California State Assembly

HEALTH

MIA BONTA
CHAIR

AGENDA

Tuesday, April 29, 2025
1:30 p.m. -- 1021 O Street, Room 1100

SPECIAL ORDER OF BUSINESS

1.	AB 224	Bonta	Health care coverage: essential health benefits.

BILLS HEARD IN FILE ORDER

2.	AB 255	Haney	The Supportive-Recovery Residence Program.
3.	AB 356	Patel	Health care districts: County of San Diego.
4.	AB 432	Bauer-Kahan	Menopause.
5.	AB 447	Mark González	Emergency room patient prescriptions.
6.	AB 448	Patel	California Health Facilities Financing Authority Act: nondesignated hospitals: loan repayment.
7.	AB 546	Caloza	Health care coverage: portable HEPA purifiers and filters. (Urgency)
8.	AB 554	Mark González	Health care coverage: antiretroviral drugs, drug devices, and drug products.
9.	AB 577	Wilson	Health care coverage: antisteering.
10.	AB 585	Patterson	Electronic death registration system.
11.	AB 682	Ortega	Health care coverage reporting.
12.	AB 725	Solache	Source plasma donation.
13.	AB 849	Soria	Health providers: medical chaperones.
14.	AB 886	Krell	Nicotine: cessation.

15.	AB 916	Lee	Safer Soap Act.
16.	AB 1032	Harabedian	Coverage for behavioral health visits. (Urgency)
17.	AB 1084	Zbur	Change of name and gender and sex identifier. (Urgency)
18.	AB 1103	Ward	Controlled substances: research.
19.	AB 1113	Mark González	Federally qualified health centers.
20.	AB 1129	Celeste Rodriguez	Birth defects monitoring.
21.	AB 1161	Harabedian	Public social services: state of emergency or health emergency.
22.	AB 1196	Gallagher	Health facilities: cardiac surgery.
23.	AB 1199	Patterson	Hospitals: employee identification.
24.	AB 1312	Schiavo	Hospital pricing.
25.	AB 1320	Patterson	California Affordable Drug Manufacturing Act of 2020: opioid antagonists.
26.	AB 1326	Ahrens	Masks: individual or public health.
27.	AB 1386	Bains	Health facilities: perinatal services.
28.	AB 1429	Bains	Behavioral health reimbursement.
29.	AB 1495	Valencia	Home health aides: training and certification.

Date of Hearing: April 29, 2025

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 224 (Bonta) – As Amended April 23, 2025

SUBJECT: Health care coverage: essential health benefits.

SUMMARY: Requires, beginning January 1, 2027, if the United States Department of Health and Human Services (HHS) approves a new essential health benefits (EHBs) benchmark plan for the State of California (state) pursuant to the submission by the state, the existing EHB benchmark plan to additionally include coverage for hearing aids, durable medical equipment (DME), and infertility benefits, as specified. Specifically, **this bill**:

1) Requires, beginning January 1, 2027, if HHS approves a new EHB benchmark plan for the state pursuant to submissions to HHS made by the state in 2025 for this purpose, the existing EHB benchmark plan to additionally include the following benefits:

    a) Services to evaluate, diagnose, and treat infertility that include all of the following:

        i) Artificial insemination;

        ii) Three attempts to retrieve gametes;

        iii) Three attempts to create embryos;

        iv) Three rounds of pre-transfer testing;

        v) Cryopreservation of gametes and embryos;

        vi) Two years of storage for cryopreserved embryos;

        vii) Unlimited storage for cryopreserved gametes;

        viii) Unlimited embryo transfers;

        ix) Two vials of donor sperm;

        x) Ten donor eggs;

        xi) Surrogacy coverage for the services described above; and,

        xii) Health testing of the surrogate for each attempted round of covered services.

    b) All of the following DME:

        i) Mobility devices, including, but not limited to, walkers and manual and power wheelchairs and scooters;

        ii) Augmented communications devices, including, but not limited to, speech generating devices, communications boards, and computer applications;

iii) Continuous positive airway pressure machines;

iv) Portable oxygen; and,

v) Hospital beds.

c) An annual hearing exam and one hearing aid per ear every three years.

EXISTING LAW:

1) Establishes the Department of Managed Health Care (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. [Health and Safety Code (HSC) § 1340, *et seq*., and Insurance Code (INS) § 106, *et seq*.]

2) Establishes California's EHB benchmark under the federal Patient Protection and Affordable Care Act (ACA) as the Kaiser Small Group Health Maintenance Organization contract. Establishes existing California health insurance mandates and the 10 ACA mandated benefits. [HSC § 1367.005 and INS § 10112.27]

3) Specifies EHBs in the following 10 categories: ambulatory patient services; emergency services; hospitalization; maternity and newborn care; mental health and substance use disorder services; prescription drugs; rehabilitative and habilitative services and devices; laboratory services; preventive and wellness services and chronic disease management; and, pediatric services, including oral and vision care. [HSC § 1367.005 and INS § 10112.27]

4) Defines "basic health care services" as all of the following:

a) Physician services, including consultation and referral;

b) Hospital inpatient services and ambulatory care services;

c) Diagnostic laboratory and therapeutic radiologic services;

d) Home health services;

e) Preventive health services;

f) Emergency health care services, including ambulance and ambulance transport services and out-of-area coverage. Basic health care services includes ambulance and ambulance transport services provided through the 911 emergency response system; and,

g) Hospice care. [HSC § 1345]

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

COMMENTS:

1) **PURPOSE OF THIS BILL.** According to the author, the ACA requires health plans sold in the individual and small group markets to offer a comprehensive package of items and services, known as EHBs. The author states that under this federal legislation each state has

the authority to choose its benchmark EHB plan, which details the EHBs that must be included in the scope of benefits for each health plan. The author continues that California's current EHB benchmark plan does not include coverage for a variety of benefits – such as hearing aids, infertility treatment or DME. In order to change California's EHBs, the author notes that the state was required to update its existing benchmark plan through a review process, which included an actuarial analysis and stakeholder process. The author continues that in order for new benefits to be in place for the 2027 plan year, the state must notify the federal government of its intention and proposed plan by May of this year. The author concludes that California has completed its review process and is now in the process of submitting a proposal to the federal government to add hearing aids, infertility treatment, and DME to California's EHB benchmark plan. This bill will codify these new EHBs if that proposal is approved.

2) BACKGROUND.

a) ACA & EHBs. Signed into law by President Obama in 2010, the ACA marked a significant overhaul of the U.S. health care system. According to the Kaiser Family Foundation, prior to the passage of the ACA high rates of uninsurance were prevalent due to unaffordability and exclusions based on preexisting health conditions. Additionally, insured people faced extremely high out-of-pocket costs and coverage limits. With the goal of addressing these issues, the ACA built upon the existing health insurance system and made significant changes to Medicare, Medicaid, and the employer-sponsored plan system. This impacted all aspects of the health system, from insurers, providers, state governments, employers, taxpayers, and consumers.

The ACA established EHBs, which are ten categories of services that plans are required to cover: (1) ambulatory patient services (outpatient care); (2) emergency services; (3) hospitalization; (4) maternity and newborn care; (5) mental health and substance use disorder services, including behavioral health treatment; (6) prescription drugs; (7) rehabilitative and habilitative services and devices; (8) laboratory services; (9) preventive and wellness services and chronic disease management; and, (10) pediatric services, including dental and vision care.

The ACA helps consumers shop for and compare health insurance options in the individual and small group markets by promoting consistency across plans, protecting consumers by ensuring that plans cover a core package of items that are equal in scope to benefits offered by a typical employer plan, and limit out of pocket expenses. Federal rules outline health insurance standards related to the coverage of EHBs and the determination of actuarial value (AV) – (which represents the share of health care expenses the plan covers for a typical group of enrollees), while providing significant flexibility to states to shape how EHBs are defined. Taken together, EHBs and AV significantly increase consumers' ability to compare and make an informed choice about health plans.

b) California's initial EHB benchmark plan selection process. HHS defines EHBs based on state-specific EHB benchmark plans and gives each state the authority to choose its "benchmark" plan. California chose the Kaiser Small Group HMO plan in 2012, and last reviewed it in 2015.

c) **Updating EHBs.** HHS issued final rules in 2018 and 2019, which provided flexibility for states by allowing three new options for the EHB benchmark plan, in addition to the option of retaining the current EHB benchmark plan. Beginning with the 2020 plan year, states could: (1) select an EHB benchmark plan used by another state for the 2017 plan year; (2) replace one or more of the ten EHB categories in the state's EHB benchmark plan with the same category or categories of EHBs from another state's 2017 EHB benchmark plan; or, (3) otherwise select a set of benefits that would become the state's EHB benchmark plan. At a minimum, the EHB benchmark plan must provide a scope of benefits equal to or greater than a typical employer plan. Furthermore, a new "generosity test" required that EHBs not exceed the generosity of the most generous among the set of ten previous 2017 benchmark comparison plan options. According to the Centers for Medicare & Medicaid Services (CMS) website, for plan years between 2020 and 2025, nine states updated their EHB benchmark plans.

   In April of 2024, new rules were finalized for EHB benchmark updates through the HHS Notice of Benefit and Payment Parameters for 2025. For plan years beginning on or after January 1, 2026, the federal government approved three revisions to the standards for state selection of EHB-benchmark plans to address long-standing requests from states to improve, and reduce the burden of, the EHB benchmark plan update process. First, states are allowed to consolidate the options for changing EHB benchmark plans, meaning a state may select a set of benefits that would become the state's EHB benchmark plan. Second, the generosity standard was removed and a revised typicality standard was introduced. Under this typicality standard a state's new EHB benchmark plan must demonstrate that it provides a scope of benefits that is equal to the scope of benefits of a typical employer plan in the state. The scope of benefits of a typical employer plan in the state would be defined as any scope of benefits that is as or more generous than the scope of benefits in the state's least generous typical employer plan, and as or less generous than the scope of benefits in the state's most generous typical employer plan. Third, the requirement for states to submit a formulary drug list as part of their documentation to change EHB-benchmark plans unless the state changes its prescription drug EHBs was removed.

d) **California's process.** On June 27, 2024, DMHC held a public meeting to discuss California's EHBs and the process for updating the benchmark plan. At that meeting, DMHC shared the timeline and introduced consultants who explained the federal rules and recently approved and proposed EHB benchmark changes from other states. A second stakeholder meeting was held on January 28, 2025. At this meeting the Wakely Consulting Group (Wakely) presented an actuarial analysis that identified the benefit allowance and potential options and prices for a proposed benchmark plan. Through a typicality test following current CMS standards, Wakely determined that California's proposed benchmark plan can impact benefit costs (which is what the plan pays for the service plus member cost share) that range between 1.06% to 2.23%. This means that the value of the benefit additions cannot exceed 2.23%. Wakely further estimated the pricing of a suite of proposed benefits that potentially could be added, including hearing aids, DME, wigs, chiropractic, infertility, and adult dental. Altogether the cost of these benefits, with the exception of adult dental would add 1.63% to 3.48% cost. These benefits exceed the allowed cost impact range by 0.57% to 1.25%. This meant choices had to be made to narrow the set of proposed benefits to be covered. A joint legislative hearing was held on February 11, 2024 to provide the Assembly and Senate Health

Committees with information about the analysis and options that may be considered for updating the EHB benchmark plan.

On March 28, 2025, DMHC announced California's intent to submit a proposal to the federal government to add three new benefits to the state's EHB benchmark plan: hearing aids, durable medical equipment, and infertility treatment. Notification from DMHC to HHS must take place by May 7, 2025 for the new benchmark to go into effect for the January 1, 2027 plan year. If the proposed EHB benchmark is approved by CMS, legislation to codify the new benchmark plan will be necessary. This bill and SB 62 (Menjivar) have been introduced to codify any benchmark changes that may come out of this process.

e) **Cost impacts to patients.** It should be noted that premiums may increase as a result of setting a new benchmark plan. Individuals who are eligible for premium subsidies may be shielded from premium increases, but those not eligible for subsidies will feel the full impact of any premium increase. Covered California announced individual insurance market rates for the 2025 coverage year indicating the preliminary statewide weighted average rate change for the 2025 coverage year is 7.9%. Northern and Central valley regions are seeing higher premium increases and the Monterey, San Benito and Santa Cruz county region are seeing the highest average increase at 15.7%. The region with the lowest average increase is San Bernardino and Riverside with 5.3%. San Francisco and Bay Area regions, Los Angeles and San Diego are seeing average premium increases in the 7 to 8% range. Orange County is seeing an average premium increase of 9.6%.

f) **ACA subsidies.** The ACA also provides federal subsidies for those who qualify, referred to as Advanced Premium Tax Credits (APTCs), to help offset the costs to purchase individual market health insurance purchased through federal or state marketplaces (or health benefit exchanges). According to Covered California, the state's health benefit exchange, in June of 2024, approximately 1.5 million Californians received an average of $519 per member per month in APTCs (this translates to $9.7 billion on an annualized basis). Approximately 19% comes from the federal Inflation Reduction Act enhanced subsidies, which are set to expire at the end of 2025. For 2024, these enhanced APTCs were roughly $1.8 billion.

g) **Defrayal of mandate costs**. Under the ACA, if states require plans to cover services beyond those defined as EHBs in law, states must pay the costs of those benefits, either by paying the enrollee directly or by paying the qualified health plan (offered through Covered California). States adopting a new benchmark plan or revising the existing plan will not result in triggering defrayal. This is the process the Legislature and Administration are currently engaged in.

3) **SUPPORT.** The Western Center on Law and Poverty (WCLP) supports this bill, stating that the current benchmark creates a significant gap in services due to its lack of coverage for DME. WCLP continues that as a result, many Californians do not have access to the wheelchairs, hearing aids, oxygen equipment or other DME that they need because private health plans in California's individual and small group markets regularly exclude or limit coverage of this equipment. WCLP notes that without adequate coverage, people go without medically necessary devices, obtain inferior ones that put their health and safety at risk, or turn to publicly-funded health care programs for help.

SEIU California supports this bill, citing the inclusion of infertility services as an EHB. SEIU California argues that this bill moves our health care delivery system forward for those seeking to start or grow their family. SEIU California notes that with 7 out of 10 of their members identifying as women and 60% as women of color, this bill is personal for many. SEIU California continues that for their members, like the physician residents and interns united in SEIU CIR, who may train and study for decades before being financially stable to consider a family, this bill is particularly important. SEIU states that with 1 in 4 physicians with wombs experiencing infertility, this allows them the reassurance that they can fulfill their professional vision while honoring their personal family vision, too.

4) **SUPPORT IF AMENDED.** The California Dental Association (CDA) writes to ask that this bill be amended to include adult dental in California's EHB plan. CDA understands the challenges with including adult dental coverage as highlighted in the benefit review analysis and is aware that adult dental is not included in the draft plan under current consideration. However, CDA urges the legislature to consider adding adult dental at the earliest opportunity as oral healthcare is not a luxury, it is a core component of overall health.

5) **CONCERNS.** The California Association of Health Plans (CAHP) and Association of California Life and Health Insurance Companies (ACLHIC) understand the intent to enhance healthcare coverage for Californians, but believe that proceeding with this bill now is premature and warrants a delay to allow for a more thorough review and consultation on several critical issues. CAHP and ACLHIC's primary concern lies with the potential premium impact and affordability for consumers. CAHP and ACLHIC also state that the federal uncertainty surrounding the future of healthcare funding also necessitates a delay in considering this legislation.

6) **RELATED LEGISLATION.**

   a) SB 62 (Menjivar) is substantially similar to this bill. SB 62 is pending in the Senate Health Committee.

