CALIFORNIA STATE SENATE

COMMITTEE ON BUDGET AND FISCAL REVIEW

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Scott Wiener, Chair

Agenda

February 19, 2025

9:00 a.m. – 1021 O Street, Room 1200

Informational Hearing – Part A

Effectiveness of Consumer Protections in California's Commercial Health Insurance Market

I. Regulation and Enforcement of State and Federal Behavioral Health Parity Law

Mary Watanabe
Director, Department of Managed Health Care

Sarah Ream
Chief Counsel, Department of Managed Health Care

II. Stakeholder Perspectives

Lauren Finke
Senior Director of Policy, The Kennedy Forum

John Drebinger III
Senior Advocate, Steinberg Institute

Le Ondra Clark Harvey
Chief Executive Officer, California Behavioral Health Association
Executive Director, California Access Coalition

Representative
California Association of Health Plans

III. Public Comment

Informational Hearing – Part B

CalRx: Current Initiatives & Future Opportunities to Lower Healthcare Costs for all Californians

I. CalRx Initiatives – Insulin, Naloxone, and Beyond

Elizabeth Landsberg
Director, Department of Health Care Access and Information

Vishaal Pegany
Deputy Director, Office of Health Care Affordability

Michael Valle
Chief Information Officer, Department of Health Care Access and Information
Presentation: SB 17 Prescription Drug Cost Transparency Report

Mary Watanabe
Director, Department of Managed Health Care
Presentation: SB 17 Prescription Drug Cost Transparency Report

II. Stakeholder Perspectives

Diana Douglas
Director of Policy and Advocacy, Health Access California

Le Ondra Clark Harvey
Chief Executive Officer, California Behavioral Health Association
Executive Director, California Access Coalition

Representative
California Association of Health Plans

III. Public Comment

Informational Hearing (Part A)

Effectiveness of Consumer Protections in California's Commercial Health Insurance Market

BACKGROUND

The Department of Managed Health Care Regulates Commercial Health Plans. The Department of Managed Health Care (DMHC) is the primary regulator of the state's 140 licensed health care service plans, which provide health, mental health, dental, vision, and pharmacy services to nearly 30 million Californians. Established in 2000, DMHC enforces the Knox-Keene Health Care Service Plan Act of 1975, California's robust oversight regime of the state's health care service plans. In fulfilling its regulatory responsibilities under the Act, DMHC conducts medical surveys and financial examinations to ensure health plan compliance and financial stability, provides a 24-hour call center to help consumers resolve health plan complaints, and administers Independent Medical Reviews of services denied by health plans.

Knox-Keene Health Care Service Plan Act of 1975. The Knox-Keene Health Care Service Plan Act of 1975 (Knox-Keene Act), and subsequent amendments, is one of the most robust regulatory regimes for health care service plans in any state in the nation. In addition to regulatory requirements related to consumer protections and plans' financial stability, the Knox-Keene Act imposes various network adequacy requirements on health care service plans designed to provide timely access to necessary medical care for those plans' beneficiaries. These requirements generally include the following standards for appointment availability: 1) Urgent care without prior authorization: within 48 hours; 2) Urgent care with prior authorization: within 96 hours; 3) Non-urgent primary care appointments: within 10 business days; 4) Non-urgent specialist appointments: within 15 business days; 5) Non-urgent appointment for ancillary services for the diagnosis or treatment of injury, illness or other health condition: within 15 business days. The Knox-Keene Act also requires plans to ensure primary care physicians are located within 15 miles or 30 minutes of a beneficiary and there is at least one primary care provider for every 2,000 beneficiaries in a plan's network.

Behavioral Health Parity – A History of Ensuring Equitable Access to Care. Despite California's Knox-Keene Act's robust regulation and oversight of health care service plans since 1975, guarantees that health plan consumers receive access to behavioral health care are a more recent phenomenon. Before 1996, there were relatively few requirements imposed on any health plans to offer behavioral health care under similar terms to medical and surgical care, or even to offer behavioral health care services at all.

Federal Laws Governing Behavioral Health Parity. In 1996, the federal Mental Health Parity Act (MHPA) prohibited large group health plans from imposing annual or lifetime dollar limits on mental benefits that are less favorable than those imposed on medical or surgical benefits. Later, the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA) would expand parity requirements to include individual health plans and small group coverage for employers with more than 50 employees, as well as expanding rules to include

coverage of substance use disorder benefits. Like MHPA, MHPAEA provided that mental health and substance use disorder benefits must be provided in a manner no more restrictive than those that apply to medical and surgical benefits. Specifically, financial benefits, such as deductibles or copays, and treatment limitations, such as limits on the number of visits, are subject to the parity requirements under MHPAEA, which were implemented by federal regulations finalized in 2013.

Although MHPAEA required parity for behavioral health coverage, until 2014 there was no requirement that health plans offer behavioral health coverage at all. In 2010, President Barack Obama signed the Patient Protection and Affordable Care Act, which required health plans to cover behavioral health services. This requirement was implemented beginning in 2014.

California Mental Health Parity Act. Not long after passage of the federal MHPA, California approved AB 88 (Thomson), Chapter 534, Statutes of 1999, the California Mental Health Parity Act, which required private health insurance plans to provide coverage for the diagnosis and medically necessary treatment of severe mental illness for adults, and serious emotional disturbances for children, under the same terms and conditions applied to medical and surgical coverage. AB 88 mandated parity of coverage for the following nine conditions: 1) schizophrenia, 2) schizoaffective disorder, 3) bipolar disorder, 4) major depressive disorders, 5) panic disorder, 6) obsessive-compulsive disorder, 7) pervasive developmental disorder (autism), 8) anorexia nervosa, and 9) bulimia nervosa. Coverage of serious emotional disturbance (SED) for children included coverage of any condition in the Diagnostic and Statistical Manual of Mental Disorders (other than a primary substance use disorder or developmental disorder) that results in behavior inappropriate to the child's age and results in various impairments, risks of removal from the home, or certain other adverse outcomes.

