholders' contracts determine how much a patient's health insurance pays for prescription drugs and the patient's OOP costs. While there are many factors that influence how health insurers cover prescription drugs, pharmaceutical manufacturer rebates are one of the key drivers. A *rebate* is the return of part of the purchase price by the seller to the buyer. Rebates are used by a wide array of

manufacturers, such as automakers, electronics companies, and pharmaceutical manufacturers, to drive demand for their products. Prescription drug rebates are generally paid by a pharmaceutical manufacturer to a PBM, who then shares a portion with the health insurer. Rebates are mostly used for high-cost brand-name prescription drugs in competitive therapeutic classes where there are interchangeable products (rarely for generics), and aim to incentivize PBMs and health insurers to include the pharmaceutical manufacturer's products on their formularies and to obtain preferred "tier" placement.

The White Paper further defines a formulary as the list of prescription drugs that a health insurer will cover and assigns particular products to one of several tiers (typically two to four in commercial formularies) with different member cost sharing. These formularies are generally developed by PBMs, which negotiate contracted prescription drug prices and rebates with pharmaceutical manufacturers on behalf of their health insurer clients. Formulary tiers are often designed to promote low-cost prescription drugs; for example, a low-cost generic prescription drug may require a $5 copay, a preferred brand prescription drug with a rebate may require a $20 copay, and a non-preferred brand prescription drug without a rebate may require a $50 copay. Rebate contract terms are trade secrets and vary widely among brands, pharmaceutical manufacturers, and health insurers, but tend to be highest for brands in therapeutic classes with competing products. This secrecy makes cost comparisons of competing brands on the basis of price alone very difficult (if not impossible) to estimate. Rebates therefore create a "black box" in the prescription drug distribution chain, the patient (and often the commercial health insurer) does not know how much the pharmaceutical manufacturers are paying in rebates, and how much of the rebates PBMs are keeping before passing the remainder to the health insurer. While average rebates are close to 20% of the price, some brands have no rebates and others are believed to offer rebates of over 60%. Together with contracted prices, rebates are a key factor in deciding whether to include a specific prescription drug on a commercial health insurer's formulary and in which tier. Therefore, rebates impact the finances of all stakeholders involved in the prescription drug distribution chain.



From CHBRP AB 933 (Daly) analysis - Source: Dieguez et al., 2018.

d) **POS**. According to CHBRP, the pharmacy POS is a system that allows pharmacies to enter outpatient, self-administered prescription claims in "real time" into the payment system. Within seconds, providers receive confirmation that a claim has been processed. A POS system is commonly used in a retail pharmacy setting. CHBRP cited a recent white paper that found almost half of individuals with Medicare Part D coverage would see a reduction in OOP spending if patient cost-sharing were based on the price negotiated after the rebate (or net price), rather than the pre-rebate list price. The most important potential benefit of POS rebates is that patients who require extended use of expensive medications for chronic conditions could have their financial burden lessened. CHBRP notes that although evidence is limited, POS rebates could improve adherence and consequently clinical outcomes. Aligning patient cost sharing with allowed retail price after rebates can enhance the effectiveness of value-based formularies if patient cost sharing are lowest, because of the POS rebates, for the most cost-effective treatment.

CHBRP notes that PBMs may react to POS rebates by adjusting formularies to achieve desired business outcomes. For instance, PBMs may reconsider the formulary tier of drugs, especially in instances where there is an opportunity to retain comparably higher rebates postmandate or achieve more appealing discounts or rebates when evaluated by plan sponsors. POS rebates give individual patients some of the money that would otherwise flow back to the plan sponsor. It should be noted that the payer no longer has the option to apply those funds to reduce health insurance premiums. In addition, POS rebates to the patient, by themselves do not address much of the financial burden faced by many patients who need high-cost medicines. Patients requiring expensive, chronic treatment may still reach their annual OOP maximum. Furthermore, while applying POS rebates can reduce OOP cost for specific patients, that is dependent on the drug and rebate amount. Finally, for those patients who have reached their OOP maximum in their respective plans, rebate savings will continue to flow directly to the payer.

e) **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 states the following in its analysis of 933 (Daly) of 2021, which is similar to this bill:

- **i)** **Enrollees covered**. CHBRP estimates that 836,000 enrollees use higher cost brand-name or specialty drugs and have plan designs for which cost sharing might change if this bill were enacted. However, the actual number of impacted enrollees will be lower as not all brand-name and specialty drugs may be eligible for manufacturer rebates. Details on manufacturer rebate programs are proprietary; for instance, manufacturers prohibit the disclosure of which drugs may have manufacturer rebates available. As such, CHBRP is unable to estimate the number of impacted individuals for which cost sharing might change if this bill were enacted.
- **ii)** **Utilization**. Among enrollees with potentially impacted cost sharing at baseline, there are 836,000 enrollees who use brand-name or specialty medications. Postmandate, the number of enrollees who use brand-name or specialty medications

with potentially impacted cost sharing would increase to 840,000 due to a reduction in cost barriers for some enrollees.

iii) Impact on expenditures. This bill would increase total net annual expenditures by $129,725,000, or 0.10%, for enrollees with health insurance subject to state-level benefit mandates. This is due to a $200,558,000 increase in total health insurance premiums and a $70,833,000 decrease in enrollee share of cost for services for newly covered members.

(1) California Public Employees' Retirement System. CHBRP projects no measurable impact to CalPERS.

(2) Covered California – Individually Purchased. CHBRP projects total premium expenditures for individually purchased plans in Covered California to increase by $33,045,000, or 0.30%.

According to CHBRP, rebates will effectively lower the price for consumers of specific drugs, which will then result in additional demand or use of those drugs. However, the spending incurred by health plans is not only focused on rebates, but the cost of *all* drugs that would be dispensed if the price was reduced to the patient and more utilization occurred at that lower price to consumers. The rebates would still need to be paid by someone, in this case the carrier would absorb the cost. Essentially, the increase in cost to the plan can be attributed to three sources:

(1) A $95,880,000 increase in medical cost to the plan caused by shifting rebates from plan to patients;

(2) A $69,488,000 increase in medical cost to the plan caused by increase in utilization; and,

(3) A $34,632,000 increase in administrative cost to the plan caused by an increase in medical costs

iv) CHBRP assumptions.

(1) Baseline Benefit Coverage. CHBRP assumed that potential rebates under this bill apply to only brand-name and specialty pharmacy claims handled by a PBM under an outpatient prescription drug benefit, typically, claims for prescription drugs filled at retail pharmacies, mail order pharmacies, and specialty pharmacies associated with the PBM. CHBRP assumed that potential rebates associated with physician-office administered drugs and other drugs paid for through medical benefits were outside the scope of this bill and did not consider these services. The population subject to the mandate includes enrollees covered by DMHC-regulated commercial insurance plans and CDI-regulated policies. CHBRP assumed 0% of the plans and policies subject to this bill currently offer coverage for POS rebates to reduce cost sharing. CHRBP recognizes that some PBMs and plan sponsors may offer this benefit, however, adoption appears to be very low. CHBRP did not conduct carrier surveys to determine the percentage of enrollees that currently have coverage for POS rebates to reduce cost sharing.

(2) Baseline Utilization and Cost. Baseline utilization and cost was modeled using Milliman's Prescription Drug Managed Care Rating Manual which provides utilization and unit cost for preferred brand drugs, nonpreferred brand-name drugs, and specialty drugs. Baseline utilization and cost was modeled separately for ages 17 and under, 18 to 64, and 65 and older. CHBRP modeled utilization and cost for each market segment using a blended age approach that reflected the segment's demographic distribution.

(3) Baseline Cost Sharing. CHBRP utilized its annual carrier survey, not specific to this bill, to determine the percentage of enrollees that are enrolled in plans by regulator, line of business, and deductible or metal tier. CHBRP used the same baseline carrier survey to determine the percentage of plans with coverage for brand or specialty drugs by line of business. Note that California law requires plans without drug coverage to cover insulin. To address the impact of this bill on these utilizers, CHBRP assumed the mandate would have no impact on enrollees without brand or specialty coverage, except for 0.85% of this population who have mandated coverage for insulin. The proportion of the population using insulin is based upon CHBRP's 2021 analysis of SB 473 (Bates). CHBRP made simplifying assumptions about the current benefit designs of individuals subject to this bill and mapped the level of cost sharing to one of three typical plan designs that reflect the plan types available in the DMHC- and CDI-regulated insurance market.