7) **PREVIOUS LEGISLATION.**

   a) AB 2914 (Bonta) of 2024 expressed the intent of the Legislature to review California's EHB benchmark plan and establish a new EHB plan for the 2027 plan year. AB 2914 was moved to the inactive file on the Senate floor.

   b) AB 2753 (Ortega) of 2024 would have included as coverage of existing EHB rehabilitative and habilitative services and devices, DME services, and repairs, if appropriately prescribed or ordered by a health professional, and prohibits a health care service plan (health plan) or health insurance policy from subjecting coverage of DME and services to financial or treatment limitations. AB 2753 defined DME to mean devices that are designed for repeated use, and that are used for the treatment or monitoring of a medical condition or injury in order to help a person to partially or fully acquire, improve, keep, or learn, or minimize the loss of, skills and functioning of daily living. AB 2753 was held on the Assembly Appropriations suspense file.

   c) SB 729 (Menjivar) Chapter 930, Statutes of 2024, requires a health plan contract or policy of disability insurance sold in the large group market (employers with more than 100 covered individuals) to provide coverage for the diagnosis and treatment of infertility

and fertility services, including services of a maximum of three completed oocyte retrievals with unlimited embryo transfers in accordance with the guidelines of the American Society for Reproductive Medicine (ASRM) using single embryo transfer when recommended and medically appropriate. A signing message from the Governor stated:

"I am signing Senate Bill 729, which will require a large group health plan to provide coverage for infertility and fertility services, including in vitro fertilization (IVF), with a maximum of three completed oocyte retrievals and unlimited embryo transfers, beginning July 1, 2025, and delay its implementation for CalPERS until July 1, 2027.

California is a reproductive freedom state. As a national leader for increasing access to reproductive health care and protecting patients and providers, including those under assault in other states, I want to be clear that the right to fertility care and IVF is protected in California. In many other states, this is not the case. I wholeheartedly agree that starting a family should be attainable for those who dream to have a child - inclusive of LGBTQ+ families. There is a better way to strengthen IVF coverage across California's health care delivery system, and the state has already begun this work. In January of this year, we started the process of updating the state's "benchmark" plan, which will set a new standard for commercial insurance health coverage. The services under evaluation specifically include infertility treatment and IVF. The state's proposed benefit design will be released later this year and adopted by the Legislature by May 2025. I expect that IVF coverage will be included in the benchmark plan proposal adopted next spring, but may differ from the one in this bill. As a part of that process, I request that the Legislature change the effective date of this measure from July 1, 2025 to January 1, 2026, upon their return in January to allow an evaluation of the costs and benefit design in this bill within that broader context."

d) SB 1290 (Roth) of 2024 was substantially similar to AB 2914. SB 1290 was moved to the inactive file on the Assembly floor.

e) SB 635 (Menjivar) of 2023 would have required health aid coverage for enrollees or insureds under 21 years of age. Governor Newsom vetoed SB 635, stating in part, that the Department of Health Care Services has developed a comprehensive plan to increase provider participation and program enrollment for the Hearing Aid Coverage for Children Program.

f) AB 1157 (Ortega) of 2023 was substantially similar to AB 2753 (Ortega). AB 1157 was held in Senate Appropriations Committee.

REGISTERED SUPPORT / OPPOSITION:

Support

American Society for Reproductive Medicine
California State Council of Service Employees International Union (SEIU California)
Children's Specialty Care Coalition
Indivisible CA: Statestrong
National Association of Pediatric Nurse Practitioners

Resolve: the National Infertility Association
Western Center on Law & Poverty

Opposition

None on file

Analysis Prepared by: Riana King / HEALTH / (916) 319-2097

Date of Hearing: April 29, 2025

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 255 (Haney) – As Amended April 21, 2025

SUBJECT: The Supportive-Recovery Residence Program.

SUMMARY: Requires the Department of Health Care Services (DHCS) to establish a certification process for supportive-recovery residences (SRRs). Expands Housing First (HF) core components to permit state entities to fund SRRs that use substance use-specific services, peer support, and physical design features supporting individuals and families on a path to recovery. Specifically, **this bill**:

1) Requires DHCS to adopt the most recent standards approved by the National Alliance for Recovery Residences (NARR), the Substance Abuse and Mental Health Services Administration (SAMHSA), or other equivalent standards as the minimum standard for SRRs that receive public funding. Permits DHCS to charge a certification fee that does not exceed $1,000 for the reasonable cost of administering the program.

2) Defines SRR as a residence that serves individuals experiencing, or who are at risk of experiencing, homelessness and who have substance use disorders (SUDs), and that does all of the following:

   a) Satisfies the core components of HF;

   b) Uses substance use-specific services, peer support, and physical design features supporting individuals and families on a path to recovery from addiction;

   c) Emphasizes abstinence; and,

   d) Offers tenants permanent housing only.

3) Requires DHCS to establish a process for determining if the SRR complies with the core components of Housing First.

4) Establishes in the State Treasury the SRR Program Fund into which all fees collected under this program will be deposited and made available to DHCS, upon appropriation by the Legislature, to support its SRR certification activities.

5) Expands HF core components to permit state departments or agencies to allow programs to fund SRRs so long as the state program meets all of the following requirements:

   a) At least 75% of program funds awarded to each jurisdiction from a notice of funding availability is used for housing or housing-based services using a harm-reduction model;

   b) The state program requires a grantee under the program, prior to awarding subgrants, to confirm that the subgrantee has achieved successful outcomes in promoting housing retention, similar to rates of housing retention as harm-reduction programs;

   c) The state performs periodic monitoring of select SRRs to ensure programs:

i) Otherwise comply with all other components of HF, including low barrier to entry;

ii) Participation is self-initiated;

iii) Holistic services and peer-based recovery supports are available and directly communicated to all program participants;

iv) The housing abides by local and state landlord-tenant laws governing grounds for eviction;

v) Relapse is not an automatic cause for eviction from housing, and tenants receive relapse support;

vi) Eviction from a SRR only occurs when a tenant's behavior substantially disrupts or impacts other people where the tenant resides, but has procedures for the tenant to reenter that SRR; and,

vii) The SRR finds alternative housing for a tenant who is no longer interested in living in that SRR or is at risk of eviction, including permanent housing that uses harm reduction principles at either a partner or other housing program. Requires the SRR to continue to house the tenant until they are successfully rehoused.

6) Makes Legislative findings and declarations regarding the need for recovery housing programs.

EXISTING LAW:

1) Establishes DHCS as the sole licensing authority for alcohol or other drug recovery or treatment facility (RTFs). Permits new licenses to be issued for a period of two years and requires DHCS to conduct onsite program visits for compliance at least once during the two-year licensing period. [Health and Safety Code (HSC) § 11834.01]

2) Defines RTF to mean a premises, place, or building that provides residential nonmedical services to adults who are recovering from problems related to alcohol, drug, or alcohol and drug misuse or addiction, and who need alcohol, drug, or alcohol and drug recovery, treatment, or detoxification services. [HSC § 11834.02]

3) Defines "recovery residence (RR)" as a residential dwelling that provides primary housing for individuals who seek a cooperative living arrangement that supports personal recovery from an SUD and that does not require DHCS licensure or does not provide RTF licensable services. Requires any certified program or licensed RTF to disclose to DHCS if any of its agents, partners, directors, officers, or owners, including a sole proprietor and member, has ownership or control of, or financial interest in, an RR. Permits an RR to include, but not be limited to, residential dwellings commonly referred to as "sober living homes (SLHs)," "sober living environments," or "unlicensed alcohol and drug free residences." [HSC § 11833.05(f)]

4) Requires California agencies and departments administering state programs created on or after July 1, 2017, to collaborate with the California Interagency Council on Homelessness (Cal ICH) to adopt or revise guidelines and regulations to incorporate HF core components,

except for the Returning Home Well Program, Specialized Treatment for Optimized Programming Program, and Long-Term Offender Reentry Recovery Program, all of which are administered by the Department of Corrections and Rehabilitation and fund "recovery housing." Defines "state programs" as those that a state entity funds, implements, or administers to provide housing or housing-based services to people experiencing or are at risk of homelessness. [Welfare and Institutions Code (WIC) § 8255 and § 8256]

5) Defines HF to mean the evidence-based model that uses housing as a tool, rather than a reward, for an individual's recovery, and that centers on providing or connecting homeless people to permanent housing as quickly as possible. Specifies that HF employs various core components that include such things as engaging tenants in services informed by a harm-reduction philosophy and recognize drug and alcohol use and addiction as a part of tenants' lives; engage tenants in nonjudgmental communication about drug and alcohol use; and offer education to avoid risky behaviors and engage tenants in safer practices with connection to evidence-based treatment, if tenants so choose. [WIC § 8255(b and d)]

6) Defines "recovery housing" to mean sober living facilities and programs that provide housing in a recovery-focused and peer-supported community for people recovering from SUD issues. Makes participation for tenants voluntary, unless it is ordered by a court or is a condition of release for individuals under the jurisdiction of a county probation department or the Department of Corrections and Rehabilitation. [WIC § 8256(c)(3)]

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

COMMENTS:

1) **PURPOSE OF THIS BILL.** According to the author, although housing that does not require sobriety works for thousands of people who aren't yet ready to enter drug free housing, it doesn't work for everyone. There are thousands of people who want, and need, to live in a strictly sober living arrangement, but they can't access it because this type of housing is limited and hard to find. The author argues this causes people to live in housing that is not best suited for their sobriety journey and puts them at a higher risk of falling back into homelessness. The author concludes this bill aligns California policy with federal policy briefs by recognizing that drug free housing is a component of the HF model and should get some statewide funding.

2) **BACKGROUND.**

   a) **Prevalence of SUD in California.** A 2024 publication from Health Management Associates and the California Health Care Foundation titled, "*Substance Use Disorder in California — a Focused Landscape Analysis"* reported that approximately 9% of Californians ages 12 years and older met the criteria for SUD in 2022. According to the report, the prevalence of SUD among individuals 12 years of age and older increased to 8.8% in 2022 from 8.1% in 2015. While the health care system is moving toward acknowledging SUD as a chronic illness, only 6% of Americans and 10% of Californians ages 12 and older with an SUD received treatment for their condition in 2021. More than 19,335 Californians ages 12 years and older died from the effects of alcohol from 2020 to 2021, and the total annual number of alcohol-related deaths increased by approximately 18% in the state from 2020 to 2021. Overdose deaths from both opioids and psychostimulants (such as amphetamines), are soaring. This issue, compounded by the

increased availability of fentanyl, has resulted in a 10-fold increase in fentanyl related deaths between 2015 and 2019. According to the California Department of Public Health's Overdose Prevention Initiative, 7,847 opioid-related overdose deaths occurred in California in 2023. In the first two quarters of 2024, 2,975 opioid-related overdose deaths were recorded in California.

b) **Alcohol and Drug Treatment Facility Licensing and Certification.** DHCS has sole authority to license RTFs in the state. Licensure is required when at least one of the following services is provided: detoxification; group sessions; individual sessions; educational sessions; or, alcoholism or other drug abuse recovery or treatment planning. Additionally, facilities may be subject to other types of permits, clearances, business taxes, or local fees that may be required by the cities or counties in which the facilities are located.

   As part of their licensing function, DHCS conducts reviews of RTF operations every two years, or as necessary. DHCS's SUD Compliance Division checks for compliance with statutes and regulations to ensure the health and safety of RTF residents and investigates all complaints related to RTFs, including deaths, complaints against staff, and allegations of operating without a license. DHCS has the authority to suspend or revoke a license for conduct in the operation of an RTF that is contrary to the health, morals, welfare, or safety of either an individual in, or receiving services from, the facility or to the people of the State of California. DHCS does not license alcohol and drug recovery residences with six or fewer beds that don't provide licensable services.

   Prior to January 1, 2025, alcohol and other drug programs were permitted to seek certification from DHCS. Under AB 118 (Committee on Budget), Chapter 42, Statutes of 2023, certification is now a requirement for many alcohol and drug programs, with exceptions for various licensed facility types, schools, jails, and prisons.

c) **RRs.** An RR is a residence for people in recovery from SUDs. It may serve as support for individuals undergoing treatment but it does not provide treatment or care, whether medical or nonmedical. The state laws and licensing requirements that govern treatment and care facilities do not currently include RRs. Therefore, the state does not keep any list of registered RRs, conduct inspections of RRs, or perform any of the other activities associated with licensing facilities. According to NARR, its standard defines the spectrum of recovery-oriented housing and services and distinguishes four residence types referred to as "levels" or "levels of support." The standard was developed with input from major regional and national recovery housing organizations, recovery residence providers from across the nation representing all four levels of support, and nationally recognized recovery support stakeholders. The NARR Standard provides guidance for certifying effective recovery residences and incorporates the collaborative values of acute care and social models of recovery. The standard is built on the lived experience of operators and residents, not the decisions of an external accreditation body. Resident wellness and opportunities to enhance recovery are at the forefront of the Standard.

   An RR may be completely self-governed or have formal on-site management, but in the latter case, the managers' duties relate to the administration of the house rather than the tenants or their recovery. The tenants of an RR pay rent and abide by house rules, which

include maintenance of sobriety and participation in a self-help program. In 2016 the California Research Bureau estimated that there were at least 12,000 sober living beds, like those offered in RRs, in the state to serve an eligible population of between 25,000 and 35,000 individuals. A 2021 article "*Estimating the Number of Substance Use Disorder Recovery Homes in the United States*" estimates 2,432 recovery homes in California. If an RR is providing any licensable services then it must obtain a valid RTF license from DHCS.

This bill seeks to create a new category of recovery home for people who are homeless or at risk of experiencing homelessness with SUD. Recovery housing, as currently defined under existing law, is not required to comply with HF requirements, although some may do so. This bill would require an SRR to comply with HF, which means that although the provider of the housing could emphasize abstinence, an individual would be offered options and would choose recovery housing over a harm-reduction approach; participation would be self-initiated; relapse is not an automatic cause for eviction from housing and tenants receive relapse support; and policies and operations must ensure individual rights of privacy, dignity and respect, and freedom from coercion and restraint, as well as continuous, uninterrupted access to housing.

d) HF. Research indicates that evidence-based approaches like supportive housing – affordable housing coupled with wrap-around services – resolves homelessness for many individuals. In addition, the state has a policy of HF, which is an approach that prioritizes providing permanent housing to people experiencing homelessness, thus ending their homelessness and serving as a platform from which they can pursue personal goals and improve their quality of life. Many state and local programs utilize these evidence-based approaches to address homelessness; however, the number of people falling into homelessness continues to overwhelm the response system and surpasses the affordable housing stock in many communities. These factors lead to persistently high rates of homelessness despite recent state and local investments. Other strategies, such as rental assistance and help with identifying and securing housing (housing navigation) can also help with those individuals who need prevention tools to avoid homelessness.

e) Harm Reduction. According to the National Institutes of Health (NIH) website, harm reduction is a strategy that aims to reduce the harms associated with certain behaviors. The National Institute on Drug Abuse (NIDA) reports that decades of research have shown that some harm reduction strategies provide significant individual and public health benefits, including preventing deaths from overdoses and preventing transmission of infectious diseases among people who use drugs and the larger community. Others reduce emergency department visits and costly healthcare services, while in some cases offering people who use drugs opportunities to connect to substance use treatment and other health care services in settings relatively free of stigma. NIDA says that, as a model of substance use care distinct from treatment or recovery support, harm reduction was created by and for people who use drugs to improve health and wellbeing, including during active drug use.

f) Shifting Funding. SB 1380 (Mitchell), Chapter 847, Statutes of 2016 required the state to adopt a HF approach and required all state-funded programs to comply with HF. Traditional recovery housing does not necessarily conform to HF because it is an abstinence-based approach to addressing substance abuse. This bill aims to set new

guidelines for how recovery homes could continue to provide an option for abstinence but also comply with HF. This bill would allow state programs to use a portion of available funding for homelessness for SRRs, as defined, provided at least 75% of program funds awarded to each jurisdiction is used for housing or housing-based services using a harm-reduction model.

3) **SUPPORT.** San Francisco Mayor Daniel Lurie is sponsoring this bill and states in support that, despite an extensive system of shelter beds and permanent supportive housing units, it is not enough to meet the needs of those experiencing homelessness. Mayor Lurie says that a key piece of this system is abstinence-based housing for those who are in the midst of their recovery journey. Mayor Lurie concludes that we have to expand abstinence-based options because we never want someone to worry about jeopardizing their recovery in exchange for a roof over their head.