SB 855 Expands Behavioral Health Parity Beyond the Nine Conditions. For twenty years, DMHC's enforcement of behavioral health parity in California was limited only to the nine conditions (and SED for children) included in AB 88, and later the expansion under MHPAEA to substance use disorders. SB 855 (Wiener), Chapter 151, Statutes of 2020, expanded behavioral health parity requirements to mental health conditions or substance use disorders that fall under the mental and behavioral disorders sections of the International Classification of Diseases or that are listed in the Diagnostic and Statistical Manual of Mental Disorders. SB 855 represented a dramatic expansion of behavioral health parity requirements for commercial and public health coverage. Specifically, SB 855 made the following changes to California behavioral health parity:

- Expanded behavioral health parity requirements to commercial health plans in all markets, including large group.
- Required coverage of all medically necessary behavioral health services, including for substance use disorders.
- Expanded parity requirements beyond the treatment of the nine severe mental illnesses or serious emotional disturbances for children, instead requiring parity for all recognized mental health disorders.
- Revised utilization management requirements and expands plan responsibilities to help plan members obtain out-of-network care when required.

After the passage of SB 855 in 2020, DMHC promulgated regulations implementing compliance procedures with the expanded behavioral health parity requirements in January 2024, releasing an All Plan Letter detailing compliance requirements for health care service plans in April 2024. The regulations require a health care service plan to maintain an adequate provider network to provide all medically necessary services, including behavioral health services, within geographic and timely access standards and in accordance with the Knox-Keene Act. If a health care service plan is not able to provide services under these conditions, the plan must arrange to pay for the services out-of-network, but may only charge in-network cost-sharing rates. Plans must arrange for an appointment with the out-of-network behavioral health provider within the following timeframes:

1. Non-urgent services: No more than 10 business days after the initial request
2. Specialist services: Within 15 business days of the request
3. Urgent with no prior authorization requirements: Within 48 hours of the initial request
4. Urgent with prior authorization requirements: Within 96 hours of the initial request

In addition, any medical necessity determinations or utilization reviews must use standards established by specified nonprofit professional associations.

DMHC Regulates Compliance With State and Federal Behavioral Health Parity Laws. In addition to its oversight of consumer protections, financial stability, and plan compliance with network adequacy and timely access standards, DMHC is responsible for ensuring California health care services plans are complying with the requirements of state and federal behavioral health parity laws. In general, DMHC accomplishes this oversight through its triennial review of plan documents (e.g. evidence of coverage, provider contracts, etc.) to ensure utilization management, network access to services, and other procedures included in plan operations comply with the provisions of behavioral health parity laws. In the context of MHPAEA enforcement, DMHC's compliance reviews consist of two components:

1. Front-end: reviews of documentation submitted by plans to determine MHPAEA compliance.
2. Back-end: onsite reviews to verify plans are operating in accordance with compliance filings.

The MHPAEA final rules require review of the health plans' processes and justifications for classifying benefits within the following six permissible classifications:

1. Inpatient, In-Network
2. Inpatient, Out-of-Network
3. Outpatient, In-Network, including:
    a. Outpatient Office Visits
    b. Outpatient Other Items and Services
4. Outpatient, Out-of-Network, including:
    a. Outpatient Office Visits
    b. Outpatient Other Items and Services
5. Emergency Care
6. Prescription Drugs

After classifying all benefits into one of these categories, health plans must determine parity for:

1. Financial requirements, such as deductibles, copays, or coinsurance.
2. Quantitative treatment limitations (QTLs), such as number of visits or days of treatment.
3. Non-quantitative treatment limitations (NQTLs), including subjective limitations on treatment, such as utilization management.

MHPAEA Enforcement Budget Augmentations. The 2014 Budget Act included 15 positions and expenditure authority from the Managed Care Fund of $4.6 million in 2014-15 for clinical consulting services to conduct initial front-end reviews for compliance with MHPAEA. The 2015 Budget Act included additional resources to support back-end review components. The 2016 Budget Act included expenditure authority from the Managed Care Fund of $529,000 for 2016-17 and 2018 to design new compliance fling instructions and forms, conduct review of plan classification of benefits and NQTLs, and resolving clinical issues arising in compliance filings. The 2018 Budget Act made these positions and resources permanent and ongoing.

SB 855 Implementation. In the context of the recently promulgated regulations enforcing the behavioral health parity requirements of SB 855, DMHC required all health plans to submit documents by June 3, 2024, to demonstrate compliance. These documents included affirmations that the plan's product or products comply with SB 855 and other provisions of the Knox-Keene Act, plan evidence of coverage documents, as well as other plan policies, procedures, and notices.

The 2021 Budget Act included five positions and expenditure authority from the Managed Care Fund of $1.5 million in 2021-22 and 5.5 positions and $1.3 million annually thereafter to support enforcement of compliance with SB 855. At the time these resources were approved, DMHC indicated these positions would support promulgation of regulations in the Office of Plan Licensing, legal guidance to health plans in the Office of Plan Monitoring, additional referrals for investigation or litigation to the Office of Enforcement, and additional complaints of non-compliance managed by the DMHC Help Center.