(4) Postmandate Utilization. CHBRP assumed that the increase in enrollee utilization of prescription drugs due to decreased cost sharing would be 3.5% of total prescriptions for enrollees in medium or high cost sharing plans. CHBRP assumed that the increase in utilization is driven by a 0.5% increase in the number of enrollees utilizing brand or specialty drugs and a 3.0% increase in the utilization for enrollees utilizing brand or specialty drugs. This induced demand estimate is based upon evidence from the RAND Health Insurance Experiment, which allows for the estimation of increased use of outpatient services based on a price elasticity of −0.2. CHBRP did not model changes in utilization due to discount card programs or other programs where individuals use a self-pay, discounted cash price to purchase brand-name or specialty drugs without using their pharmacy benefit. It is possible that lower cost sharing would cause enrollees currently using discount card programs to shift their utilization to their insured pharmacy benefit.

(5) Postmandate Cost. CHBRP assumed no change to the postmandate unit cost paid by health plans or health insurers and that the allowable charges for prescription drugs prior to rebates applied is assumed to be unchanged. Similarly, the total available funds available from manufacturer rebates is assumed to be unchanged. An impacted enrollee would receive the benefit of 90% of these funds which would have otherwise been retained by the plan sponsor at baseline. The impact of POS rebates to reduce cost-sharing was assumed to directly increase plan sponsor responsibility by reducing the total rebate dollars received by the plan sponsor with an offset for the reduction in cost sharing. CHBRP assumed varying rebates for preferred brand, nonpreferred brand, and specialty medications and modeled each of these drug classifications separately to arrive at the blended unit costs weighted based on utilization.

(6) Postmandate Cost Sharing. The Milliman Prescription Drug Managed Care Rating Manual was used to determine the level of cost-sharing postmandate when POS rebates impact the applicable cost sharing. The industry has not yet determined the standard way of reflecting POS rebates. One approximation commonly used for modeling is the concept that the rebates would be applied as a flat percentage reduction. For mandates analyzed by CHBRP with cost-sharing impacts, the typical approach is to assume an increase in premiums to offset reduced cost sharing, which is the approach CHBRP has taken with this bill. Given the uncertainty of implementation of this bill, CHBRP recognizes

that plan sponsors may consider several approaches: Plan sponsors may increase cost sharing for other benefits to offset the impact of this bill; or, plan sponsors may offer modified plan designs, for instance copayment plans with $0 deductibles which would have no change in prescription drug cost sharing under this bill.

f) Other State and Federal Laws. CHBRP notes that in 2020 and 2021, seven states introduced legislation related to this bill. Proposals vary in diverting 51% to 100% of rebate dollars to the enrollee or plan sponsor, with calculation occurring at the POS. In West Virginia, HB 2263 was enacted in 2021, requiring enrollee cost sharing to be calculated at the POS based on a price reduced by at least 100% of all rebates received. Any rebate exceeding this must be passed on to the health plan to reduce premiums. In the 2021 legislative session, Oklahoma introduced SB 721, requiring discounts, rebates, price concessions, and fees related to medication claims to be passed to enrollees at the POS and proposing that enrollee cost sharing be the lesser of the copayment, maximum allowable cost, maximum allowable claim, adjusted OOP maximum, the amount the enrollee would pay without insurance, and the amount the pharmacy would be reimbursed by the PBM. In the 2020 legislative session, Georgia introduced HB 1027, requiring enrollee cost sharing to be calculated at the POS based on a price reduced by at least 80% of all rebates received. Indiana introduced HB 1219 and SB 160, requiring enrollee cost sharing to be calculated at the POS (based on a price reduced by at least 75% and 85% of all rebates received, respectively). Iowa introduced HF 2465, diverting 51% of rebate dollars to enrollee cost sharing, and Missouri introduced HB 2527, diverting 100% of rebate dollars to enrollee cost sharing.