   The Bay Area Council, On Lok Senior Health Services, the Salvation Army, and United Playaz support this bill stating that overdose deaths among California's homeless population have increased a tragic and unacceptable 488% since 2010. Substance use is both a cause and a result of homelessness, and California must do more to follow evidence-based approaches to addressing both. These supporters state that the U.S. Department of Housing and Urban Development (HUD) recognizes "the importance of providing individual choice to support various paths towards recovery" from addiction, including the "preference for an abstinence-focused residential or housing program where they can live among and be supported by a community of peers who are also focused on pursuing recovery from addiction–environments." HUD recommends these supportive-recovery residences can and should be a component of any Continuum of Care" that needs it. They argue that current law, while well-intended, deprives homeless Californians seeking recovery from obtaining these proven lifesaving options by requiring that all state-funded housing for homeless residents tolerate onsite use of drugs and alcohol.

4) **OPPOSITION.** The County of Santa Clara opposes this bill noting significant concerns that it undermines the HF approach and will divert funding towards abstinence-based programs that are proven to be less effective at reducing homelessness. Santa Clara argues that, while this bill attempts to prevent automatic eviction for individuals in abstinence-based housing who relapse, the County remains concerned that people will return to homelessness at a higher rate than those who participate in HF programs. Additionally, Santa Clara states that local governments are facing extreme uncertainty from the federal budget that will affect core funding and basic operations of safety net services. Santa Clara believes this bill weakens the HF approach to ending homelessness and particularly at a time of scarce resources.

5) **CONCERNS.** The Corporation for Supportive Housing, Housing California, and the National Alliance to End Homelessness have concerns with this bill stating that unlike other models of housing, no evidence supports recovery housing as a solution to homelessness. Recovery housing was developed in the 1800's as a response to drug and alcohol addiction, not as a response to homelessness. They recommend limiting investment to 10% of an entire grant a county receives and recommend measuring outcomes to build evidence on effectiveness of these interventions, especially as compared to other housing interventions. They also state that the addition clarifying that "relapse is not an *automatic* cause for eviction" is vague and invites providers to interpret as they see fit. It introduces a concept

contrary to HF: permitting evictions from housing (and potential returns to homelessness) based on reasons unrelated to the tenants' compliance with the lease terms. They argue that it allows providers opportunity to evict people from housing for relapse, even though relapse is part of recovery.

6) **DOUBLE REFERRAL.** This bill is double referred; it was heard in the Assembly Housing and Community Development Committee on April 24, 2025 and passed by a vote of 12-0.

7) **RELATED LEGISLATION.**

a) AB 20 (DeMaio) would, among other things, delete the requirement that a state agency or department revise or adopt guidelines to include HF policies and would repeal related provisions requiring adherence to HF, as specified. Would authorize a state program to review the suitability of an applicant based on their housing readiness and impose program rules and requirements related to sobriety, substance abuse, completion of treatment, mental health, participation in services, and compliance with program rules. AB 20 failed passage in the Assembly Housing and Community Development Committee.

b) AB 492 (Valencia) would require DHCS to notify a city or county, in writing, of the issuance of a new license to an RTF within the local government's jurisdiction. AB 492 is pending on the Assembly Floor.

c) AB 1037 (Elhawary) would update several SUD licensing and public health laws by expanding those authorized to receive opioid antagonists and eliminate the requirement that they receive training, and require DHCS to offer a combined application for entities to be licenses as an RTF and to provide incidental medical services. AB 1037 is pending in the Assembly Judiciary Committee.

d) SB 43 (Umberg) would require all programs certified and all facilities licensed, no later than July 15, 2026, and annually each July 15 thereafter, to submit to DHCS a report of all money transfers between the program or facility and a recovery residence during the previous fiscal year. SB 43 is pending in the Senate Judiciary Committee.

8) **PREVIOUS LEGISLATION.**

a) SB 1339 (Allen) of 2024 would have required DHCS, by January 1, 2027, to establish a voluntary certification program for "supportive community residences" (SCRs) using HF core components. SB 1339 was not heard in the Assembly Health Committee.

b) AB 2479 (Haney) of 2024 was substantially similar to this bill in its HF provisions, but did not include the provision requiring DHCS to certify SCRs. AB 2479 was not heard in the Senate Housing Committee.

c) AB 1098 (Daly) of 2021 would have required the Secretary of California Health and Human Services to develop and publish on DHCS's website consensus-based guidelines and nationally recognized standards for counties to use to promote the availability of high-quality RRs. AB 1098 was held on the Assembly Appropriations Committee suspense file.

d) AB 1220 (Luz Rivas) Chapter 398, Statutes of 2021 restructures the Homeless Coordinating and Financing Council (HCFC), such as renaming it Cal ICH; removing all required members that are not department or agency heads and placing them on an advisory board that includes Legislative appointees and a person who has experienced homelessness; and, requiring it to meet regularly with the advisory board and seek its counsel.

e) SB 992 (Hernández) Chapter 784, Statutes of 2018 requires programs licensed or certified by DHCS to disclose business relationships with RRs. SB 992 also made changes and improvements in DHCS's licensing requirements for RTFs.

f) SB 1380 (Mitchell), Chapter 847, Statutes of 2016 established HF in this state and created the HCFC.

g) SB 1283 (Bates) of 2016 would have permitted a city, county, or city and county to adopt by ordinance a registration process, health and safety standards, enforcement mechanisms for structured SLHs. SB 1283 was not heard in the Senate Health Committee.

9) **POLICY COMMENT.** Recent author's amendments clarified that relapse is not an "automatic" cause for eviction from housing, rather than stating clearly that relapse is not a cause for eviction. While potentially intended as a clarification, the addition of "automatic" may allow SRR providers greater latitude to evict for relapse, and may run counter to the HF principles the bill otherwise attempts to protect. Should this bill move forward, the author may wish to consider if this addition provides more clarity or less, and what latitude it ultimately allows SRRs to evict a resident for relapse, which is a known part of SUD recovery. The author may also wish to consider how SAMHSA guidance could potentially change in coming years and whether referencing it as a standard is necessary in accomplishing the goals of this bill.

REGISTERED SUPPORT / OPPOSITION:

Support

Mayor Daniel Lurie, City and County of San Francisco (Sponsor)
Bay Area Council
California Catholic Conference
Code Tenderloin
Gensler
Golden Gate Restaurant Association (GGRA)
LeadingAge California
Mayor Matt Mahan, City of San Jose
Mid Market Community Benefit District
North Bay Leadership Council
On Lok Senior Health Services
The Salvation Army
Union Square Alliance
United Playaz

Opposition

County of Santa Clara

Analysis Prepared by: Logan Hess / HEALTH / (916) 319-2097

Date of Hearing: April 29, 2025

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 356 (Patel) – As Amended April 9, 2025

SUBJECT: Health care districts: County of San Diego.

SUMMARY: Requires the Department of Health Care Access and Information (HCAI) to convene a working group to study and make recommendations regarding the provision of health care services in health care districts in the northern region of the County of San Diego. Specifically, **this bill**:

1) Requires HCAI to convene a working group to study and make recommendations regarding the provision of health care services in health care districts in the northern region of the County of San Diego.

2) Requires the working group to include representatives of each of the following areas:

   a) The Palomar Health Care District;

   b) The Fallbrook Health Care District;

   c) The Tri-City Health Care District;

   d) The San Diego Delegation of the California Legislature;

   e) The University of California hospitals;

   f) Trade associations representing health care districts;

   g) Trade associations representing hospitals;

   h) Trade associations representing special districts; and,

   i) Any other relevant stakeholder interests, as determined by HCAI.

3) Specifies that this bill does not affect or limit any other statutory, regulatory, or contractual obligations of public health care providers or health care districts operating in the San Diego region.

4) Requires the working group described in 1) above to do both of the following:

   a) Review and discuss the statutory or other responsibilities of each health care district to provide health care services to the communities they serve and evaluate their capacity to meet those responsibilities; and,

   b) Examine whether current resources, funding, and organizational structures in the northern region of the County of San Diego can fulfill the goal of providing adequate health care access to all residents, including underserved and vulnerable communities.

5) Requires the working group to convene as soon as practicable following the operative date of this bill, and on or before June 1, 2026, to submit its findings and recommendations to the California Legislature, and to make these findings available to any relevant county or state agencies upon request.

6) Repeals the provisions of this bill is on June 1, 2030.

7) Finds and declares that a special statute is necessary and that a general statute cannot be made applicable because of the uniquely integrated services provided by the local health districts of the northern region of the County of San Diego.

EXISTING LAW:

1) Establishes Department of Health Care Access and Information (HCAI) in the California Health and Human Services Agency to expand equitable access to quality, affordable health care for all Californians through resilient facilities, actionable information, and the health workforce each community needs. [Health and Safety Code (HSC) § 127000, *et seq*.]

2) Establishes the California Health Facilities Financing Authority (CHFFA) within the office of the State Treasurer to be the State's vehicle for providing financial assistance to public and non-profit health care providers through loans, grants, and tax-exempt bonds. [Government Code (GOV) § 15430 *et seq.*]

3) Authorizes CHFFA to make secured or unsecured loans to, or purchase secured or unsecured loans of, any participating health institution in accordance with an agreement between CHFFA and the participating health institution to refinance indebtedness incurred by that participating health institution or a participating health institution that controls or manages, is controlled or managed by, is under common control or management with, or is affiliated with that participating health institution, in connection with projects undertaken or for health facilities acquired or for working capital. [GOV § 15432 (j)]

4) Establishes the Distressed Hospital Loan Program (DHLP) until January 1, 2032, which will provide interest free cashflow loans to not-for-profit hospitals and public hospitals, as defined, in significant financial distress, or to governmental entities representing closed hospitals. Requires HCAI to administer the DHLP and to enter into an interagency agreement with CHFFA to implement the DHLP. [HSC § 129381]

5) Establishes "The Local Health Care District Law," under which a local hospital district may be organized, incorporated and managed. Permits a district to include incorporated or unincorporated territory, or both, in any one or more counties. Requires health care districts to be governed by an elected board of five members, who are required to live within the healthcare district. [HSC § 32000 *et seq.*, § 32001, § 32100]

6) Provides local health care districts with certain powers, including establishing and operating health facilities or other health care programs, and to establish and operate, or provide assistance in the operation of, free clinics, diagnostic and testing centers, health education programs, wellness and prevention programs, rehabilitation, aftercare, and any other health care services providers, groups, and organizations that are necessary for the maintenance of good physical and mental health in the communities served by the district. [HSC § 32121]

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

COMMENTS:

1) **PURPOSE OF THIS BILL.** According to the author, public healthcare districts are essential pillars of California's healthcare system, providing accessible, culturally competent, and affordable care, especially to underserved and vulnerable communities. In San Diego County, public healthcare districts represent a critical public investment designed to ensure democratic accountability and responsiveness to local health needs. However, the current instability and financial distress facing the Palomar Healthcare District, a cornerstone of healthcare for nearly 850,000 residents, threatens access to essential healthcare services. The closure of the Fallbrook Regional Healthcare District's hospital has already created a healthcare desert, underscoring the potential consequences of inaction. Without proactive collaboration, oversight, and strategic solutions, the viability of these crucial public health services in North San Diego County is at risk. The author states that this bill seeks to convene stakeholders, evaluate systemic challenges, and recommend solutions to ensure the long-term sustainability and effectiveness of healthcare districts in the region. The author concludes that by addressing these pressing issues, we can safeguard vital health care access, protect vulnerable populations, and maintain the public accountability and community-specific care that residents depend upon.

2) **BACKGROUND.**

   a) **Health Care Districts.** Near the end of World War II, California faced a severe shortage of hospital beds. To respond to the inadequacy of acute care services in rural areas, the Legislature enacted the Local Hospital District Law to provide medically underserved areas without access to hospital facilities the ability to form special districts that could be a source of tax dollars for constructing and operating community hospitals. SB 1169 (Maddy), Chapter 696, Statutes of 1994 changed the name of the law to "The Local Healthcare District Law" to better reflect the shift in the provision of healthcare services outside hospital settings.

   The powers and duties granted to healthcare districts under existing law have remained largely unchanged while the demographics of areas the districts serve, access and provision of healthcare services, and the districts themselves have vastly changed. For example, following the change in law in 1994, fourteen healthcare districts have filed for bankruptcy, and over one-third of the healthcare districts in California have either closed or sold their hospital, thus moving away from the original legislative intent of "hospital districts."

   State law allows healthcare districts to exercise various powers, including to lease or own property; build and operate healthcare facilities and services, including emergency services, free clinics, diagnostic and testing centers, health education programs, wellness and prevention programs, rehabilitation, and aftercare; to provide assistance to other entities to carry out those services; and to sell their assets. Healthcare districts, like other special districts, are subject to review in a municipal service review or special study by a LAFCO to examine the efficiency and effectiveness of the services they provide. Similarly, healthcare districts must also receive approval from LAFCO to exercise its powers or change its boundaries.

New healthcare districts can be formed according to procedures laid out in the Local Healthcare District Law, the District Organization Law, and LAFCO Law. These procedures provide multiple opportunities for local agencies and voters to weigh in on the question of district formation. These procedures include: an impartial analysis by the LAFCO of the proposed formation; a determination that the district is "feasible, economically sound, and for the public interest," and a requirement that a majority of voters approve of the formation of the district.

A five-member board of directors manages each healthcare district. Each member must be a registered voter residing in the district and serves a four-year term, with the exception of the initial board. The board of supervisors of the county with the greatest share of land in the district appoints the initial board. Upon appointment, the board selects two members by lot to serve two-year terms with the remaining three serving four-year terms.

Most healthcare districts receive a share of local property taxes; some levy special parcel taxes, and some charge for services. Some healthcare districts generate revenues from district resources, such as property lease income; and some districts receive grants from public and private sources.

b) Palomar Healthcare District. The healthcare districts in San Diego County represent a significant public investment in the healthcare system. Fallbrook Regional Healthcare District no longer operates a hospital, creating a care desert in portions of San Diego. Fallbrook serves approximately 57,000 residents. Tri-City serves 414,928 residents and operates a 386-bed general acute care hospital.

However, according to recent press reports, systemic issues exist across these local governments that need to be addressed. Specifically, they center around Palomar Healthcare District, which operates two district hospitals, Palomar Medical Center Escondido and Palomar Medical Center Poway. Combined the hospitals serve well above the statewide average for Medi-Cal patients and are essential to the care continuum.

Palomar Health serves nearly 850,000 residents and reported $165 million in operational loss in fiscal year 2024 and has over $700 million in outstanding debt. Palomars' Bond rating has been downgraded.

c) Mesa Rock. Palomar Health is also currently undergoing a Fair Political Practices Commission investigation regarding "Mesa Rock," and its governance structure.

In February of 2024 Palomar Health's board of directors approved a 15-year management services-agreement that made its top management begin working for a private nonprofit company, a decision the board said was intended to stabilize the public health care district's declining finances. However, according to press reports, some in the community were uncomfortable with the move, calling it a hasty reduction of the elected hospital board's administrative powers. A majority of the board said they believe the unique agreement with Mesa Rock Health Care Services would better equip the state's largest public health care district to compete and collaborate with private providers, such as Kaiser Permanente, Sharp HealthCare and Scripps Health.

On Jan. 27, 2025 a board majority agreed to suspend the Mesa Rock agreement for at least 12 months. According to board documents, the pause is due to "declines in Palomar Health's financial performance caused by broad market trends that disproportionately impact safety-net hospitals" and as the district enters "a forbearance agreement and two-year financial turnaround plan with Assured Guaranty." After approving the Mesa Rock agreement last February, Palomar Health suffered a $165 million operating loss in fiscal year 2024. The district has two years to turn its finances around. Given Palomar's financial standing, Mesa Rock has not taken any of the 1% revenue it was entitled to under the agreement.