Recent Actions to Enforce Plans' Behavioral Health-Related Responsibilities. The 2020 Budget Act included 14.5 positions and expenditure authority from the Managed Care Fund of $2.8 million in 2020-21, 18.5 positions and $4.7 million in 2021-22, and 18.5 positions and $4.7 million annually thereafter to conduct focused investigations and enforcement of health plan compliance with behavioral health parity requirements. According to DMHC, the goal of these investigations is to identify and understand the challenges and barriers enrollees may still face in obtaining behavioral health care services, and to identify systemic changes that can be made to improve the delivery of care. The department conducts these focused investigations for up to five health plans in each year, beginning in 2021.

For 2021, DMHC launched Phase One of its behavioral health focused investigations, evaluating the following health plans:

1. Cigna HealthCare of California, Inc.
2. Community Care Health Plan, Inc.
3. Contra Costa Health Plan
4. Sutter Health Plan

5. Ventura County Health Plan

The department identified 21 violations of the Knox-Keene Act among these five plans. The findings included violations of requirements related to: appointment availability and timely access, utilization management, pharmacy benefits, quality assurance, grievances and appeals, claims submission and payment, and cultural competency/health equity/language assistance. For each violation, the department made recommendations for ameliorating the violations, but also referred all the identified violations to the department's Office of Enforcement along with corrective action plans submitted by each plan.

	Knox-Keene Act Violations	Health Plans
Appointment Availability and Timely Access		
1	Failure to ensure the waiting time for an enrollee to speak by telephone with a knowledgeable and competent health plan customer service representative did not exceed 10 minutes. Rule 1300.67.2.2(c)(10)	• Contra Costa Health Plan
2	Failure to implement prompt corrective action when provider appointment availability monitoring revealed the behavioral health network was not sufficient to ensure timely access. Rules 1300.67.2.2(d)(3) and 1300.67.2.2(g)(2)(C)	• Contra Costa Health Plan
3	Failure to monitor provider referrals and specialist care as required by Rule 1300.67.1(e)	• Ventura County Health Care Plan
4	Failure to have a process for determining geographic accessibility and timely access for medically necessary pervasive developmental disorder and autism health care services. Rule 1300.74.73(a)(3)	• Community Care Health Plan, Inc.
Utilization Management, including Triage and Screening		
5	Health plans, or their behavioral health delegates, are operating at variance with utilization management policies and procedures filed with the Department. Section 1351 or Section 1352(a) or (b)	• Cigna HealthCare of California, Inc. • Contra Costa Health Plan

6	Failure to consistently notify requesting providers of utilization management decisions within 24 hours of making the decision. Section 1367.01(h)(3)	• Community Care Health Plan, Inc. • Contra Costa Health Plan
7	Failure to timely implement the requirements of Sections 1374.72 and 1374.721 (SB 855)	• Cigna HealthCare of California, Inc.
	Pharmacy	
8	Failure to demonstrate the pharmacy benefit manager has policies and procedures for formulary exception requests as required by state and federal laws, or that such policies and procedures were filed with the Department. Sections 1367.24 (a)(d) and (k); 45 C.F.R. 156.122(c)	• Community Care Health Plan, Inc.
	Quality Assurance	
9	Failure to establish and implement a quality assurance process that assesses and evaluates compliance with utilization management requirements. Rule 1300.70(a)(3) and Rule 1300.70(c)	• Contra Costa Health Plan
10	Failure to ensure only appropriately licensed health care professionals modify requests for services and failure to send providers and enrollees written notification letters required for modifications. Additionally, the Plan's behavioral health delegate is operating at variance with its utilization management policies and procedures filed with the Department. Statutory/Regulatory Reference(s): Sections 1386(b)(1), 1367.01(e) and 1367.01(h)(4)	• Sutter Health Plus • Ventura County Health Care Plan
11	The Plan's behavioral health delegate was operating at variance with its Evidence of Coverage filed with the Department. Statutory/Regulatory Reference(s): Section 1386(b)(1)	• Community Care Health Plan, Inc.
12	The Plan is operating at variance with its filed Medical Group Provider Agreement by allowing its delegate to resolve grievances. Section 1386(b)(1)	• Community Care Health Plan, Inc.
13	Failure to perform oversight of behavioral health delegate to ensure enrollees are able to obtain timely, medically necessary behavioral health services. Rules 1300.67.2.2(c)(1), 1300.67.2(f), 1300.70(a)(3), 1300.67.2(d), 1300.67.2, and 1300.51(H)	• Community Care Health Plan, Inc.
14	Operating at variance with its filed Medical Group Provider Agreement by allowing the delegate to perform quality assurance functions. Sections 1351, 1352(a), (b), 1351(d), 1386(b)(1)	• Community Care Health Plan, Inc.

15	Failure to consistently review quality of care and performance of medical personnel when a potential quality issue is identified. Section 1370 and Rule 1300.70(a)(1)	• Sutter Health Plus • Ventura County Health Care Plan
16	Failure to ensure customer service staff are knowledgeable and competent regarding enrollee questions and concerns. Rule 1300.67.2.2(c)(10).	• Community Care Health Plan, Inc.
Grievances and Appeals		
17	Failure to consistently identify grievance categories as required. Rule 1300.68(e)(2)	• Community Care Health Plan, Inc.
18	Failure of customer service representatives to identify all enrollee grievances. Rule 1300.68(a)(1)	• Contra Costa Health Plan • Sutter Health Plus
19	Failure to consistently notify grievant of the right to contact the Department regarding urgent grievances. Section 1368.01(b) and Rule 1300.68.01(a)(1)	• Cigna HealthCare of California, Inc.
Claims Submission and Payment		
20	Failure to timely pay claims. Section 1371(a)(1)	• Contra Costa Health Plan
Cultural Competency, Health Equity and Language Assistance		
21	Failure to provide adequate training to health plan staff concerning the health plan's language assistance program with respect to understanding the cultural diversity of the enrollee population and sensitivity to cultural differences relevant to delivery of health care interpretation services. 1300.67.04(c)(3)(D)	• Community Care Health Plan, Inc. • Contra Costa Health Plan