b) Rebate Rule. In January 2019, the Office of the Inspector General (OIG) under the Trump Administration proposed a rebate rule it believes "may curb list price increases, reduce financial burdens on beneficiaries, lower or increase Federal expenditures, improve transparency, and reduce the likelihood that rebates would serve to inappropriately induce business payable by Medicare Part D and Medicaid managed care organizations." The OIG proposed safe harbor changes to the Anti-Kickback Statute (prohibits payments to induce or reward the referral of business under federal health care programs) to ban rebate arrangements it believes are harmful, while protecting discount and services arrangements it believes are beneficial. The rebate rule would have also created a new safe harbor for rebates paid directly to patients, and fixed fee service agreements between manufacturers and PBMs. Ultimately, the Trump Administration retracted (but did not withdraw) the rebate rule in July of 2019, amidst criticism and uncertainty about its potential outcomes. While supporters argued that rebate reform would have made the pricing system more transparent and begun transformation of a broader system by beginning with federal programs, critics pointed to added complexity, limited scope, a high price tag, and ambiguity about potential outcomes. The Congressional Budget Office estimated that the direct effect of implementing the proposed rule would be to increase federal spending on Part D premiums by about $170 billion over the 2020–2029 period. That increase stemmed from manufacturers' withholding 15% of current-law rebates, increases in federal subsidies for premiums, changes in the annual thresholds at which beneficiaries' cost- sharing requirements and other program rules change, and the costs of implementation.

On November 20, 2020, as part of a release of several drug pricing rules, the U.S. Department of Health and Human Services Office of Inspector General adopted a Final Rule modifying the discount safe harbor and adding two new safe harbors to reform drug pricing in Medicare Part D. The Final Rule requires PBMs and Part D Plans to abandon the use of rebates unless they are passed on to the consumer at the POS. The Final Rule may significantly change Part D drug pricing between manufacturers and Part D plan sponsors. The Final Rule creates a new POS prescription drug price reduction safe harbor that would exempt manufacturer rebates paid to Part D plan sponsors and Medicaid managed care organizations for prescription drugs if those rebates are passed through to the enrollee at the POS. The changes to the discount safe harbor, including loss of discount safe harbor protection for rebates to Part D plan sponsors, had planned to go into effect on January 1, 2022. Presumably, according to CHBRP, the purpose of the delayed effective date of the discount safe harbor changes is to allow manufacturers and plan sponsors time to enter into agreements. According to the Pharmaceutical Care Management Association, recently proposed bipartisan legislation would impose a moratorium on the implementation of the Final Rule until January 1, 2026.

3) **SUPPORT**. The California Access Coalition, Patient Pocket Protector Coalition, and Diabetes Patient Advocacy Coalition, cosponsors, write that pharmacy middlemen, or PBMs, determine the formulary of drugs covered by health insurers. Pharmaceutical manufacturers pay rebates to insurers and their PBMs – 40% of the medicine's list price on average. PBMs are then supposed to pass savings on to patients, but research by the Office of the Inspector General shows that's not happening. According to the report, "The large rebates offered by manufacturers… benefit plan sponsors but provide little relief to beneficiaries who received the drugs." Although rebates were never intended to flow to PBMs, in 2021, these rebates totaled $1.7 billion in California alone, up from $1.4 billion in 2020 and $1.2 billion in 2019. The current, broken rebate system only benefits PBMs and insurers and does nothing to benefit patients. In fact, patients often end up paying more for the prescription than the PBM and insurer even paid for it. Due to high costs at the pharmacy counter, thousands of Californians struggle to have their prescription medications filled to treat acute or chronic conditions. Lawmakers must stand with patients and shed light on the fraudulent practices that leave so many struggling to afford and maintain their medications. The co-sponsors conclude that sharing rebates with patients at the POS will not only reduce OOP costs for patients, but the co-sponsors state will also improve medication adherence rates, as demonstrated by UnitedHealth's OptumRx practice of sharing rebates at the pharmacy counter, which enabled patients to save an average of $130 per eligible prescription and improved adherence rates between 4-16%.