Competition from other not-for profit hospitals could also potentially exacerbate Palomar's financial issues. Kaiser Permanente San Marcos is located within 3-miles of Palomar Health, and, Scripps Health has stated its intent to build another hospital in the same region, creating additional market pressures that could affect the public healthcare district.

3) **OPPOSE UNLESS AMENDED.** Scripps Health and Rady Children's Hospital are opposed to this bill unless it is amended, noting that they should be included in any discussions or studies related to health care service provision in the region. They note that excluding key stakeholders diminishes the value and comprehensiveness of the proposed working group, as it overlooks one of the region's most prominent health care providers.

4) **OPPOSITION.** Palomar Health (PH) is opposed to this bill stating that while they understand the goal of strengthening health care access, it believes this bill could unintentionally hinder local progress, duplicate efforts already underway, and divert critical resources away from patient care.

   PH states that as a public, community-based health care district—not a private, profit-driven system – it is governed by local leaders and committed to providing care to every patient who walks through its doors, regardless of ability to pay. PH states its trauma center alone spans a service area of 2,204 square miles, attending over one million residents from southern Riverside County to the Anza Borrego desert and the coastline. When every second counts, it is the hospital that saves lives.

   Palomar states that, like many hospitals across California, is navigating a strained healthcare landscape: more than 50% of hospitals are operating at a loss, and 20% are at risk of closure. Despite these challenges, Palomar continues to deliver more than $120 million in charity care annually. Participating in a new, state-mandated study—on a five-month timeline—would impose an added administrative burden on already overextended health care districts. Additional oversight and reporting obligations risk pulling resources away from essential services such as emergency care, infrastructure upgrades, and community-based health programs. These trade-offs must be carefully weighed.

   San Diego's Local Agency Formation Commission (LAFCO) is already conducting a comprehensive Municipal Service Review (MSR) of the very health districts identified in this bill, including Palomar, Fallbrook, Grossmont, and Tri-City. That review, which includes significant public input and stakeholder engagement, is scheduled for release in June 2025. This bill would duplicate this effort, adding confusion and administrative complexity, while potentially generating conflicting findings. PH believes the most productive path forward is to leverage the MSR already in progress and to support implementation strategies based on

its findings. PH concludes that they would rather consider alternative approaches to this bill that invest directly in local health care solutions. This could include targeted funding for health districts, grants for innovation in care delivery, and collaborative models that allow health systems to share and scale effective practices. In its experience, local, community-led efforts are more responsive and impactful than top-down directives.

5) **RELATED LEGISLATION.** AB 448 (Patel) requires the California Health Facilities Financing Authority (CHFFA) to extend the repayment period for nondesignated public hospitals (NDPHs) participating in a bridge loan program authorized under the Budget Act of 2022 which CHFFA has determined are unable to repay their loan within the time required. Delays the repayment timeframe by requiring the NDPH to begin monthly repayments on the loan 36 months after the date of that loan, and requires the NDPH to discharge the loan within 60 months of the date of that loan, instead of the NDPH being required to repay and discharge the loan within 24 months of the date of the loan under the existing Budget Bill Language (BBL) from the Budget Act of 2022. AB 448 is pending in the Assembly Health Committee.

6) **PREVIOUS LEGISLATION.** AB 2098 (Garcia) of 2024 would have extended the repayment requirements for nondesignated public hospitals participating in a California Health Facilities Financing Authority loan program to require monthly repayments on the loan 24 months after the date of that loan. AB 2098 was vetoed by Governor Newsome, who stated in part, "Hospitals are critical to the health and safety of our communities, and it is a priority of my Administration to assist hospitals that are struggling financially. For this reason, together with the Legislature, in 2022 we funded the Public Hospital Bridge Loan Program II with $40 million, and we authorized $300 million for the Distressed Hospital Loan Program. Many of the hospitals affected by this bill received both. While I support efforts to ensure loan repayment requirements are feasible, this bill would advantage one subset of hospital loans above others that did not receive such an extension. Extending the timeline for repayment will affect our budget structure in the out years, and would be better discussed as a part of the annual budget process."

REGISTERED SUPPORT / OPPOSITION:

Support

None on file

Opposition

Association of California Healthcare Districts
District Hospital Leadership Forum
Palomar Health

Analysis Prepared by: Lara Flynn / HEALTH / (916) 319-2097

Date of Hearing: April 29, 2025

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 432 (Bauer-Kahan) – As Amended April 23, 2025

SUBJECT: Menopause.

SUMMARY: Requires a health care service plan (health plan) or health insurer to cover evaluation and treatment options for perimenopause and menopause, without utilization management (UM). Requires a health plan or health insurer to annually provide clinical care recommendations, as specified, for hormone therapy to all contracted primary care providers who treat individuals with perimenopause and menopause. Specifically, **this bill**:

1) Requires a health plan or health insurance contract issued, amended, or renewed on or after January 1, 2026 to cover, without UM, evaluation and treatment options for perimenopause and menopause, including:

    a) At least one option in each formulation of, and the associated method of administration for, federal Food and Drug Administration-regulated systemic hormone therapy;

    b) At least one option in each formulation of, and the associated method of administration for, nonhormonal medications for each menopause symptom;

    c) At least one option in each formulation of, and the associated method of administration for, treatment for genitourinary syndrome of menopause; and,

    d) At least one from each class of medications approved to prevent and treat osteoporosis.

2) Requires coverage under this section to authority for the treating provider to adjust the dose of a drug consistent with clinical care recommendations.

3) Requires a health plan or health insurer to annually provide current clinical care recommendations for hormone therapy from the Menopause Society or other nationally recognized professional associations to all contracted primary care providers who treat enrollees with perimenopause and menopause. Requires a health plan or health insurer to encourage primary care providers to review those recommendations.

4) Defines “formulation” as all of the following:

    a) A tablet or capsule;

    b) A transdermal patch;

    c) A topical spray;

    d) A cream, gel, or lotion; and,

    e) A vaginal suppository, cream, or silicone ring.

5) Defines "method of administration" as a formulation via an oral, topical, vaginal, subcutaneous, injectable, or intravenous route of administration.

6) Prohibits discrimination on the basis of gender expression or identity in coverage for the evaluation and treatment options for perimenopause and menopause.

7) Requires physicians who have a patient population composed of 25% or more adult women under 65 years of age to complete at least 10% of all mandatory continuing medical education (CME) hours in a course in perimenopause, menopause, and postmenopausal care.

EXISTING LAW:

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

2) Establishes California's essential health benefits (EHBs) benchmark under the federal Patient Protection and Affordable Care Act (ACA) as the Kaiser Small Group Health Maintenance Organization contract, establishes existing California health insurance mandates and the 10 ACA mandated benefits. [HSC § 1367.005 and INS § 10112.27]

3) Defines "basic health care services" as all of the following:

   a) Physician services, including consultation and referral;

   b) Hospital inpatient services and ambulatory care services;

   c) Diagnostic laboratory and therapeutic radiologic services;

   d) Home health services;

   e) Preventive health services;

   f) Emergency health care services; and,

   g) Hospice care, as specified. [HSC § 1345 and INS § 10112.281]

4) Requires the criteria or guidelines used by health plans and insurers, or any entities with which plans or insurers contract for utilization review or utilization management functions, to determine whether to authorize, modify, or deny health care services to:

   a) Be developed with involvement from actively practicing health care providers;

   b) Be consistent with sound clinical principles and processes;

   c) Be evaluated, and updated if necessary, at least annually;

   d) If used as the basis of a decision to modify, delay, or deny services in a specified case under review, be disclosed to the provider and the enrollee or insured in that specified case; and,

e) Be available to the public upon request. [HSC § 1363.5 and INS § 10123.135]

5) Requires reviews, for purposes of Independent Medical Review (IMR), to determine whether the disputed health care service was medically necessary based on the specific medical needs of the enrollee or insured and any of the following:

   a) Peer-reviewed scientific and medical evidence regarding the effectiveness of the disputed service;

   b) Nationally recognized professional standards;

   c) Expert opinion;

   d) Generally accepted standards of medical practice; or,

   e) Treatments that are likely to provide a benefit to a patient for conditions for which other treatments are not clinically efficacious. [HSC § 1374.33 and INS § 10169.3]

6) Requires every health plan or disability insurer that covers hospital, medical, or surgical benefits and health plan to provide an external IMR to examine the plan's or insurer's coverage decisions regarding experimental or investigational therapies for an individual with a life-threatening or seriously debilitating condition, as specified. [HSC § 1370.4 and INS § 10145.3]

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

COMMENTS:

1) **PURPOSE OF THIS BILL.** According to the author, although menopause is a natural occurrence that one million Americans experience every year, it has been treated as unworthy of proper care, research, and basic understanding. The author cites a recent survey which found a majority of women felt that they were 'not informed at all' when it came to menopause and perimenopause. The author continues that medical students get less than one hour training in menopause, and 80% of graduating OB/GYN residents admit to feeling "barely comfortable" talking to their patients about menopause. The author states that quality, evidence-based care is critical as the hormonal changes that occur at menopause have profound effects on health and wellbeing for the remainder of a woman's life. The author continues that menopause impacts women who are often in the peak of their careers and when not provided adequate treatment and support it can cause massive financial ramifications. The author states that according to the Mayo Clinic, the annual cost of untreated menopause symptoms in workplace productivity and related health care costs is $150 billion globally and 26.6 billion in the United States. The author continues that this bill mandates coverage for healthcare treatment plans for people experiencing perimenopause and menopause related symptoms. The author argues that menopause isn't just a personal experience; it's a public health issue that deserves our attention and action. The author concludes that it is time we stop devaluing women after their reproductive years.

2) **BACKGROUND.** Menopause is part of the normal aging process in which menstruation has ceased for 12 consecutive months. This transition to a new stage of life (rather than a condition or disease) is experienced by every woman and most often occurs naturally

between ages 45 and 55 years but may occur between ages 40 and 64 years (median age 51 years). Some women experience bothersome symptoms prompting requests for treatment. Perimenopause is the stage where menstruation becomes irregular in frequency, duration, and bleeding intensity for a variable amount of time (median duration 4 years) before periods stop completely. Menopause is the stage where there is a complete cessation of menstruation for 12 consecutive months. The period after the 12 consecutive months is sometimes referred to as "postmenopause." There are approximately 5 million women aged 40 to 64 years in California, many of whom experience mild, moderate, or severe menopause symptoms for a few months to more than 12 years.

a) **Menopause symptoms.** Genitourinary (vaginal atrophy and/or dryness) and vasomotor symptoms (night sweats, hot flushes - colloquially called hot flashes) are the two most commonly reported symptoms of menopause and can occur throughout the menopausal stages. The genitourinary syndrome of menopause (GSM) includes symptoms such as dysuria (burning, stinging, itching during urination), and dyspareunia (painful intercourse due to vaginal dryness or atrophy). For those who experience moderate-to-severe vasomotor symptoms (VMS), sleep disruption and insomnia can occur which, in turn, may affect memory, cognition, and mood (irritability or depression). Memory and cognition (without sleep disruption) may decline during the early menopausal stage, but decrements can reverse during later menopause.

   Women may also experience decreased libido, which could be related to other menopause symptoms such as GSM or depression. A subset of menopausal women with low libido may be diagnosed with hypoactive sexual desire disorder (HSDD), which is defined as persistent or recurrent absence of desire for sexual activity which causes personal distress or interpersonal difficulties. Additionally, accelerated loss of bone density and strength occurs in early menopause but slows during the later stages; menopause experienced at younger ages produces lower bone density as women age, which results in more fractures.

b) **California Health Benefits Review Program (CHBRP).** CHBRP was created in response to AB 1996 (Thomson), Chapter 795, Statutes of 2002, which 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. 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 to CHBRP's purview.

   i) **Baseline coverage.** CHBRP determined that at baseline, no enrollees are in plans or policies that are fully compliant with this bill because not all medications are included in benefit coverage as would be required by this bill, and several medications or medication classes have utilization management at baseline. This bill would not exceed essential health benefits (EHBs).

   ii) **Utilization.** CHBRP estimates no changes in utilization for evaluation of menopause symptoms and medications since lab tests used for evaluation are fully covered without utilization management at baseline. Utilization of medications would increase

due to 1) changes in baseline benefit coverage and/or 2) elimination of utilization management.

(1) Systemic and Local Hormone Drug Therapies. CHBRP estimates that utilization for the oral systemic combination estrogen-SERM therapy increases from an estimated 14 monthly prescriptions at baseline to 99 monthly prescriptions under this bill. High-dose systemic vaginal systemic therapy utilization would increase from an estimated 299 monthly prescriptions at baseline to 891 monthly prescriptions. Utilization of prasterone would increase from an estimated 106 monthly prescriptions at baseline to 394 monthly prescriptions. CHBRP further estimates that utilization for topical systemic testosterone, and low-dose local vaginal estrogen would increase more modestly due to higher existing coverage at baseline, with the changes driven by the removal of utilization management. Utilization of topical systemic testosterone would increase from an estimated 276 monthly prescriptions at baseline to 385 monthly prescriptions. Utilization of low-dose local vaginal estrogen would increase by 3%.

(2) Nonhormonal Drug Therapies. Utilization for fezolinetant and ospemifene would increase substantially due to both an increase in coverage and the removal of utilization management. Changes in utilization for these two therapies would be 226% and 167%, respectively. For example, utilization of fezolinetant would increase from 4,246 monthly prescriptions at baseline to 13,837 monthly prescriptions. Additionally, a portion of baseline utilization would shift from non-covered to being covered.

(3) Osteoporosis Medications. CHBRP assumed a small (2%) increase in utilization due to the removal of utilization management for the following drugs for the prevention and treatment of osteoporosis that had 100% coverage at baseline: bisphosphonates, monoclonal antibodies, and synthetic parathyroid hormone. CHBRP assumed a larger (190%) increase in the utilization of SERMs due to both increased coverage and the removal of utilization management.

iii) Cost impact. CHBRP estimates that in 2026 this bill would increase total premiums by $74,501,000 (0.05%). Cost sharing for covered benefits for enrollees would increase by $21,083,000, and enrollee out-of-pocket expenses for non-covered benefits would decrease overall by $33,365,000. As a result, total net expenditures would increase by $62,220,000 (0.04%). Of the total expenditure impact due to this bill, CHBRP estimates that 86% (or $53.5 million) would be due to additional benefit coverage, whereas the other 14% (or $8.7 million) would be due to the removal of utilization management on medications impacted by this bill. Although many women already receive treatment for menopause symptoms at baseline, CHBRP projects that the bill would result in an additional 22,274 women who may receive new prescriptions for menopause symptoms in the first year of this bill going into effect. This increase in utilization would improve quality of life for these women.

iv) Medical effectiveness. CHBRP found several treatments are endorsed by existing clinical practice guidelines and widely covered by insurance without utilization management. CHBRP reviewed the literature for medications that are not fully

covered by insurance at baseline and/or have utilization management. CHBRP found that high-dose vaginal estrogen and fezolinetant are effective at treating vasomotor symptoms and that ospemifene, vaginal DHEA, and low-dose estrogen are effective at treating genitourinary syndrome of menopause. CHBRP also found that systemic testosterone therapy (oral and non-oral) can improve symptoms of hypoactive sexual desire disorder. Of the drugs that prevent and treat osteoporosis, CHBRP found that bisphosphonates are effective as first-line treatment and that monoclonal antibodies and synthetic parathyroid hormone are effective as second-line treatments.

v) **Public health impacts.** CHBRP found that health impacts include improved quality of life through reduction in GSM and VMS symptoms. Some women experiencing moderate-to-severe VMS may experience reduced productivity, reduced capacity to work, and poorer work experience. Use of the newly covered drugs may improve sleep and memory/cognitive function as symptoms abate. Additionally, some of these women may experience improved productivity or presenteeism as their VMS subside (and sleep improves). CHBRP notes that these women may also experience drug side effects, which may or may not influence decisions to continue the drug therapy. There is evidence of side effects and potential harms from drugs that treat menopause symptoms. However, for drugs approved by the United States Food and Drug Administration, there is evidence that the benefits of symptom relief outweigh the potential harms (assuming the drugs are appropriately prescribed, and patients are monitored properly).