Source: DMHC Behavioral Health Investigations, Phase One Summary Report, 2023

For 2022, the Phase Two investigations included:

1. Western Health Advantage
2. Alameda Alliance for Health
3. Sharp Health Plan
4. Anthem Blue Cross of California

The department planned to include Kaiser Permanente in these investigations, but delayed after a significant enforcement action taken in 2023 requiring the plan to make several significant changes in its delivery of behavioral health care services. In this report, the department identified 10 violations of the Knox-Keene Act. The findings included violations of requirements related to: appointment availability and timely access, utilization management, pharmacy benefits, quality assurance, grievances and appeals, and claims submission and payment. For each violation, the department made recommendations for ameliorating the violations, but also referred violations to the department's Office of Enforcement along with corrective action plans submitted by each plan.

	Knox-Keene Act Violations	Health Plans
	Appointment Availability and Timely Access	
1	Failure to ensure after-hours emergent and urgent information was provided to all enrollees. Additionally, the plan is operating at variance with filed policies and procedures. Rule 1300.67.2.2 (c)(8)(B)(1)	• Sharp Health Plan
	Utilization Management, including Triage and Screening	
2	The Plan failed to timely implement the requirements of Sections 1374.72 and 1374.721 (SB 855).	• Alameda Alliance For Health
	Pharmacy	
3	The Plan does not make its determinations on formulary exception requests and provide notification to enrollee, enrollee's delegate or prescriber on a timely basis. Section 1367.24(k); 45 C.F.R. 156.122(c)(3)(ii)	• Anthem Blue Cross
	Quality Assurance	
4	The Plan failed to perform oversight of its behavioral health providers to ensure triage and screening services are provided in a timely manner appropriate for the enrollee's condition, and that the triage and screening waiting time does not exceed 30 minutes. Rules 1300.67.2.2(c)(8)(A), (B)	• Sharp Health Plan
5	Failure of the health plan [or its delegate] to consistently document quality of care provided is being reviewed, problems are being identified and/or ensure effective action is taken to improve care where violations are identified, and follow-up is planned where indicated. Rules 1300.70(a)(1), 1300.70(a)(1), 1300.70(b)(1)(A), (B)	• Alameda Alliance For Health • Anthem Blue Cross • Sharp Health Plan
6	The Plan failed to document follow-up when quality of care issues were identified. Section 1370; Rule 1300.70(a)(1) and 1300.70(b)(1)(A) and (B)	• Sharp Health Plan
	Grievances and Appeals	
7	The Plan does not consistently provide immediate notification to grievants of the right to contact the Department about expedited grievances. Section 1368.01(b) and Rule 1300.68.01(a)(1)	• Anthem Blue Cross
8	Failure to maintain the required log of exempt grievances and failure to demonstrate periodic review of the log of exempt grievance data. Rule 1300.68(d)(8)	• Anthem Blue Cross • Sharp Health Plan
9	The Plan's customer service representatives failed to identify all grievances. Rules 1300.68(a)(1), (a)(2)	• Sharp Health Plan
	Claims Submission and Payment	
10	The Plan failed to pay a claim for previously authorized services. Section 1371.8	• Western Health Advantage

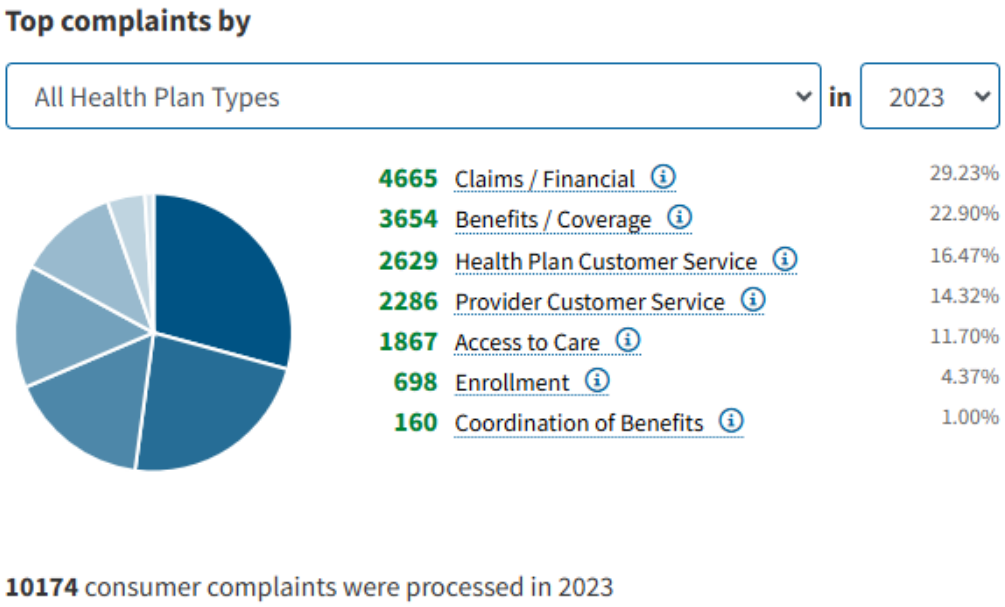
Source: DMHC Behavioral Health Investigations, Phase Two Summary Report, June 2024

Kaiser Permanente Settlement Agreement. In October 2023, after ongoing complaints regarding noncompliance with behavioral health parity and other requirements triggered an enforcement investigation, DMHC and Kaiser Permanente reached a settlement agreement and corrective action plan to improve quality and ensure compliance. The Agreement included a $50

million fine, required Kaiser to take corrective action to address deficiencies in delivery of behavioral health care, and required Kaiser to make an additional significant investment of $150 million over five years for programs to improve the delivery of behavioral health services to all Californians. The corrective actions included the following components:

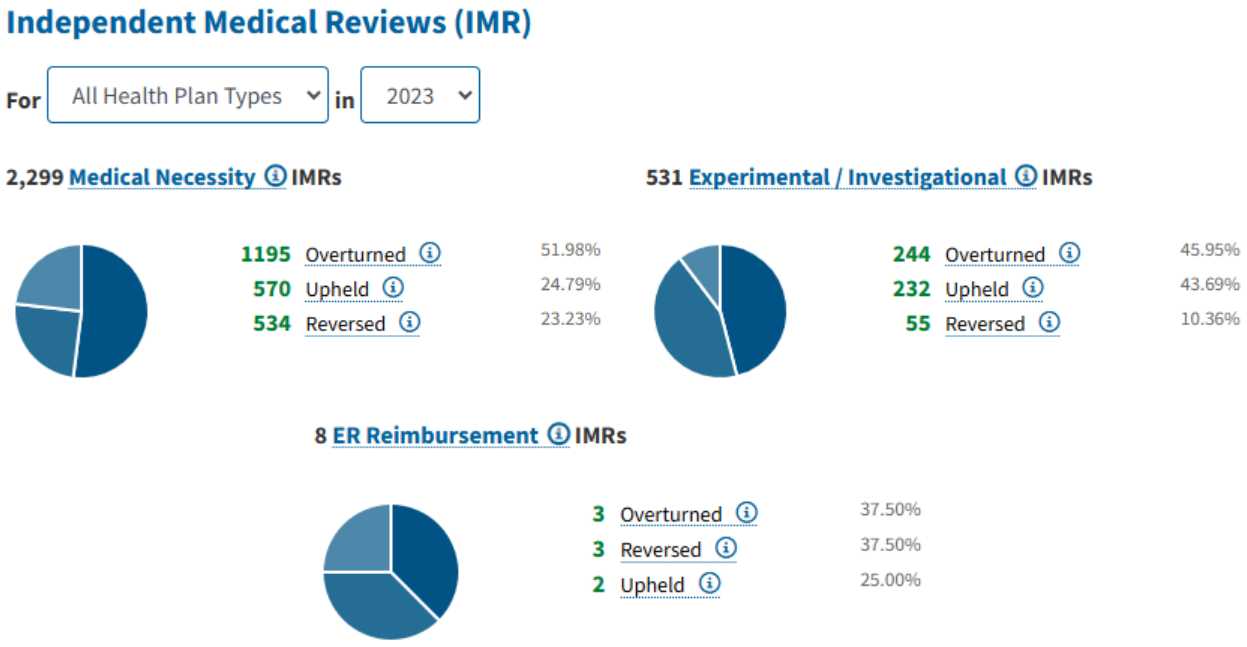
1. Oversight – Kaiser was required to improve its Quality Assurance Program to ensure timely access, network adequacy, continuity of care, level of care, and quality of care. In addition, Kaiser was required to implement policies and procedures for intervention for situations in which enrollees are not ensured reasonable access to behavioral health care services.
2. Access – Kaiser was required to improve its procedures to ensure enrollees can access behavioral health appointments consistent with timely access standards.
3. Networks and Referrals – Kaiser was required to improve its enrollees' ability to access its provider network for behavioral health services, and improve access to out-of-network providers if Kaiser cannot offer enrollees timely care.
4. Grievance and Appeals – Kaiser was required to improve its grievance and appeals policies and procedures, making sure enrollee grievances are acknowledged, adequately considered, and responded to within statutorily required timeframes, as well as providing access to grievance coordinators for enrollees with delays or difficulty in obtaining timely behavioral health appointments.
5. Mental Health Parity – Kaiser was required to develop processes to ensure compliance with all behavioral health parity laws.

Delays or Denials – Plan Grievance Processes and Independent Medical Review (IMR). DMHC's Help Center educates consumers about their health care rights, resolves consumer complaints against health plans, helps consumers navigate and understand their coverage and assists consumers in getting timely access to appropriate health care services. The Help Center provides direct assistance in all languages to health care consumers through the department's website (www.HealthHelp.ca.gov) and a toll free number (1-888-466-2219). DMHC collects data on calls received by the Help Center to identify common challenges experienced by consumers to inform potential changes to health plan oversight, regulation, or statutory authority. Common complaints include cancellation of coverage, billing issues, quality of services, coverage disputes, and access complaints. The Help Center often addresses consumer issues through a three-way call between its staff, the consumer, and the health plan. Complaints involving serious or urgent medical issues are routed to nurses who provide immediate assistance 24 hours a day, seven days a week.



Source: DMHC Consumer Complaints Dashboard for 2023

The Help Center also oversees the independent medical review (IMR) program. IMR is available to consumers if a health plan denies, modifies, or delays a request for a services as not medically necessary or as experimental or investigational. First, a consumer must file a grievance through the established health plan grievance process. If the health plan upholds the denial, modification, or delay, or the grievance is unresolved after 30 days, then the consumer may apply to DMHC for an IMR. During an IMR, independent physicians review the request made by the consumer and make a determination about whether the service should be provided. If an IMR determines the consumer should receive the service, health plans must provide it promptly. In 2023, approximately 72 percent of enrollees submitting IMR requests received the service or treatment.



Source: DMHC Independent Medical Review Dashboard for 2023

ISSUES FOR CONSIDERATION

DMHC Enforcement of Behavioral Health Parity Laws and Regulations. California has led the nation in providing robust protections for health plan consumers who need access to medically necessary behavioral health services. However, health plan adherence to, and DMHC monitoring and enforcement of, behavioral health parity laws and regulations have been uneven and inconsistent. The Legislature may wish to consider how best to ensure DMHC has the tools, the resources, and the necessary statutory mandates to ensure Californians are not inappropriately denied access to the medically necessary behavioral health services to which they are entitled by law.