4) **OPPOSITION**. The California Association of Health Plans, the Association of California Life and Health Insurance Companies, and America's Health Insurance Plans write that this bill will raise consumer premiums by $200 million, according to an independent analysis of a substantially similar bill. The original list price of a drug, determined solely by the drug manufacturer, drives the entire pricing process. The problem is the price: if the original list price is high, then the final cost that patients pay will be high. Rebates are generally offered by manufacturers only when there are two or more competing drugs within the same therapeutic class. To lower drug costs, health plans and insurers (and their contracted PBMs) leverage these competing drugs when negotiating with manufacturers. POS rebates won't help the majority of patients who take generic drugs, which account for more than 90% of the market. When the Trump Administration adopted a similar mandate in the Medicare Part D

program, the Centers for Medicare and Medicaid Services' own actuaries estimated that it would increase premiums by 25%, costs taxpayers between $200 and $400 billion, and lead to a $137 billion windfall for pharmaceutical manufacturers. The Senate Appropriations Committee refused to advance that bill due to the increased premium cost; Congress has continually disallowed the federal "rebate rule" to take effect. The opposition also state that a mandate to provide POS rebates is incredibly difficult to operationalize. In addition to the cost of these programs, requiring rebates to be passed on to consumers at the POS represents an enormous administrative challenge because rebates are not paid by pharmaceutical manufacturers in real time. Rebates are paid retrospectively to health plans, insurers, and/or PBMs based on several factors, including the volume of prescriptions utilized by the plan's members. The opposition concludes that this bill represents a dangerous trend of taking away the few tools that health plans and insurers have to hold down prescription drug costs for all consumers.

5) RELATED LEGISLATION.

a) AB 948 (Berman) makes permanent existing law provisions that prohibit the copayment, coinsurance, or any other form of cost sharing for a covered outpatient prescription drug for an individual prescription from exceeding $250 for a supply of up to 30 days or $500 for bronze products, except as specified; and, requires a non-grandfathered individual or small group plan contract or insurance policy to use specified definitions for each tier of a drug formulary. AB 948 is pending in Assembly Appropriations Committee.

b) SB 70 (Wiener) prohibits limiting or excluding coverage of a drug, dose of a drug, or dosage form of a drug that is prescribed for off-label use if the drug has been previously covered for a chronic condition or cancer, regardless of whether or not the drug, dose, or dosage form is on the plan's or insurer's formulary. Prohibits a health plan contract or health insurance policy from requiring additional cost sharing not already imposed for a drug that was previously approved for coverage. SB 70 is pending in Senate Appropriations Committee.

6) PREVIOUS LEGISLATION.

a) SB 1361 (Kamlager) of 2022 would have required health plans and insurers to reduce enrollee and insured cost-sharing to reflect drug manufacturer rebates at the POS and reporting of POS rebates until 2025 and additional reporting on rebates and PBMs until 2025; terminated an existing annual report on prescription drug costs published by DMHC; established multiple definitions related to PBMs; and, required PBMs to owe a duty to enrollees, health plans, and providers. SB 1361 was held in the Senate Appropriations Committee.

b) AB 2942 (Daly) of 2022 would have required enrollee's or insured's defined cost sharing for each prescription drug to be calculated at the POS based on a price that is reduced by an amount equal to 90% of all rebates received, or to be received, in connection with the dispensing or administration of the drug. Would have required a health plan or health insurer to, among other things, pass through to each enrollee or insured at the POS a good faith estimate of their decrease in cost sharing. AB 2942 was never heard in Assembly Health Committee.

c) AB 933 (Daly) of 2021 is substantially similar to this bill and was held on suspense in the Assembly Appropriations Committee.

d) AB 315 (Wood), Chapter 905, Statutes of 2018, provides for the registration of PBMs to the DMHC. AB 315 requires DMHC, by July 1, 2019, and in collaboration with other agencies, departments, advocates, experts, health plan representatives, and other entities and stakeholders that it deems appropriate, to convene a Task Force on PBM Reporting to determine what information related to pharmaceutical costs, if any, it should require to be reported by health plans or their contracted PBMs, in addition to reporting required in existing law. AB 315 requires the Task Force to consider inclusion of information including, but not limited to: WAC of pharmaceuticals; rebates; payments to network pharmacies; and, exclusivity arrangements between health plans or contracted PBMs with manufacturers

e) AB 265 (Wood), Chapter 611, Statutes of 2017, prohibits prescription drug manufacturers from offering discounts or other reduction in an individual's OOP expenses associated with his or her insurance coverage, if a lower cost therapeutically equivalent generic drug is available. Specifies a number of exceptions that allow discounts even if a lower cost therapeutically equivalent generic drug is available.

f) 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 WAC of a prescription drug by specified amounts. Requires drug manufacturers to notify Office of Statewide Health Planning and Development (OSHPD and now the Department of Health Care Access and Information - HCAI) 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.