vi) **Long-term impacts.** CHBRP notes that most drugs across the bill-specified categories are already covered at baseline. Therefore, CHBRP anticipates that a limited number of women (especially those with high risk for or history of hormone-sensitive cancers) will access the newly covered medications or may access different treatments due to the removal of utilization management. These women would be expected to experience reductions in or abatement of moderate-to-severe VMS and GSM over the course of their treatment, which might last four to 12 years after they start menopause. These treatments rarely have negative long-term effects, so no population-level harms are expected in the long-term.

c) **EHBs.** The ACA requires health plans sold in the individual and small group markets to offer a comprehensive package of items and services, EHBs, with no dollar limits. Under the ACA, the federal government gave each state the authority to choose its "benchmark" EHB plan. EHBs require plans to cover ten categories of services: (1) ambulatory patient services (outpatient care); (2) emergency services; (3) hospitalization; (4) maternity and newborn care; (5) mental health and substance use disorder services, including behavioral health treatment; (6) prescription drugs; (7) rehabilitative and habilitative services and devices; (8) laboratory services; (9) preventive and wellness services and chronic disease management; and, (10) pediatric services, including dental and vision care. Under the ACA, if states require plans to cover services beyond those defined as EHBs in law, states must pay the costs of those benefits, either by paying the enrollee directly or by paying the qualified health plan (offered through Covered California). The federal department of Health and Human Services (HHS) issued rules in 2018, 2019, and 2024 that provided states with new flexibilities to augment their EHBs. California is currently undergoing the process of updating the state's benchmark EHB plan. After a series of public meetings and a Legislative hearing, DMHC announced California's intent to

submit a proposal to the federal government to add three new benefits to the state's EHB benchmark plan: hearing aids, durable medical equipment, and infertility treatment. Notification from DMHC to HHS must take place by May 7, 2025 for the new benchmark to take effect by the January 1, 2027 plan year. If the proposed EHB benchmark is approved, legislation to codify the new benchmark plan will be necessary. AB 224 (Bonta) and SB 62 (Menjivar) have been introduced this session to codify any benchmark changes that may come out of this process.

d) **Office of Health Care Affordability (OHCA) cost targets.** OHCA was established in 2022 in response to widespread cost-related access challenges across California. According to the California Health Care Foundation, over half of Californians say they skip or delay care due to costs. OHCA collects, analyzes, and publicly reports data on total health care expenditures and enforces spending targets. OHCA's spending targets are intended to reduce excess spending and slow health care spending growth. In April of 2024, OHCA approved a statewide cost growth target of 3.5% starting in 2025 and phasing down to 3% by 2029. Health care entities, including health plans, are subject to the statewide spending target and are subject to progressive enforcement if the entity's costs exceed the target. Some entities have raised concerns that new legislative benefit mandates will make it difficult for them to meet the established cost growth target.

   Current law does not explicitly require OHCA to adjust the cost growth targets based on changes to state policy, such as mandates, that may increase spending. However, it does require OHCA to consider state benefit mandates in its development and enforcement of cost growth targets. Specifically, when establishing cost growth target methodology, OHCA is required to review relevant state policy changes impacting covered benefits, provider reimbursement, and costs, among other factors. In addition, in enforcing cost growth targets, OHCA is required to consider factors that contribute to spending in excess of the applicable target, and the extent to which each entity has control over the applicable components of its cost target.

3) **SUPPORT.** The California Legislative Women's Caucus supports this bill, stating that menopause and perimenopause affect 50% of the population, and yet the research and knowledge surrounding these conditions are far from adequate. These natural changes women experience continue to be a taboo subject, forcing women to "tough it out" in silence rather than seek professional medical advice and treatment. The Caucus argues that California does not have adequate healthcare coverage options for women experiencing perimenopause or menopause, and doctors are not adequately prepared to treat and support their menopause patients. The Caucus notes that currently, continuing menopause education is only a suggested course for physicians. The Caucus continues that there is an alarming disparity for women of color trying to receive adequate care during menopause. The Caucus states that evidence confirms that Black women experiencing menopause are more likely to face harsher symptoms compared to their female white counterparts. The Caucus concludes that substantial gains in health, financial stability, and well-being are possible by ensuring quality menopause care for all women.

4) **OPPOSITION.** The California Chapter of the American College of Cardiology (California ACC) opposes this bill. California ACC believes CME courses should be chosen by physicians based on the needs of their patients related to the specialty in which the physician is trained. California ACC states that for cardiologists to be required to take a CME course

which may not be a central part of the scope of services they provide would take away from CME courses they would take to provide better care for their patients. California ACC continues this would not preclude cardiologists from taking a course on menopause rather it would be left to the physician to choose what courses are needed to provide the best care for their patients. The California Rheumatology Alliance, California Orthopedic Association, and California Society of Plastic Surgeons oppose on similar grounds.

5) **OPPOSED UNLESS AMENDED.** The American College of Obstetricians and Gynecologists (ACOG) District IX writes with concerns about this bill's requirement for physicians to complete a mandatory CME course. ACOG states that while increasing education on under-discussed conditions through CME may seem beneficial, imposing mandates sets a concerning precedent that could lead to legislative requirements for numerous medical topics, many of which may be more effectively addressed by expanding educational opportunities and public awareness campaigns. While ACOG recognizes and respect the author's goal, they cannot agree with the current approach and are opposed to this bill unless amended to remove the CME mandate from the bill. The California Medical Association is also opposed unless the mandatory CME course requirement is removed.

6) **PREVIOUS LEGISLATION.**

   a) AB 2467 (Bauer-Kahan), of 2024, was substantially similar to this bill. AB 2467 was vetoed by Governor Newsom, who stated in part:

   "I appreciate the author's intent to ensure access to comprehensive and up-to-date treatment of perimenopause and menopause. However, this bill's expansive coverage mandate in conjunction with a prohibition on UM is too far-reaching. Health plans use UM to ensure enrollees receive the right care at the right time, which is especially important when there are new and emerging treatments. Further, a mandate to cover non-FDA approved treatments, without UM, is unprecedented. These factors, in conjunction with ambiguities in the bill for undefined terms, raise concerns for cost containment and bill implementation.

   I encourage the Legislature and stakeholders to continue to work towards a more tailored solution that can improve access to perimenopause and menopause care, inform patients of their options, and encourage providers to stay informed of the latest clinical care recommendations."

   b) SB 523 (Leyva), Chapter 630, Statutes of 2022, establishes the Contraceptive Equity Act of 2022, and makes various changes to expand coverage of contraceptives by a health plan contract or health insurance policy issued, amended, renewed, or delivered on and after January 1, 2024, including requiring a health plan or health insurer to provide point-of-sale coverage for over-the-counter FDA-approved contraceptive drugs, devices, and products at in-network pharmacies without cost sharing or medical management restrictions.

REGISTERED SUPPORT / OPPOSITION:

Support

Black Women for Wellness Action Project

CA Legislative Women's Caucus
California Commission on the Status of Women and Girls (CCSWG)
National Women's Political Caucus of California
One individual

Opposition

California Chapter American College of Cardiology
California Orthopedic Association
California Rheumatology Alliance
California Society of Plastic Surgeons

Analysis Prepared by: Riana King / HEALTH / (916) 319-2097

Date of Hearing: April 29, 2025

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 447 (Mark González) – As Amended April 9, 2025

SUBJECT: Emergency room patient prescriptions.

SUMMARY: Permits a prescriber to dispense an unused portion of a dangerous drug (a prescription drug) that is acquired by the hospital pharmacy to an emergency room (ER) patient upon discharge, subject to specified conditions. Expands the existing licensure exemption for an automated unit dose system (AUDS) that is used by a prescriber in a hospital or a psychiatric health facility to dispense dangerous drugs to ER patients under this bill and existing law. Specifically, **this bill**:

1) Permits a prescriber, notwithstanding any other provision of the Pharmacy Law, to dispense an unused portion of a dangerous drug acquired by the hospital pharmacy to an ER patient upon discharge under the following conditions:

    a) The dangerous drug is not a controlled substance;

    b) The dangerous drug has been ordered and administered to the ER patient;

    c) The dangerous drug was administered from multiuse packaging and can be self-administered by the patient, including, but not limited to, an inhaler, eye drop, ear drop, nose drop or spray, topical product, or liquid product;

    d) Dispensing the unused portion of the dangerous drug is required to continue treatment of the ER patient; and,

    e) The prescriber ensures that the label on the drug contains all of the information required by existing law drug labeling requirements.

2) Expands the existing licensure exemption for an AUDS that exempts AUDSs used by prescribers to provide doses to ER patients under the existing law authority to do so when the hospital pharmacy is closed, as specified, and under the authority authorized by this bill.

EXISTING LAW:

1) Establishes the California State Board of Pharmacy (BoP), and requires the licensure and regulation of pharmacists and pharmacies. [Business and Professions Code (BPC) § 4000 *et seq.*]

2) Permits a prescriber to dispense a dangerous drug, including a controlled substance, to an ER patient if all of the following apply:

    a) The hospital pharmacy is closed and there is no pharmacist available in the hospital;

    b) The dangerous drug is acquired by the hospital pharmacy;

c) The dispensing information is recorded and provided to the pharmacy when the pharmacy reopens;

d) The hospital pharmacy retains the dispensing information and, if the drug is a Schedule II, Schedule III, or Schedule IV controlled substance, reports the dispensing information to the Department of Justice pursuant to the Controlled Substance Utilization Review and Evaluation System (CURES);

e) The prescriber determines that it is in the best interest of the patient that a particular drug regimen be immediately commenced or continued, and the prescriber reasonably believes that a pharmacy located outside the hospital is not available and accessible at the time of dispensing to the patient; and,

f) The quantity of drugs dispensed to any patient under these provisions is limited to that amount necessary to maintain uninterrupted therapy during the period when pharmacy services outside the hospital are not readily available or accessible, but not to exceed a 72-hour supply. [BPC § 4068]

3) Requires the prescriber, in when dispensing a danger drug pursuant to 2) above, to ensure that the label on the drug contains all the information required by Section 4076. [BPC § 4068]

4) Prohibits a pharmacist from dispensing a prescription except in a container that meets the requirements of state and federal law and is correctly labeled, which includes the manufacturer's trade name or the commonly used name or the principal active ingredients of the drug, the directions for use of the drug, the name/names of the patient, the name of the prescriber, the date of issue and the condition or purpose for which the drug was prescribed. [BPC § 4076]

5) Requires an automated drug delivery system installed, leased, owned, or operated in California to be licensed by the BoP. [BPC § 4427.2]

6) Defines an "automated drug delivery system" (ADDS) to means a mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of drugs. Requires an ADDS to collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability. [BPC § 4017.3]

7) Defines an "AUDS" as an ADDS for storage and retrieval of unit doses of drugs for administration to patients by persons authorized to perform these functions. [*Ibid*.]

8) Exempts a AUDS operated by a licensed hospital pharmacy that is used solely to provide doses administered to patients while in a licensed general acute care hospital facility or a licensed acute psychiatric hospital facility from the requirement to obtain an ADDS license, if the licensed hospital pharmacy owns or leases the AUDS and owns the dangerous drugs and dangerous devices in the AUDS. [BPC § 4427.2]

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

COMMENTS:

1) **PURPOSE OF THIS BILL.** According to the author, access to health care remains a significant challenge for communities across California. Whether due to financial barriers, difficulties reaching medical facilities, or limited time off work, many Californians struggle to obtain the care they need. This bill seeks to ease this burden by allowing ER patients to take home the remaining doses of non-narcotic medications they started during treatment. Under this bill, patients will no longer be forced to make an additional trip to a pharmacy to continue essential treatment—reducing both unnecessary expenses and delays in care. This policy will not only save patients time and money but also help combat excessive medical waste in our health care system.

2) **BACKGROUND ON DISPENSING TO ER PATIENTS.** Existing law permits a prescriber to dispense a dangerous drug (including a controlled substance) to an ER patient if certain requirements are met, including that the hospital pharmacy is closed, there is no pharmacist available in the hospital, and the quantity of drugs is limited to a 72-hour supply. This bill applies in a broader situation (current law applies when a hospital pharmacy is closed) but to a narrower class of drugs. Specifically, this bill permits a prescriber to dispense an unused portion of a dangerous drug from a multiuse package that can be self-administered by the patient, when the unused portion is required to continue treatment of the ER patient. Specific example this bill would apply to include are an inhaler, eye drop, ear drop, nose drop or spray topical product, or liquid product. The authority to dispense an unused portion of a drug authorized under this bill does not apply to controlled substances.

3) **BACKGROUND ON AUDS.** Hospital pharmacies often use an automated drug delivery system, or ADDS to streamline the processing and distribution of drugs. An ADDS is an automated cabinet that securely stores medications for ready access by authorized employees. Hospitals may also use a subtype of ADDS known as an automated unit dose system, or AUDS, which specifically dispenses individually-packaged doses for hospital personnel to administer to patients. The use of an AUDS can help reduce human error and expedite delivery of medications. Operators of an ADDS must obtain a license from the BoP (the original licensure application fee is $525 and the renewal fee is $453), and prior to the issuance of the license, the BoP is required to conduct a pre-licensure inspection within 30 days of a completed application for an ADDS license.

   However, if an ADDS is an AUDS operated by a licensed hospital pharmacy and is used solely to administer doses to patients in an acute care hospital, the ADDS is exempt from the licensure requirement. When an ADDS that is used by a prescriber to dispense medication to an ER patient under the existing prescriber dispensing authority (for example, up to a 72-hour supply when the pharmacy is closed). This bill would expand the licensure exemption to expressly exempt AUDSs used to provide medication to ER patients under existing prescriber dispensing authority, and under the additional authority to dispense drugs from multiuse packaging that can be administered by the patient in this bill. The author indicates the purpose of this change is that without the exemption, many hospitals may choose not to dispense medications, and it will only result in a minimal loss of revenue to the BoP.

4) **SUPPORT.** This bill is sponsored by the California Chapter of the American College of Emergency Physicians (Cal-ACEP), which writes that patients often present to the ER with conditions that require prescription treatments. These treatments are dispensed from the

hospital pharmacy containing more doses than will be used in the duration of the emergency department (ED) visit. Frequently, one dose of a multi-use medication, including eye drops, inhalers and liquid antibiotics are administered and then the remainder must be disposed of. Cal-ACEP states that, under existing law, the remaining doses cannot be sent home with the patient they were prescribed for, and they cannot be used for other patients. Patients who receive these types of treatments leave the ED with a prescription for the same medication that they must pick up at an outpatient pharmacy to continue treating their condition. In areas where there are no 24-hour pharmacies, this can mean waiting until business hours start and potentially missing treatment doses. Even when readily available, it is an unnecessary, duplicate expense. Cal-ACEP states that, while ER-specific data is not currently available, studies of other care settings have found that as much as 50% of prepared multiuse drugs, including eye drops and inhalers, are discarded instead of being used again or dispersed to the patient. Current California law results in redundant prescriptions, increased cost to the health system, and increased medical waste. Allowing patients to take home the remaining doses of their multiuse medication will reduce unnecessary spending, medical waste, and guarantee timely access to necessary prescriptions.

5) **PREVIOUS LEGISLATION.** SB 1913 (Committee on Business and Professions) Chapter, 695, Statutes of 2004, among other provisions, authorizes the dispensing of prescription drugs to an ER patient under the above described circumstances.

6) **DOUBLE REFERRAL.** This bill is double referred, and it passed the Assembly Committee on Business and Professions Committee with a 15-0 vote on April 8, 2025.

7) **CLARIFYING AMENDMENTS.** Following discussions, the author has agreed to amend this bill to clarify the authority to dispense an unused portion applies when "all" of the circumstances in this bill are met, to clarify drugs administered under this bill are from single "patient use multi-dose packaging," and to clarify that the exemption from licensure for an AUDS operated by a licensed hospital pharmacy applies to drugs "dispensed" under the existing law authority and as expanded by this bill.