Streamlining Consumer Grievances and Referral to Independent Medical Review. Despite the best enforcement, there will often be wide variation in health plan interpretations of their requirements to provide medically necessary treatment, which makes the availability of the plan grievance process and DMHC independent medical review (IMR) absolutely critical to adjudicating issues of access to care. However, the frequency with which adverse plan decisions are overturned by IMR suggests that plans may be privileging their own decision-making as part of their internal grievance processes. The Legislature may wish to consider how DMHC could provide technical assistance and financial incentive structures to ensure plan grievance processes are aligned in their evaluation metrics of medical necessity with evaluations undertaken during the IMR process.

Informational Hearing (Part B)

CalRx – Current Initiatives and Future Opportunities to Lower Healthcare Costs for All Californians

BACKGROUND

The California Affordable Drug Manufacturing Act. SB 852 (Pan), Chapter 207, Statutes of 2020, the California Affordable Drug Manufacturing Act of 2020, requires the California Health and Human Services Agency (CalHHS) to enter into partnerships or contracts resulting in the production or distribution of generic prescription drugs, with the intent that these drugs be made widely available to public and private purchasers, providers, suppliers, and pharmacies. SB 852 targets failures in the market for generic drugs resulting from supplier concentration and other anti-competitive practices that lead to higher prices for consumers and health care service providers. CalHHS is required to prioritize production and distribution of drugs that would have the greatest impact on lowering patient drug costs, increasing competition, addressing shortages, and improving public health. In making these determinations, CalHHS must consider the drug expenditure reporting from the Department of Managed Health Care and the Department of Insurance pursuant to SB 17 (Hernandez), Chapter 603, Statutes of 2017, as well as prioritize the production of at least one form of insulin, drugs for chronic and high-cost conditions, and those that can be delivered through mail order.

State manufacturing of drugs is not a new concept. California, through the California Department of Public Health's (CDPH) Infant Botulism Treatment and Prevention Program (IBTPP), has been manufacturing the only treatment for infant botulism since 2003. In 1989, CDPH was designated by the federal Food and Drug Administration (FDA) to develop and test a Botulism Immune Globulin Intravenous (BIG-IV) for the treatment of infant botulism. CDPH conducted a randomized, double-blinded, placebo-controlled, clinical trial between 1992 and 1997, and in October 2003, the FDA licensed BIG-IV as BabyBIG. Federal law permits and California law requires CDPH, as the sponsor of Baby BIG, to charge a fee for BabyBIG in order to meet but not exceed the IBTPP operational expenses, including the developmental and on-going production costs of BabyBIG.

CalRx Implementation. The 2021 Budget Act included one position to serve as Project Manager, and General Fund expenditure authority of $2.2 million in 2021-22, and $184,000 annually thereafter to establish CalRx, consistent with the requirements of SB 852, within the Department of Health Care Access and Information (HCAI). According to HCAI and CalHHS, CalRx enables California to manufacture generic drugs in highly concentrated, low competition drug markets. CalRx has the potential to become a "producer of last resort," remedying drug shortages and addressing what researchers have described as oligopolistic market structures and other market failures that plague the pharmaceutical industry.

Biosimilar Insulin Initiative. The 2022 Budget Act included one-time General Fund expenditure authority of $100 million to establish the Biosimilar Insulin Initiative, consistent with the mandate included in SB 852 to prioritize the production of insulin. Of this amount, $50 million was

allocated to enter into a partnership with a contract manufacturer to develop and bring to market interchangeable biosimilar insulin products in both vial and pen form. According to HCAI, the potential market for these biosimilar insulin products will be substantial for consumers and would likely be widely available through a variety of major outlets, generating significant system wide savings. Many Californians, such as the uninsured, underinsured, and those with high deductible plans, are exposed to high list prices, and would benefit enormously from broadly available low-cost insulin. In the long run, all consumers would also benefit if the branded insulin manufacturers lower their prices in response to the entry of a low-cost option.

According to HCAI, the benefits of the Biosimilar Insulin Initiative include:

- *Priority Access*. California would have priority of supply, so that the state's volume needs are met, but with no minimum volume commitment from the state.
- *Branding*. CalRx insulin products sold within California would be labeled with California-related branding, such as the logo with a California Golden Bear, or verbiage such as "CalRx Insulin" or "CalRx Insulin – Brought to you by the State of California".
- *Low Cost Implementation*. Compared to direct manufacturing, HCAI and CalHHS believe a partnership in contract manufacturing would be the lowest cost and most feasible option for the state to bring biosimilar insulin products to market.

In addition to the partnership contract, the remaining $50 million was allocated for the construction of an insulin manufacturing facility based in California. CalHHS and HCAI, in partnership with the Governor's Office of Business and Economic Development (GO-Biz) were tasked with managing the construction including site review, permit assistance, and other related activities. According to HCAI and CalHHS, the development of the facility would spur economic development, create highly technical positions for Californians, and support and strengthen insulin supply chains within the state. Since the approval of these resources, the Administration has not provided an update on the status of construction of this facility.

Biosimilar Insulin Initiative Has Produced No Insulin To Date. In March 2023, the Administration announced it had selected CivicaRx, a generic drug manufacturer, to produce biosimilar insulin for California. According to the agreement, CivicaRx would make insulin available for no more than $30 per vial and $55 for five injectable pens. Previously, vials of insulin could cost more than $300 and a box of injectable pens more than $500.