7) COMMITTEE AMENDMENTS. To address concerns specified under Policy Comments below, the Committee recommends this bill to be amended to instead require the California Health and Human Services Agency to study POS rebate proposals in other states and at the federal level and make recommendations to the Legislature regarding the viability of implementing this bill in California.

8) POLICY COMMENTS.

a) High Price Tag and Adverse Impact on Controlling Health Care Costs. The author points out that this bill is intended to save consumers OOP costs for prescription drugs. However, CHBRP notes that this bill will actually increase total net annual health expenditures by over $129 million even after the $70,833,000 decrease in enrollee share of cost for services. As stated by CHBRP above, rebates will effectively lower the price for consumers of specific drugs, which will then result in additional demand or use of those drugs. The spending incurred by health plans is not only focused on rebates, but the cost of all drugs that would be dispensed if the price was reduced to the patient and more

utilization occurred at that lower price to consumers. The rebates would still need to be paid by someone, in this case the carrier would absorb the cost (who can then pass the costs to consumers). When costs and savings are evaluated in health care, what could be claimed as consumer savings actually costs the entire health care system more. For purposes of this bill, although patients directly impacted could potentially save OOP costs for their prescription drugs, these "savings" actually impact the costs of premiums as payers no longer have the option to apply the rebates to reduce health insurance premiums. By removing the role of rebates in prescription drug pricing, payers lose a mechanism at which to offset high list prices of prescription drugs. Because of the overall impact of this bill on health care pricing, it is important for the Committee to consider the magnitude that this bill could have on overall health care spending. Given CHBRP's assessment of the cost impact of this bill, this Committee may wish to consider whether this bill actually curbs the growth of prescription drug prices or shifts the savings into higher premiums and inadvertently undermining cost containment efforts at a time when California needs innovative solutions to address the continuous growth in all aspects of health care spending, including prescription drugs.

b) Covered California Impact. According to the CHBRP analysis, total premium expenditures for individually purchased plans in Covered California are expected to increase by $33,045,000. This is a significant cost impact to the individual market since the enrollee is solely responsible for their monthly health insurance premium.

c) Perverse Incentive to Use Brand Name Drugs. As pointed out by CHBRP, this bill would impact the 836,000 enrollees who use brand-name or specialty medications and post mandate, this number would increase. As the SB 17 report pointed out, the cost of specialty drugs continues to be a driver of overall health care costs. Overall, specialty drugs accounted for 1.6% of the total number of drugs prescribed, but 62.9% of the total annual spending on prescription drugs. Generic drugs made up 88.2% of all the drugs prescribed but represented only 16.3% of total annual spending on prescription drugs. Additionally, brand name drugs made up 10.2% of all the drugs prescribed in 2021 and represented 20.8% of total spending on prescriptions drugs. Additionally, as stated in the Commonwealth Fund study evaluating the impact of the BBA of 2018 on Medicare Part D drugs, incentives to use brand-name products may decrease the market share for generics or even discourage manufacturers from developing more of them. The Committee may wish to consider whether this bill creates a perverse incentive where consumers are encouraged to use higher cost branded drugs because they would spend less of their own money than those taking a lower cost generic.

d) Prescription Drug Pricing. As drafted, there is nothing in this bill that guarantees or controls how much manufacturers could increase their prices. HCAI regularly releases to the public information and data visualizations on new prescription drugs introduced to market in California with a WAC that exceeds the Medicare Part D specialty drug cost threshold. For example**,** in calendar year 2022, approximately 81% of reported new drugs were introduced to market with a WAC greater than $1,000. In calendar year 2022, over a quarter of reported new drugs were introduced to market with a WAC greater than $10,000. To truly realize savings for consumers and the health care system, should this bill be amended to include a provision similar to those introduced in other states to regulate price increases for the 25 drugs that get rebates at POS.