REGISTERED SUPPORT / OPPOSITION:

Support

California Chapter of the American College of Emergency Physicians (sponsor)
California Emergency Nurses Association
California Hospital Association
California Medical Association
California State Association of Psychiatrists

Opposition

None on file

Analysis Prepared by: Scott Bain / HEALTH / (916) 319-2097

Date of Hearing: April 29, 2025

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 448 (Patel) – As Amended April 21, 2025

SUBJECT: California Health Facilities Financing Authority Act: nondesignated hospitals: loan repayment.

SUMMARY: Requires the California Health Facilities Financing Authority (CHFFA) to extend the repayment period for nondesignated public hospitals (NDPHs) participating in a bridge loan program authorized under the Budget Act of 2022 which CHFFA has determined are unable to repay their loan within the time required. Delays the repayment timeframe by requiring the NDPHs to begin monthly repayments on the loan 36 months after the date of that loan, and requires the NDPH to discharge the loan within 60 months of the date of that loan, instead of the NDPH being required to repay and discharge the loan within 24 months of the date of the loan as required in the Budget Act of 2022. Specifically, **this bill**:

1) Requires CHFFA to extend the repayment period for NDPHs participating in the loan program authorized under the Budget Act of 2022 (AB 178 [Ting], Chapter 45, Statutes of 2022) that had received a loan approval from and entered into a loan and security agreement with CHFFA, and that CHFFA has determined are unable to repay their loan within the time required under the loan and security agreement.

2) Requires an NPDH that had received a loan approval from, and entered into a loan and security agreement with CHFFA, to begin monthly repayments on the loan 36 months after the date of that loan, and requires the NDPH to discharge the loan within 60 months of the date of that loan. Requires the monthly payments to be amortized over the term of the loan, at 0% interest, and prohibits any prepayment penalty.

3) Prohibits this bill from being construed to amend or otherwise affect the requirements of, or the authorities conferred to implement, the loan program.

EXISTING LAW:

1) Establishes CHFFA within the office of the State Treasurer to be the State's vehicle for providing financial assistance to public and non-profit health care providers through loans, grants, and tax-exempt bonds. [Government Code (GOV) § 15430 et seq.]

2) Appropriates, pursuant to the Budget Act of 2022, $65 million for CHFFA to provide cash flow loans not to exceed $40 million to NDPHs, as needed, due to the financial impacts of the COVID-19 public health emergency. [AB 178 (Ting), Chapter 45, Statutes of 2022, Section 47, which amends Item 0977-101-0001 of Section 2.00 of the Budget Act of 2022]

3) Permits CHFFA, of the funds appropriated, to allocate an amount not to exceed 1% of each hospital’s loan. Permits the Department of Finance to transfer up to $400,000 to administer the loans, and requires any transferred funds to be available for encumbrance or expenditure until June 30, 2025. [Ibid.]

4) Requires CHFFA, pursuant to AB 178, to determine, in consultation with NDPHs, the application process, eligibility criteria, and methodology for distribution of the loans. [Ibid.]

5) Requires NDPHs to repay and discharge the loan within 24 months of the date of the loan. [Ibid.]

6) Requires security for the cash flow loans to be Medi-Cal reimbursements due to these NDPHs from the Department of Health Care Services (DHCS). Caps CHFFA's recoupment of these cash flow loans from exceeding 20% of the NDPHs' respective Medi-Cal check write payments until the loan amount has been satisfied. [Ibid.]

7) Defines a NPPHs as a public hospital, excluding those affiliated with county health systems (county and University of California hospitals are known as "designated public hospitals"). [Ibid.]

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

COMMENTS:

1) PURPOSE OF THIS BILL. According to the author, health care districts are essential pillars of California's health care system, providing accessible, culturally competent, and affordable care, especially to underserved and vulnerable communities. In San Diego County, public health care districts represent a critical public investment designed to ensure democratic accountability and responsiveness to local health needs.

However, the current instability and financial distress facing the Palomar Healthcare District—a cornerstone of health care for nearly 850,000 residents—threatens access to essential health care services. The closure of the Fallbrook Regional Healthcare District's hospital has already created a health care desert, underscoring the potential consequences of inaction. Without proactive collaboration, oversight, and strategic solutions, the viability of these crucial public health services in North San Diego County is at risk.

2) BACKGROUND.

a) CHFFA "Bridge" loans. During the pandemic, district and municipal hospitals (referred to in law as "NDPHs") were struggling with staffing shortages, supply shortages, and increased expenses. DHCS also transitioned its Medi-Cal managed care program from a Fiscal Year to Calendar Year, and this impacted the timing of Medi-Cal supplemental payment programs, delaying over a $100 million of payments. The District Hospital Leadership Forum (DHLF), which represents district hospitals on financing and reimbursement issues, advocated for the establishment of two $40 million loan programs. The first bridge loan program was established through budget bill language in a follow-up bill to the Budget Act of 2021 in SB 170 (Skinner), Chapter 240, Statutes of 2021). The second bridge loan program was appropriated through the Budget Act of 2022.

These loan programs were administered by CHFFA to "bridge" some of the cash flow gap for those hospitals most in need. These interest free loans had a two-year repayment term as it was expected that hospitals would exit the pandemic and return to a better fiscal situation. The funding for the first round of loans was provided in two separate amounts ($17.7 million and $22.1 million). Payments on the first round of loans from the 2021

follow-up budget bill appropriation were repaid and are not affected by the provisions of this bill.

The $40 million loans from the Budget Act of 2022 went to eight NDPHs and Palomar Health, which has two district hospitals. The second bride loans to two of the NDPHs and the loan to Palomar Health have not been repaid, which is the issue addressed by this bill. El Centro Regional Medical Center had an approved bridge loan amount approved of $5.6 million, with a loan due date of December 16, 2024, Palomar Health (a health care district which has two NDPHs, one in Poway and another in Escondido) had an approved bridge loan amount of $8.6 million with a loan due date of December 20, 2025, and Palo Verde Hospital had an approved bridge loan amount of $600,000, with a loan due date of December 16, 2024.

The BBL establishing the bridge loan program requires security for the cash flow loans to be Medi-Cal reimbursements due to these NDPHs from DHCS. This means amounts owed to repay the loan would be deducted from the check writes that Medi-Cal reimburses these hospitals for services they provide in the fee-for-service (FFS) component of the Medi-Cal program (separate from the services paid by Medi-Cal managed care plans). These security amounts are capped at 20% of the NDPHs' respective Medi-Cal check write payments until the loans amount have been satisfied.

CHFFA indicates Palo Verde Hospital is in default, and CHFFA is recouping the loan amounts from Medi-Cal payments, but to-date, it has only recouped $16,000. CHFFA indicates full recoupment will take many years. CHFFA indicates the other hospital and Palomar Health hospitals have outstanding debt owed to other entities, and if CHFFA issues a letter of default on the unpaid bridge loans, it could potentially trigger actions by other debt-holders of these two hospitals. CHFFA staff indicate if it were to do a margin call on the other loans, it would put the affected hospital and Palomar Health in a precarious financial situation with other holders of the affected hospitals' debt.

3) **AFFECTED HOSPITALS.** El Centro Regional Medical Center has 161 licensed beds and a basic emergency department and is located in El Centro in Imperial County. Eight-eight percent of its inpatient revenue and 87.1% of its outpatient revenue was from Medicare and Medi-Cal (managed care and FFS) from July 1, 2022 to June 30, 2023 per HCAI data. Palomar Health in San Diego County has two NDPHs. Palomar Medical Center in Escondido has 292 licensed beds and is a trauma center with a basic emergency department. Seventy-nine percent of its inpatient revenue and 71% of its outpatient revenue were from Medicare and Medi-Cal (managed care and FFS) from July 1, 2022 to June 30, 2023 per HCAI data. Palomar Medical Center in Poway has 236 licensed beds, and a basic emergency department, and 80.2% of its inpatient revenue and 64% of its outpatient revenue was from Medicare and Medi-Cal (managed care and FFS) from July 1, 2022 to June 30, 2023 per HCAI data.

   Palo Verde Hospital has 25 licensed beds and a standby emergency department and is located in Blythe in Riverside County. Eighty-four percent of its inpatient revenue and 82.1% of its outpatient revenue were from Medicare and Medi-Cal (managed care and FFS) from July 1, 2021 to June 30, 2022 per HCAI data.

   Press coverage of Palomar Health report the district announced in December 2024 it was laying off about 2% of its 4,200 employees, Palomar Health has borrowed from two other San Diego health systems, Palomar Health suffered a $165 million operating loss in fiscal

year 2024, the ratings agency Moody's downgraded Palomar Health's revenue rating to "Caa1" from "B2" after previous downgrades in 2024, and Palomar Health has asked its lenders not to enforce borrowing terms that could push the provider into bankruptcy.

4) **SUPPORT**. El Centro Regional Medical Center (ECRMC) writes in support that this bill would ensure its doors remain open and it can continue to serve Imperial County, which has one of the lowest incomes and highest unemployment rates of all of California's counties. ECRMC writes that, since February 2023, when UC San Diego began operating and managing ECRMC, it has worked tirelessly to revitalize its organization, and it remains committed to working with the City of El Centro, UC San Diego Health and the newly-formed Imperial Valley Health Care District (IVHD) to continue its shared mission of delivering high-quality and affordable health care closer to home for Imperial Valley residents. ECRMC states that if this bill does not pass, two major impacts will occur. First, ECRMC will not meet its required 45 days of cash on hand, which may trigger a default and cause an increase in the assessed interest rate on its bond up to 5% or an additional $1.6 million annually. Second, ECRMC's days of cash on hand may become less than $5 million, which may delay ECRMC's merger into IVHD as part of the implementation of AB 918 (Garcia), Chapter 549, Statutes of 2024. That legislation combined Pioneers Memorial Healthcare District and Heffernan Memorial Healthcare District and required the initial board of directors of IVHD to enter into negotiations with the ECRMC to decide the terms of the acquisition of the hospital as part of one large countywide health care district (IVHD). ECRMC states the other two districts merged last year and both the City Council of El Centro and IVHD voted to approve the term sheet for the merger in early March 2025 but health care in Imperial Valley is fragile and will not be sustainable until AB 918 is fully implemented, which it hopes to occur by the end of 2025.

5) **CONCERNS**. The Service Employees International Union California State Council (SEIU) writes expressing concerns with the current version of this bill. SEIU states that, while it appreciates the author's goal of preserving access to care and providing funding flexibility, it has concerns with the language in print and its failure to meet the standards of public dollars. SEIU states that CHFFA loan programs are carefully designed to balance efficiency, transparency, and guardrails to ensure appropriate use of state funds. SEIU states it is concerned that the nearly automatic extensions created by this bill lack essential guardrails and transparency, and thereby limit the ability of CHFFA and other stakeholders, including labor, to effectively engage NDPHs around compliance with the terms of their loans. SEIU requests that the bill moving forward includes additional guardrails to protect these dollars and further the state's goal of access to quality care.

6) **RELATED LEGISLATION.** AB 356 (Patel) would require the Department of Health Care Access and Information (HCAI) to convene a working group to study and make recommendations regarding the provision of health care services in the northern San Diego region. Require that the working group include representatives of certain health care entities and members of the San Diego delegation of the Legislature, and to issue a report to the Legislature, on or before June 1, 2026, with its findings and recommendations. Sunsets these provisions on June 1, 2030. AB 356 is scheduled for hearing in the Assembly Health Committee on April 29, 2025.

7) PREVIOUS LEGISLATION.

a) AB 2098 (Garcia) of 2024 would have extended the repayment period for specified bridge loans for district hospitals, made through CHFFA under authorization and funding from the 2022 Budget Act and which were required to be repaid within two years of the date of the loan, to instead require hospitals to make monthly payments within 24 months of the date of the loan, and for the loan to be repaid within 72 months of the date of the loan. AB 2098 was vetoed by Governor Newsom, who stated that while he supported efforts to ensure loan repayment requirements are feasible, this bill would advantage one subset of hospital loans above others that did not receive such an extension. The Governor stated extending the timeline for repayment will affect our budget structure in the out years, and would be better discussed as a part of the annual budget process.

b) AB 918 (Garcia), Chapter 549, Statutes of 2023 created the IVHD to provide healthcare services across Imperial County, and gave the district various powers and responsibilities, and dissolved the Pioneers and Heffernan Memorial Healthcare Districts. Required the initial board of directors of IVHD to enter negotiations with the ECRMC to decide the terms of the acquisition of the hospital, and upon reviewing the financial feasibility studies conducted by the Imperial County LAFCO and Kaufman Hall and confirming the financial viability of integrating the ECRMC into IVHD, the initial board of directors of IVHD to determine the terms of the acquisition of ECRMC. If the initial board of directors chooses to acquire the ECRMC, existing law requires ECRMC to be acquired with all of its assets and liabilities.

c) AB 2271 (Ortega) of 2024 would have required HCAI to approve, subject to review and approval by the Department of Finance, the forgiveness of the $17.65 million loan awarded to St. Rose Hospital in Hayward from the Distressed Hospital Loan Program. AB 2271 was vetoed by Governor Newsom. In his veto message, the Governor stated that while he appreciated the author's effort to support Alameda Health System's potential acquisition of St. Rose Hospital in her community, this bill would circumvent the loan forgiveness application process in existing law to secure full forgiveness for one hospital through statute, and this unfairly advantages St. Rose and sets a precedent for the remaining 15 hospitals that received loans.

d) AB 2637 (Schiavo) would have required CHFFA to establish financial eligibility standards for working capital loans by studying the creditworthiness of a participating health institution, together with the amount of pledged revenues, debt service coverage, and basic security; and, prohibit a participating health institution that is determined by CHFFA to be in financial distress from being deemed financially eligible for working capital loans. AB 2637 was vetoed by Governor Newsom. In his veto message, the Governor stated that while he supported support efforts to ensure loan repayment requirements are feasible, this bill would result in an open-ended timeframe without any required end date that loans must be repaid. Extending the timeline for the recoupment of CHFFA loans would be better discussed as a part of the annual budget process.

8) LEGISLATIVE POLICY AND BUDGET PROCESS TIMING. Because the bridge loans from the Budget Act of 2022 were due in December 2024 and January 2025, AB 2098 (Garcia) of 2024 was seen as the last opportunity for a longer repayment schedule for the affected entities that received bridge loan funding. Any additional legislation similar to AB

2098 would have required a bill to be passed on an urgency basis and signed into law in January 2025 when the Legislature re-convened. Even then, for five of the nine loan recipients, the bridge loan due date would have passed as the loans were due in December 2024, and the loan due dates for the other four bridge loans with due dates in January 2025 were January 3, 18, 20 and 27, 2025.

Because this policy bill will likely follow the normal policy and fiscal timeframes, the soonest this bill would likely become law would be September or October 2025 (the Governor has until October 12, 2025 to sign or veto bills). An alternative and likely faster way to address the repayment timeframe would be through the legislative budget process and the inclusion of the contents of this bill in a budget trailer bill or by BBL (the two bridge loan programs were established via BBL). This change would then take effect upon enactment of the annual budget act, which is likely to occur in late June 2025 or early July 2025, assuming an on-time budget. The author has written to the Assembly Budget Committee seeking flexibility in repayment of the state loan. Making this change via a policy bill would delay the financial relief to the hospital for each week payments are deducted from payments made to affected hospitals from Medi-Cal's weekly FFS payment, if CHFFA were to begin withholding from the other affected hospitals' Medi-Cal FFS payments in the absence of legislative action to extend the repayment period.

REGISTERED SUPPORT / OPPOSITION:

Support

El Centro Regional Medical Center
University of California

Opposition

None on file

Analysis Prepared by: Scott Bain / HEALTH / (916) 319-2097

Date of Hearing: April 29, 2025

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 546 (Caloza) – As Introduced February 11, 2025

SUBJECT: Health care coverage: portable HEPA purifiers and filters.