Since the announcement of the state's contract with CivicaRx, as well as intense focus at the federal level during the Biden Administration on the cost of insulin, insulin manufacturers have announced significant price reductions, some of which are competitive with the expected price of the CivicaRx product at $30 per vial. However, despite the expectation that biosimilar insulin would be available during the 2024 calendar year, CivicaRx has yet to produce any of the insulin products for which the state has invested $50 million. During that time, legislative efforts to cap the cost to consumers of insulin were rejected by the Governor, citing the impending production of biosimilar insulin by CalRx. It is unclear when CalRx will be able to make biosimilar insulin available to Californians.

Naloxone Access Initiative. In response to the opioid epidemic, which has had a devastating impact on individuals, families, and communities across the United States, the 2023 Budget Act included one position and expenditure authority from the Opioid Settlements Fund of $30 million in 2023-24 and $120,000 annually thereafter for CalRx to implement the Naloxone Access Initiative. Naloxone in its nasal spray formulation has become increasingly popular as a medication that counteracts the effects of opioid overdose by blocking the effects of opioids on the brain. On March 29, 2023, the federal Food and Drug Administration (FDA) approved Narcan, a naloxone nasal spray, for over the counter sale directly to consumer without a prescription. However, according to HCAI the price for Narcan is still too expensive for individuals with lower incomes and a low-cost naloxone spray is necessary to ensure access. Under the Naloxone Access Initiative, CalRx has utilized its contracting authority to collaborate with Amneal Pharmaceuticals to offer 4 mg naloxone nasal spray to California businesses and organizations for $24 per twin-pack.

Much of the product of the naloxone partnership is being distributed through the Naloxone Distribution Project (NDP) administered by the Department of Health Care Services (DHCS). Under the NDP, qualifying organizations can get over-the-counter 4 mg naloxone and intramuscular 3 mg naloxone for free. Eligible NDP entities include first responders, law enforcement and criminal justice partners, community organizations (e.g. libraries, harm reduction, homelessness services, etc.), schools and universities, county public health and behavioral health agencies, local city agencies, tribal entities, substance use recovery facilities, hospitals and emergency departments, and community clinics. CalRx has made no announcements about whether state-contracted naloxone products are available elsewhere, such as at retail pharmacies or other locations.

CalRx Reproductive Health Drug Procurement – Mifepristone and Misoprostol. The 2023 Budget Act included transfer of unspent General Fund expenditure authority of $2 million, originally appropriated for capital infrastructure security for reproductive health clinics, to instead support procurement of mifepristone or misoprostol through CalRx to ensure continued access to these drugs for Californians in need of safe and effective medication abortion. In *Alliance for Hippocratic Medicine v. Food and Drug Administration*, plaintiffs were challenging the federal Food and Drug Administration's (FDA) approval of the drug mifepristone in 2000, which is used in a two-drug combination with the drug misoprostol for medication-induced abortions. While medication-induced abortions may be accomplished with misoprostol alone, the two-drug combination results in fewer potentially harmful side effects. The 2023 Budget Act adjustment was intended to procure a state stockpile of misoprostol or mifepristone, to preserve access in the event of an adverse ruling from the U.S. Supreme Court. However, on June 13, 2024, the court preserved access to mifepristone. CalRx has not provided a status update on this program, or whether drugs were procured.

Drug Cost Transparency Reporting Intended to Drive Future CalRx Initiatives. While SB 852 requires CalRx to prioritize the production of one or more forms of insulin, the bill also requires CalRx to prioritize production and distribution of drugs that would have the greatest impact on lowering patient drug costs, increasing competition, addressing shortages, and improving public health. SB 852 requires CalRx to utilize, among other sources, the Prescription Drug Cost Transparency Reports prepared annually by HCAI and DMHC, pursuant to SB 17. The

HCAI report gathers reporting from prescription drug manufacturers regarding increases in drug prices over a certain percentage or introduction of new drugs with costs over a certain threshold. The DMHC report evaluates the impact of the cost of prescription drugs on health plan premiums.

In its most recent report covering measurement year 2023, DMHC's SB 17 report found that generic drugs made up 89.2 percent of all prescription drugs, but only 12.7 percent of annual spending. Brand name drugs made up 8.8 percent of all prescribed drugs, but 21.5 percent of the cost. Specialty drugs made up two percent of prescribed drugs, but represented 65.8 percent of the cost.

Volume of Prescription Drugs and Total Annual Spending on All Prescription Drugs

Category	Generic	Brand Name	Specialty	Overall
Measurement Year – 2023				
2023 Volume of All Prescription Drugs	89.2%	8.8%	2.0%	100.0%
2023 Annual Spending on All Prescription Drugs	12.7%	21.5%	65.8%	100.0%
Measurement Year – 2022				
2022 Volume of All Prescription Drugs	88.9%	9.5%	1.6%	100.0%
2022 Annual Spending on All Prescription Drugs	14.4%	21.6%	64.0%	100.0%
Measurement Year – 2021				
2021 Volume of All Prescription Drugs	88.2%	10.2%	1.6%	100.0%
2021 Annual Spending on All Prescription Drugs	16.3%	20.8%	62.9%	100.0%
Measurement Year – 2020				
2020 Volume of All Prescription Drugs	89.1%	9.3%	1.6%	100.0%
2020 Annual Spending on All Prescription Drugs	18.1%	21.7%	60.2%	100.0%

Source: DMHC Prescription Drug Cost Transparency Report, Measurement Year 2023

The 12.7 percent annual expense on generic drugs in 2023 is down significantly from the 18.1 percent spent in 2020. However, health plans paid approximately $13.6 billion for prescription drugs in 2023, which suggests they spent approximately $1.7 billion on generics. While driving down the cost of brand name and specialty drugs would provide the most value to the state, there are few options available to accomplish this goal. However, CalRx is uniquely positioned to help reduce the cost of generics, which still represents a significant portion of the state's prescription drug expenditures, by continuing its efforts to selectively contract for inappropriately high-cost generic drugs. According to the DMHC SB 17 report, the most costly generic drugs by annual expenditures, and the highest year-over-year increase in total expenditures are reflected below:

25 Most Costly Generic Drugs by Total Annual Spending

Rank	Prescription Drug Name	Therapy Class
1	DEXTROAMPHETAMINE	Central Nervous System Agents
2	WIXELA	Bronchodilators, Sympathomimetic
3	ESTRADIOL	Hormonal Agents - Sex Hormones/Modifiers
4	ALBUTEROL	Respiratory Tract/Pulmonary Agents
5	LEVOTHYROXINE	Antibacterials; Hormonal Agents - Thyroid
6	ATORVASTATIN	Cardiovascular Agents
7	EMTRICITABINE AND TENOFOVIR DISOPROXIL FUMARATE	Antivirals
8	ROSUVASTATIN	Cardiovascular Agents
9	ERTUGLIFLOZIN PIDOLATE	Respiratory Tract/Pulmonary Agents
10	MESALAMINE	Inflammatory Bowel Disease Agents
11	METHYLPHENIDATE	Central Nervous System Agents
12	METFORMIN	Blood Glucose Regulators
13	BUPROPION	Antidepressants
14	BUDESONIDE	Hormonal Agents - Adrenal
15	LOSARTAN	Cardiovascular Agents
16	LISDEXANFETAMINE	Cardiovascular Agents, Other
17	TACROLIMUS	Dermatological Agents; Immunological Agents; Immunological Agents
18	BUPRENORPHINE	Anti-Addiction/Substance Abuse Treatment Agents; Analgesics
19	TESTOSTERONE	Hormonal Agents - Sex Hormones/Modifiers
20	IBUPROFEN	Analgesics; Anti-Inflammatory Agents
21	SERTRALINE	Antidepressants
22	GABAPENTIN	Anticonvulsants
23	AMLODIPINE	Cardiovascular Agents
24	TRETINOIN	Dermatological Agents; Antineoplastics
25	LISINOPRIL	Cardiovascular Agents; Central Nervous System Agents

Source: DMHC Prescription Drug Cost Transparency Report, Measurement Year 2023

25 Generic Drugs with the Highest Year-Over-Year Increase in Total Spending

Rank	Prescription Drug Name	Therapy Class
1	DEXTROAMPHETAMINE	Central Nervous System Agents
2	CYCLOSPORINE	Immunological Agents
3	SODIUM SULFATE/POTASSIUM	Laxatives
4	AMOXICILLIN	Antibacterials
5	ERTUGLIFLOZIN PIDOLATE	Respiratory Tract/Pulmonary Agents
6	ESTRADIOL	Hormonal Agents - Sex Hormones/Modifiers
7	MESALAMINE	Inflammatory Bowel Disease Agents
8	LISDEXANFETAMINE	Cardiovascular Agents, Other
9	FLUTICASONE	Dermatological Agents; Respiratory Tract/Pulmonary Agents
10	LURASIDONE	Antipsychotics
11	ROSUVASTATIN	Cardiovascular Agents
12	ATORVASTATIN	Cardiovascular Agents
13	GAVILYTE	Blood Glucose Regulators; Gastrointestinal Agents
14	BUPROPION	Antidepressants
15	BUPRENORPHINE	Anti-Addiction/Substance Abuse Treatment Agents; Analgesics
16	VILAZODONE	Serotonin Modulators
17	DOTTI	Estrogens
18	METFORMIN	Blood Glucose Regulators
19	ADDERALL	Central Nervous System Agents
20	PROGESTERONE	Hormonal Agents, Stimulant/Replacement/Modifying (Sex Hormones/Modifiers)
21	CLOMIPHENE	Estrogens
22	AMLODIPINE	Cardiovascular Agents
23	TACROLIMUS	Dermatological Agents; Immunological Agents; Immunological Agents
24	NICOTINE POLACRILEX	Anti-Addiction/Substance Abuse Treatment Agents
25	SERTRALINE	Antidepressants

Source: DMHC Prescription Drug Cost Transparency Report, Measurement Year 2023

ISSUES FOR CONSIDERATION

Controlling Costs for Biosimilar Insulin. California's efforts to control the cost of generic drugs through CalRx have the potential to help stabilize the market for generic drugs by preventing price gouging and increasing competition. In particular, California's efforts to produce biosimilar insulin may have already had their intended effect, with major manufacturers lowering the price of insulin products currently on the market, despite the delay of entry of California's branded insulin. The Legislature should continue to evaluate the status of the Biosimilar Insulin Initiative, including whether the project is continuing to meet its intended goals of lowering the cost of biosimilar insulin, and whether the resources invested in building a manufacturing facility are being spent effectively, or whether they are being spent at all. In addition, as Californians wait for CalRx to produce biosimilar insulin for the California market, the Legislature may wish to consider

alternative strategies to ensure consumers do not pay inappropriately high prices for insulin products.

Future CalRx Projects Must Be Consistent With Legislative Mandates of SB 852. While the implementation of the Naloxone Access Initiative and the reproductive health procurement program are necessary to fulfill specific statewide goals, such as improving opioid overdose reversals and maintaining access to medication-induced abortions, these initiatives are not strictly consistent with CalRx' legislative mandate to lower patient drug costs, increase competition, address shortages, and improve public health. The Legislature should evaluate whether CalRx has sufficient resources to accomplish its statutory goals and whether additional direction should be provided regarding future CalRx procurement or manufacturing strategies, either through budget actions or statutory language.