e) Implementation Barriers. The author and sponsor of this bill point to West Virginia as a model for this bill's implementation in California. However, there are important considerations when evaluating the West Virginia model and how it can be duplicated in this state:

i) The POS rebate proposal in West Virginia is administered differently in comparison to this bill. Savings are passed onto consumers differently depending upon whether they have a copayment or coinsurance for their prescription drug. More importantly, West Virginia currently has regulatory authority over PBMs to ensure that rebate savings are returned to consumers. Since there is no robust regulatory scheme for PBM's in California (PBM's are only required to register with DMHC), it would be difficult to take action against PBMs that do not comply with this bill.

ii) As noted by the opposition above, requiring rebates to be passed on to consumers at the POS represents an enormous administrative challenge because rebates are not paid by pharmaceutical manufacturers in real time. Rebates are paid retrospectively to health plans, insurers, and/or PBMs based on several factors, including the volume of prescriptions utilized by the plan's members. To actualize the savings to consumers, should pharmaceutical manufacturers also pay rebates in real time?

iii) This bill also lacks details on implementation at the POS and end of the year reconciliation. The author may wish to consider addressing these issues to avoid further administrative confusion and expenses.

f) Rebates. As drafted, this bill currently prohibits health plans, insurers, DMHC, and CDI from revealing information regarding the actual amounts of rebates and specifies that information as protected as trade secret, and not a public record. The CHBRP analysis notes that critics of PBMs argue that the opaque system through which rebates are collected and distributed does not allow payers to adequately discern the proportion of rebates that they are receiving, and thus whether a PBM's administration of those rebates serves the best interest of the payer. One of the goals of this bill is to ensure patients benefit from negotiated rebates, however, if the rebate information continue to be confidential, it is unclear how consumers and payers could determine whether the POS rebate is accurate. Additionally, since the state does not have regulatory authority over PBMs, there is no state mechanism to verify whether the actual rebates are being passed on to consumers. The Committee may wish to consider amending this bill to make the rebate information publicly available and increase drug pricing transparency.

REGISTERED SUPPORT / OPPOSITION:

Support

California Access Coalition (cosponsor)
Diabetes Patient Advocacy Coalition (cosponsor)
Patient Pocket Protector Coalition (cosponsor)
Albie Aware Breast Cancer Foundation
Als Association; the
American Diabetes Association
American Legion, Department of California
Amvets, Department of California
Applied Pharmacy Solutions

Biocom California
California Academy of Family Physicians
California Association of County Veterans Service Officers
California Black Health Network
California Chronic Care Coalition
California Council of Community Behavioral Health Agencies (CBHA)
California Health Collaborative
California Hepatitis C Task Force
California League of United Latin American Citizens
California Life Sciences
California Manufacturers and Technology Association
California Podiatric Medical Association
California Rheumatology Alliance
California State Commanders Veterans Council
Chronic Disease Coalition
Community Health Action Network
Crohns and Colitis Foundation
Cystic Fibrosis Research, INC. (CFRI)
Epilepsy Foundation of San Diego County
Hemophilia Council of California
International Bipolar Foundation
International Foundation for Autoimmune and Inflammatory Arthritis
Keck Medicine of University of Southern California
Liver Coalition of San Diego
Liver Coalition of Sd
Liver Health Foundation
Looms for Lupus
Los Angeles Wellness Station
Lupus Foundation of America, Southern California Region
Lupus Foundation of Southern California
Mexican American Opportunity Foundation
Military Officers Association of America, California Council of Chapters
Murdoch, Walrath & Holmes
National Multiple Sclerosis Society, Ms-can
Neighborhood Wellness Foundation
Pharmaceutical Research and Manufacturers of America
Vietnam Veterans of America, California State Council

Opposition

Association of California Life & Health Insurance Companies
California Association of Health Plans
California Chamber of Commerce
Pharmaceutical Care Management Association

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