SUMMARY: Requires a health care service plan (health plan) or health insurer to include coverage for high-efficiency particulate air (HEPA) purifiers and filters for enrollees or insureds who are pregnant or diagnosed with asthma or chronic obstructive pulmonary disease (COPD). Contains an urgency clause to ensure that the provisions of this bill go into immediate effect upon enactment. Specifically, **this bill**:

1) Requires a health plan contract or health insurance policy issued, amended, or renewed on or after January 1, 2026, to include coverage for HEPA purifiers and filters for enrollees or insureds who are pregnant or diagnosed with asthma or COPD.

2) Prohibits coverage of the HEPA purifier and filters from being subject to deductible, coinsurance, or copayment requirements.

3) Specifies that a portable HEPA purifier and filter uses a mechanical air filter that can remove at least 99% of airborne particles that are 10 microns in size or have a minimum efficiency reporting value (MERV) of 13 or higher.

4) Specifies that a HEPA filter includes a filter used for air purification systems for home use or portable use.

5) Specifies that this bill does not apply to Medi-Cal managed care plans, federally regulated self-insured employer plans, or a Medicare supplemental policy or specialized plan contract that only covers dental or vision benefits.

EXISTING LAW:

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

2) Establishes California's essential health benefits (EHBs) benchmark under the federal Patient Protection and Affordable Care Act (ACA) as the Kaiser Small Group Health Maintenance Organization contract, establishes existing California health insurance mandates and the 10 ACA mandated benefits. [HSC § 1367.005 and INS § 10112.27]

3) Defines “basic health care services” as all of the following:

    a) Physician services, including consultation and referral;

    b) Hospital inpatient services and ambulatory care services;

    c) Diagnostic laboratory and therapeutic radiologic services;

d) Home health services;

e) Preventive health services;

f) Emergency health care services; and,

g) Hospice care, as specified. [HSC § 1345]

4) Establishes the Medi-Cal Program, administered by DHCS, to provide comprehensive health benefits to low-income individuals who meet specified eligibility criteria. [Welfare and Institutions Code (WIC) § 14000 *et seq*.]

5) Establishes the California Advancing and Innovating Medi-Cal (CalAIM) Act, and requires the implementation of CalAIM to support the following goals:

a) Identify and manage the risk and needs of Medi-Cal beneficiaries through whole-person-care approaches and addressing social determinants of health;

b) Transition and transform the Medi-Cal program to a more consistent and seamless system by reducing complexity and increasing flexibility; and,

c) Improve quality outcomes, reduce health disparities, and drive delivery system transformation and innovation through value-based initiatives, modernization of systems, and payment reform. [WIC § 14184.100]

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

COMMENTS:

1) **PURPOSE OF THIS BILL.** According to the author, the recent devastating wildfires in Los Angeles County and throughout our state have underscored the urgent need to address the long-term health impacts of wildfire-related air pollution. The author states that smoke, soot, and debris from the recent wildfires have severely impacted air quality across the state, creating hazardous conditions due to increased levels of toxic particulate matter and carcinogens like lead, asbestos, and silica. The author continues that studies have consistently shown that exposure to wildfire smoke is linked to an elevated risk of serious lung damage and costly hospitalization. The author argues that air purifiers and filters are an important tool in reducing the harm to at-risk communities and cheaper alternatives to costly emergency hospitalizations and urgent care visits. The author concludes that this bill would address this issue and ensure we have clean air for our most vulnerable.

2) **BACKGROUND.**

a) **Air pollution and related health impacts.** Air pollution refers to harmful gases, tiny particles, or biological substances in the air that can negatively impact human health. Air pollution can come from outdoor sources, such as wildfires and factories, and indoor sources, such as cooking, smoking, and heating. Fine particulate matter, known as PM2.5, is a major type of air pollutant. PM2.5 includes any particles that measure 2.5 microns or smaller in diameter—about 30 times smaller than the width of a human hair.

Because these particles are so small, they can penetrate deeply into the lungs, causing serious health problems.

i) **Wildfire smoke.** Wildfire smoke contains a complex mixture of harmful air pollutants, including PM2.5, carbon monoxide, volatile organic compounds, and other toxic gases. Inhalation of these pollutants can irritate the respiratory system, leading to symptoms such as coughing, wheezing, chest tightness, and shortness of breath. Prolonged exposure can exacerbate pre-existing respiratory conditions such as asthma, bronchitis, and COPD. Wildfire pollution has been linked to an increased risk of cardiovascular problems, including heart attacks, stroke, and arrhythmias. PM2.5 from wildfire smoke can penetrate deep into the lungs and enter the bloodstream, triggering inflammation and oxidative stress, which can contribute to cardiovascular disease development and exacerbation. Several studies have demonstrated a correlation between exposure to wildfire smoke and an increase in mortality rates, particularly among vulnerable populations such as the elderly, children, and individuals with pre-existing health conditions. The most severe health impacts often occur during periods of intense wildfires or prolonged exposure to heavy smoke.

ii) **Air filtration.** Indoor air filtration equipment can be used to remove harmful particles from indoor air. This bill specifically addresses the following types of air filtration equipment:

   (1) **Portable air filtration devices and their associated HEPA filters.** HEPA filters capture at least 99.97% of particles 0.3 microns in diameter, including PM2.5. Portable devices typically clean the air in a single room and require regular filter replacements. Larger, more powerful devices can clean bigger spaces but tend to cost more; and,

   (2) **Household filters**. These filters are installed in heating, ventilation, and air conditioning (HVAC) systems. They use the MERV rating to show their particle-capturing ability. This bill specifically covers HVAC filters rated MERV 13, which trap at least 85% of particles between one and three microns in size, roughly the size of PM2.5. MERV 13 filters do not capture very small particles as efficiently as true HEPA filters. True HEPA filters are rarely used in HVAC systems because they significantly restrict airflow, requiring special equipment. Like portable filters, HVAC system filters must also be replaced regularly.

b) **Medi-Cal benefits for asthma prevention.** Existing law requires DHCS, subject to appropriation, to regularly analyze asthma morbidity and mortality data and periodically assess the burden of asthma on the state's medical and economic resources. DHCS must also offer public and professional education on the most current information on asthma, and administer available funds to organizations working on innovative asthma interventions and health care services, improving patient education and self-management skills, and developing local policies that support asthma prevention and control.

In 2022, California began implementation of the CalAIM initiative as part of a larger effort to reform the Medi-Cal program. One of the foundational supports of CalAIM is Community Supports, which are services intended to address beneficiaries' health-related social needs and avoid higher, costlier levels of care. Medi-Cal Managed Care plans may opt in to providing Community Supports; not all services are offered by all plans in the

counties they serve. Asthma remediation is a Community Support that provides a lifetime maximum of $7,500 in reimbursements for physical modifications to a home to reduce environmental asthma triggers, including HEPA-filtered vacuums, air filters, minor mold removal and remediation services, and integrated pest management services. Eligibility is limited to Medi-Cal beneficiaries with "poorly controlled asthma" for whom a licensed health care provider has determined that the service will likely avoid asthma-related hospitalizations, emergency department visits, or other high-cost services.

Six months after the launch of the asthma remediation Community Support, the Centers for Medicare & Medicaid approved a California state plan amendment allowing DHCS to launch the Asthma Preventive Services benefit under Medi-Cal. The benefit includes coverage for clinic- and home-based asthma self-management education, and in-home environment trigger assessments when medically necessary for eligible beneficiaries of any age.

c) **California Health Benefits Review Program (CHBRP).** CHBRP was created in response to AB 1996 (Thomson), Chapter 795, Statutes of 2002, which 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. 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 to CHBRP's purview.

   i) **Baseline coverage.** CHBRP determined that there is no current coverage for any enrollees in DMHC or CDI-regulated plans or policies for air filtration equipment. This bill would increase coverage for 100% of enrollees with asthma, COPD, or who are pregnant. CHBRP highlighted that this bill may exceed the state's EHBs.

   ii) **Utilization.** CHBRP estimates there are 85,195 households containing enrollees with asthma or COPD, or who are pregnant that use air filtration equipment at baseline. CHBRP estimates the number would increase under this bill by 76.05%. More specifically, the number of households with pregnant enrollees that will obtain air filtration equipment will increase from 24,307 to 32,494, those with enrollees with asthma will increase from 57,476 to 111,480, and those with enrollees with COPD will increase from 3,412 to 6,015 households.

   iii) **Cost impact.** CHBRP estimates that this bill would increase total net annual expenditures by approximately $13.6 million for enrollees with DMHC and CDI-regulated plans and policies. This figure includes an increase in premiums of $33,785,000, an approximate $20.2 million decrease in enrollee expenses for non-covered benefits, and cost offsets due to a reduction in the number of medications used for enrollees with asthma, and a reduction in urgent care visits for enrollees with COPD.

   Changes in premiums due to this bill would vary by market segment. Because none of the insurance market segments had baseline coverage for air filtration equipment, the increases in premiums are driven primarily by the underlying populations of people with asthma and COPD, and the pregnant population in each market segment. The largest increases in premiums will occur in the DMHC-regulated large group

(0.0295%) and small group market (0.0301%) and the CDI-regulated small-group (0.0309%) and individual market (0.0304%). The smallest change was 0.0242% in the DMHC-regulated individual market. Enrollees in Covered California DMHC-regulated small group products would experience a 0.0299% increase in premiums, whereas Covered California DMHC-regulated individual market products would see a 0.0242% premium increase. There was not sufficient data to project an increase in the CDI-regulated Covered California small group or individual market.

iv) **Medical effectiveness.** CHBRP found some evidence that HEPA filtration is effective in the reduction of negative health outcomes in those with asthma who were exposed to cigarette smoke, but conflicting evidence for the general asthma population. CHBRP found some evidence for the effectiveness of HEPA filtration on health outcomes for people with COPD or who are pregnant. CHBRP noted that it is well established that HEPA filtration is effective at cleaning indoor air and that exposure to polluted air, especially that due to smoke, leads to adverse health outcomes. However, CHBRP stated that the current research is insufficient with regard to the direct impact of HEPA filtration on health outcomes for those exposed to polluted air. CHBRP found no studies on the effectiveness of household HVAC filters on health outcomes for the populations impacted by this bill.

v) **Public health impacts.** CHBRP estimates that this bill would lead to various public health improvements. This includes improvements in respiratory health status for enrollees with asthma, especially the 3,800 living in homes where they are exposed to tobacco smoke, including a significant reduction in the use of steroids and inhalers. Additionally, CHBRP estimates improvement in respiratory health status and quality of life for 2,600 enrollees with COPD, including 484 fewer urgent care visits. CHBRP further estimates an improvement in fetal growth and cognitive development for babies born in the 8,200 homes with pregnant enrollees.

vi) **Long-term impacts.** CHBRP notes that future climate shifts are expected to increase the frequency and severity of wildfires in California. More frequent wildfires will result in increased air pollution and greater health risks. Given these projected increases in ambient air pollution, increased use of air filtration equipment could be more beneficial in the coming years.

d) **EHBs.** The ACA requires health plans sold in the individual and small group markets to offer a comprehensive package of items and services, EHBs, with no dollar limits. Under the ACA, the federal government gave each state the authority to choose its "benchmark" EHB plan. EHBs require plans to cover ten categories of services: (1) ambulatory patient services (outpatient care); (2) emergency services; (3) hospitalization; (4) maternity and newborn care; (5) mental health and substance use disorder services, including behavioral health treatment; (6) prescription drugs; (7) rehabilitative and habilitative services and devices; (8) laboratory services; (9) preventive and wellness services and chronic disease management; and, (10) pediatric services, including dental and vision care. Under the ACA, if states require plans to cover services beyond those defined as EHBs in law, states must pay the costs of those benefits, either by paying the enrollee directly or by paying the qualified health plan (offered through Covered California). The federal department of Health and Human Services (HHS) issued rules in 2018, 2019, and 2024 that provided states with new flexibilities to augment their EHBs. California is currently

undergoing the process of updating the state's benchmark EHB plan. After a series of public meetings and a Legislative hearing, DMHC announced California's intent to submit a proposal to the federal government to add three new benefits to the state's EHB benchmark plan: hearing aids, durable medical equipment, and infertility treatment. Notification from DMHC to HHS must take place by May 7, 2025 for the new benchmark to take effect by the January 1, 2027 plan year. If the proposed EHB benchmark is approved, legislation to codify the new benchmark plan will be necessary. AB 224 (Bonta) and SB 62 (Menjivar) have been introduced this session to codify any benchmark changes that may come out of this process.

e) **Office of Health Care Affordability (OHCA) cost targets.** OHCA was established in 2022 in response to widespread cost-related access challenges across California. According to the California Health Care Foundation, over half of Californians say they skip or delay health care due to costs. OHCA collects, analyzes, and publicly reports data on total health care expenditures and enforces spending targets. OHCA's spending targets are intended to reduce excess spending and slow health care spending growth. In April of 2024, OHCA approved a statewide cost growth target of 3.5% starting in 2025 and phasing down to 3% by 2029. Health care entities, including health plans, are subject to the statewide spending target and are subject to progressive enforcement if the entity's costs exceed the target. Some entities have raised concerns that new legislative benefit mandates will make it difficult for them to meet the established cost growth target.

   Current law does not explicitly require OHCA to adjust the cost growth targets based on changes to state policy, such as mandates, that may increase spending. However, it does require OHCA to consider state benefit mandates in its development and enforcement of cost growth targets. Specifically, when establishing cost growth target methodology, OHCA is required to review relevant state policy changes impacting covered benefits, provider reimbursement, and costs, among other factors. In addition, in enforcing cost growth targets, OHCA is required to consider factors that contribute to spending in excess of the applicable target, and the extent to which each entity has control over the applicable components of its cost target.

3) **SUPPORT.** The Coalition for Clean Air supports this bill, stating that recent wildfires in Los Angeles County have further elevated concerns about air pollution and the serious health risk from toxic smoke, soot, and debris. The Coalition continues that fires released harmful pollutants like particulate matter, lead, asbestos, and silica, all of which can cause long-term respiratory damage. The Coalition notes that vulnerable groups, including pregnant individuals, children, seniors, and those with chronic respiratory issues, face increased risks of sever lung damage form wildfire smoke. The Coalition cites that the Centers for Disease Control and Prevention highlights that this smoke is particularly dangerous for those with pre-existing lung conditions, and research from University of California, Los Angeles indicates that its effects can persist for weeks or months. The Coalition continues that experts caution that standard air quality measurements may underestimate pollution levels, complicating protective measures for at-risk populations. The Coalition notes that despite the inclusion of asthma remediation under CalAIM, other health insurance plans do not cover these essential interventions. The Coalition concludes that this bill would address this by requiring health plans to cover HEPA air purifiers for enrollees that are highly susceptible to health impacts from air pollution.

4) **OPPOSITION.** The California Association of Health Plans (CAHP) and Association of California Life and Health Insurance Companies (ACLHIC) oppose this bill, stating that it does not specify the types or brands of HEPA purifiers and filters to be covered. CAHP and ACLHIC continue that without clear guidelines, there is ambiguity regarding what constitutes an eligible device, potentially leading to covering certain purifiers without medical necessity. CAHP and ACLHIC argue that by prohibiting deductibles, coinsurance, or copayments, the bill removes standard cost-sharing mechanisms that help prevent overutilization and ensure responsible use of health care resources. CAHP and ACLHIC contend that the unrestricted nature of the benefit, combined with no cost-sharing, raises concerns about individuals possibly obtaining multiple devices, other fraudulent activities, and overall increased costs. CAHP and ACLHIC continue that covering household appliances like air purifiers sets a concerning precedent for health plans to cover non-medical equipment, potentially resulting in further mandates that extend beyond traditional health care services.

5) **PREVIOUS LEGISLATION.** AB 391 (Chiu) of 2017, would have established the Asthma Preventive Services Program Act of 2017 to require DHCS to seek an amendment to its Medicaid state plan to authorize qualified asthma preventive services providers as providers of asthma preventive services, as defined, under the Medi-Cal program. AB 391 was vetoed by Governor Brown who stated in part: "DHCS…has considerable administrative authority to make changes to benefits based upon new medical evidence and clinical guidelines. Therefore, these statutory changes are unnecessary."

6) **AUTHORS AMENDMENTS:** The author has submitted amendments to do the following:

   a) Delete mandate to cover filters;

   b) Limit the coverage mandate to large group plans and group insurers;

   c) Delete prohibition on cost sharing;

   d) Limit coverage to counties where a local or state emergency has been declared due to wildfires;

   e) Provide coverage pursuant to d) until one year from the date the local or state emergency is lifted, whichever is later;

   f) Require the HEPA purifier to cost $500 or less, adjusted for inflation; and,

   g) Make technical and clarifying changes.

REGISTERED SUPPORT / OPPOSITION:

Support

Aids Healthcare Foundation
Bay Area Air Quality Management District
California Nurses Association
Center for Environmental Health
Coalition for Clean Air

Opposition

Association of California Life & Health Insurance Companies
California Association of Health Plans

Analysis Prepared by: Riana King / HEALTH / (916) 319-2097

Date of Hearing: April 29, 2025

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 554 (Mark González) – As Amended March 3, 2025

SUBJECT: Health care coverage: antiretroviral drugs, drug devices, and drug products.

SUMMARY: Prohibits a nongrandfathered or grandfathered health plan contract or health insurance policy from imposing any cost-sharing or utilization review (UR) requirements for antiretroviral drugs, devices, or products (ARVs) that are either approved by the United States Food and Drug Administration (FDA) or recommended by the federal Centers for Disease Control and Prevention (CDC) for the prevention of human immunodeficiency virus (HIV)/ acquired immunodeficiency syndrome (AIDS). Prohibits a health plan or health insurer from subjecting ARVs that are either approved by the FDA or recommended by the CDC for the prevention HIV/AIDS, to prior authorization or step therapy, but authorizes prior authorization or step therapy if at least one therapeutically equivalent version is covered without prior authorization or step therapy and the insurer provides coverage for a non-covered therapeutic equivalent antiretroviral drug, device, or product without cost sharing pursuant to an exception request. Specifically, **this bill**:

1) Prohibits a health plan or insurer from subjecting ARVs that are either approved by the FDA or CDC for HIV/AIDS prevention, including pre-exposure prophylaxis (PrEP) and postexposure prophylaxis (PEP), to prior authorization, step therapy, or any other protocol designed to delay treatment, except as specified in 2) below.

2) Permits a health plan or insurer not to cover all of the therapeutically equivalent versions without prior authorization or step therapy, if at least one therapeutically equivalent version is covered without prior authorization or step therapy and the plan or insurer provides coverage for a non-covered therapeutic equivalent ARVs without cost sharing pursuant to an exception request. Specifies that a long-acting injectable drug is not therapeutically equivalent to a long-acting injectable drug with a different duration.

3) Requires a nongrandfathered health plan contract or insurance policy to provide coverage for, and prohibits imposing any cost-sharing or UR requirements for, ARVs that are either approved by the FDA or recommended by the CDC for the prevention of HIV/AIDS, including PrEP or PEP.

4) Requires a plan contract or insurance policy that is a grandfathered health plan or insurer to provide coverage, and prohibits from imposing any cost-sharing or utilization review requirements, for ARVs that are either approved by the FDA or recommended by the CDC for the prevention of HIV/AIDS, including PrEP or PEP.

5) Requires a health plan or insurer to provide coverage under the outpatient prescription drug benefit for ARVs that are either approved by the FDA or recommended by the CDC for the prevention of HIV/AIDS, including by supplying providers directly with a drug, device, or product and is not self-administered, in addition to the coverage a health care service plan provides for prescription drugs that are not self-administered.

6) Exempts specialized health plan contracts or insurance policies that covers only dental or vision benefits, Medi-Cal managed care plans, and Medicare supplement contract from the provisions of this bill.

7) Applies the provisions of this bill regardless of whether or not an ARV is self-administered.

8) Authorizes the California Department of Insurance (CDI) and CDI Commissioner to implement and enforce this bill, as specified.

9) Requires a health plan contract or insurance policy that is a high deductible health plan (HDHP) under federal law to comply with the cost-sharing requirements of this bill unless the application conflicts with HDHP's federal requirements, and if so, applies the cost-sharing limits once a contract's deductible has been satisfied for the plan year.

EXISTING LAW:

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

2) Establishes California's essential health benefits (EHBs) benchmark under the Patient Protection and Affordable Care Act (ACA) as the Kaiser Small Group Health Maintenance Organization, establishes existing California health insurance mandates, and the 10 ACA mandated benefits, including prescription drug coverage. [HSC § 1367.005 and INS § 10112.27]

3) Requires health plans and insurers, at a minimum, to provide coverage for and prohibits any cost-sharing requirements for several services including, but not limited to evidence-based items or services that have in effect a rating of "A" or "B in the recommendations of the United States Preventive Services Taskforce and immunizations that have in effect a recommendation from the Advisory Committee on Immunization Practices of the CDC. [HSC § 1367.002 and INS § 10112.2]

4) Requires health plans and insurers to provide coverage for home test kits for sexually transmitted diseases, as defined, and the laboratory costs for processing those kits, that are deemed medically necessary or appropriate and ordered directly by a health care provider or furnished through a standing order for patient use based on clinical guidelines and individual patient health needs. [HSC § 1367.34 and INS § 10123.208]

5) Defines "basic health care services" as all of the following:

    a) Physician services, including consultation and referral;

    b) Hospital inpatient services and ambulatory care services;

    c) Diagnostic laboratory and therapeutic radiologic services;

    d) Home health services;

e) Preventive health services;

f) Emergency health care services, including ambulance and ambulance transport services and out-of-area coverage. Basic health care services includes ambulance and ambulance transport services provided through the 911 emergency response system; and,

g) Hospice care, as specified. [HSC § 1345 and INS § 10112.281]

6) Requires the criteria or guidelines used by health plans and insurers, or any entities with which plans or insurers contract for UR or utilization management (UM) functions, to determine whether to authorize, modify, or deny health care services to:

a) Be developed with involvement from actively practicing health care providers;

b) Be consistent with sound clinical principles and processes;

c) Be evaluated, and updated if necessary, at least annually;

d) If used as the basis of a decision to modify, delay, or deny services in a specified case under review, be disclosed to the provider and the enrollee or insured in that specified case; and,

e) Be available to the public upon request. [HSC § 1363.5 and INS § 10123.135]

7) Authorizes a health plan or insurer that provides coverage for prescription drugs to require step therapy if there is more than one drug that is clinically appropriate for the treatment of a medical condition. [HSC § 1367.206 and INS § 10123.201]

8) Requires a health plan or insurer to expeditiously grant a request for a step therapy exception within the applicable time limit if a prescribing provider submits necessary justification and supporting clinical documentation that the required prescription drug is inconsistent with good professional practice for provision of medically necessary covered services, taking into consideration the enrollee's or insured's needs and medical history. Permits the basis of the provider's determination to include, but not be limited to, any of the following criteria:

a) The prescription drug required by the plan or insurer is contraindicated or is likely, or expected, to cause an adverse reaction or physical or mental harm in comparison to the requested prescription drug;

b) The required prescription drug is expected to be ineffective based on the known clinical characteristics of the enrollee or insured and the known characteristics and history of the enrollee's or insured's prescription drug regimen;

c) The enrollee or insured has tried the required prescription drug while covered by their current or previous health coverage or Medicaid, and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse reaction. Permits the plan or insurer to require the submission of documentation demonstrating that the enrollee or insured tried the required prescription drug before it was discontinued;

d) The required prescription drug is not clinically appropriate for the enrollee or insured because the required drug is expected to do any of the following, as determined by the prescribing provider:

i) Worsen a comorbid condition;

ii) Decrease the capacity to maintain a reasonable functional ability in performing daily activities; or,

iii) Pose a significant barrier to adherence to, or compliance with, the enrollee or insured's drug regimen or plan of care.

e) The enrollee or insured is stable on a prescription drug selected by the prescribing provider for the medical condition under consideration while covered by their current or previous health coverage or Medicaid. [HSC § 1367.206 and INS § 10123.201]

9) Authorizes a health care provider or prescribing provider, enrollee, insured, or their designee or guardian to appeal a denial of an exception request for coverage of a nonformulary drug, prior authorization request, or step therapy exception request consistent with the plan's or insurer's current UM process. [HSC § 1367.206 and INS § 10123.201]

10) Prohibits a health plan or insurer from subjecting antiretroviral drugs that are medically necessary for the prevention of AIDS/HIV, including PrEP or PEP, to prior authorization or step therapy. Permits a health plan or insurer not to cover all of the therapeutically equivalent versions without prior authorization or step therapy, if at least one therapeutically equivalent version is covered without prior authorization or step therapy, if the FDA has approved one or more therapeutic equivalents of a drug, device, or product for the prevention of AIDS/HIV. Limits coverage to a 60 day supply to a single patient once every two years, unless the pharmacist has been directed otherwise by a prescriber. [HSC § 1342.74 and INS § 10123.1933]

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

COMMENTS:

1) **PURPOSE OF THIS BILL.** According to the author, amid the chaos and attacks on healthcare access from the federal administration, California must take bold steps to safeguard and expand lifesaving HIV prevention. The author states that the HIV epidemic continues to disproportionately affect historically disadvantaged communities, and cost and access remain major barriers to effective treatment. The author argues that this bill ensures that all health insurance policies cover HIV PrEP without cost-sharing, eliminating out-of-pocket costs for one million Californians. Additionally, the author notes that current laws exclude certain FDA-approved long-lasting injectable medications, further limiting patient choice and disproportionately impacting Latino and Black/African American communities, which face the highest rates of new HIV diagnoses. The author continues that by mandating full coverage for safe and effective prevention methods and allowing local clinics to receive reimbursement, this bill protects patient and provider choice while reducing the risk of HIV/AIDS in marginalized communities. The author concludes that California must lead

where the federal government fails—ensuring equitable access to HIV prevention for those who need it most.

2) **BACKGROUND.** HIV attacks the body's CD4 and/or T-cells (i.e., a type of white blood cell), which are integral to the body's immune function. If undiagnosed and left untreated, HIV invades and effectively destroys CD4 cells during the virus replication process, leading to opportunistic infections, opportunistic cancers, and death. Without initial treatment and routine adherence to treatment, HIV typically progresses through three stages of disease: acute HIV infection; chronic HIV infection; and AIDS. There is no cure for HIV/AIDS; however, with routine care and proper treatment, HIV-related morbidity and mortality can be prevented through ARV therapy.

   a) **ARVs for prevention of HIV/AIDs.** Preventing the transmission of HIV to the HIV-negative population has been the focus of a concerted U.S. public health effort for more than 30 years. According to the California Health Benefits Review Program (CHBRP), ARV therapy is the use of HIV medicines — also referred to as an HIV regimen — to treat or prevent HIV. There are more than 30 FDA-approved ARV drugs from eight drug classes that may be used to prevent initial HIV infection (PREP or PEP) or treat HIV infection, prevent HIV transmission to other people, and prevent progression to AIDS. Given the availability of ARV drugs, it is possible for people living with HIV to achieve a life expectancy similar to that of the general population.

   b) **CHBRP.** CHBRP was created in response to AB 1996 (Thomson), Chapter 795, Statutes of 2002, which 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. 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 to CHBRP's purview.

      i) **Baseline coverage.** CHBRP estimates that at baseline, 8,794,000 (95.5%) Californians with state-regulated insurance subject to this bill are enrolled in plans or policies that are fully compliant with this bill and have coverage for ARV drugs without cost sharing. Approximately 2.1% of health plans and policies are in partial compliance (i.e., provide coverage but with cost sharing), and 2.4% are out of compliance (i.e., do not provide coverage). Under this bill, 100% of enrollees with health insurance subject to its provisions would have coverage for ARV drugs without cost sharing.

      ii) **Utilization.** CHBRP estimates there are 63,155 enrollees who utilize ARV drugs each year, about half (53.5%) of whom also have cost sharing.

      iii) **Cost impact.** CHBRP notes that this bill would apply to grandfathered and nongrandfathered DMHC- and CDI-regulated plans and policies in the large group market in Year 1. In Year 2, the bill would extend to include small group and individual market insurance. Medi-Cal plans are excluded. Under this assumption, CHBRP estimates that this bill would result in an additional $30.5 million (0.02%) in net annual expenditures after the first year, including a $73.6 million increase in total

premiums, and a decrease of $43 million (0.23%) in enrollee cost sharing for enrollees in large group plans and policies regulated by DMHC and CDI. In its second year, CHBRP estimates this bill would result in a net annual expenditure of $37,087,000 (0.02%), including an increase in total premiums paid by employers and enrollees for newly covered benefits by $135,988,000, and a decrease in enrollee cost sharing by $98,901,000 (0.48%) compared to baseline.

CHBRP was unable to estimate additional cost offsets related to the number of HIV infections prevented due to increased use of ARV drugs. Furthermore, the vast array of AIDS-related diseases, hospitalizations, and other related health care costs that could occur and would be prevented cannot be quantified. However, in general, prevention of these conditions and their associated costs would provide an offset to CHBRP's estimated premium increases due to this bill.

iv) **Long-term impacts.** CHBRP notes that cost impacts over the long term would be proportional to any increase in utilization. New ARV drugs, devices, and products that may be developed in the future could have additional impacts on utilization in the long-term. However, cost is not the only barrier to access to ARV therapy. Provider awareness, stigma, inequities in healthcare access, low perception of risk, and other factors also create challenges that impact ARV drug utilization and adherence, and ultimately the incidence and prevalence of HIV/AIDS.

c) **Grandfathered vs. nongrandfathered health plans.** Grandfathered plans are those that were in existence on March 23, 2010 and have stayed basically the same. Grandfathered plans are not required to provide all of the benefits and consumer protections required by the ACA. For example, a grandfathered plan might not cover preventive health services, it might charge higher premiums based on health status or gender, and it might exclude coverage for pre-existing conditions. According to the Commonwealth Fund, all grandfathered plans are exempt from certain requirements so long as employers do not significantly lower their premium contributions to employee plans and plans do not increase people's cost-sharing requirements beyond certain limits or reduce benefits. Health plans can retain grandfathered status if the changes they make do not reduce the comprehensiveness of a plan. Health plans are free to increase the number and type of benefits offered, make changes to comply with state or federal regulations, voluntarily adopt other consumer protections of the ACA, and make modest adjustments in benefits, cost-sharing, and premiums.

d) **EHBs.** The ACA requires health plans sold in the individual and small group markets to offer a comprehensive package of items and services, EHBs, with no dollar limits. Under the ACA, the federal government gave each state the authority to choose its "benchmark" EHB plan. EHBs require plans to cover ten categories of services: (1) ambulatory patient services (outpatient care); (2) emergency services; (3) hospitalization; (4) maternity and newborn care; (5) mental health and substance use disorder services, including behavioral health treatment; (6) prescription drugs; (7) rehabilitative and habilitative services and devices; (8) laboratory services; (9) preventive and wellness services and chronic disease management; and, (10) pediatric services, including dental and vision care. Under the ACA, if states require plans to cover services beyond those defined as EHBs in law, states must pay the costs of those benefits, either by paying the enrollee directly or by paying the qualified health plan (offered through Covered California). The federal

department of Health and Human Services (HHS) issued rules in 2018, 2019, and 2024 that provided states with new flexibilities to augment their EHBs. California is currently undergoing the process of updating the state's benchmark EHB plan. After a series of public meetings and a Legislative hearing, DMHC announced California's intent to submit a proposal to the federal government to add three new benefits to the state's EHB benchmark plan: hearing aids, durable medical equipment, and infertility treatment. Notification from DMHC to HHS must take place by May 7, 2025 for the new benchmark to take effect by the January 1, 2027 plan year. If the proposed EHB benchmark is approved, legislation to codify the new benchmark plan will be necessary. AB 224 (Bonta) and SB 62 (Menjivar) have been introduced this session to codify any benchmark changes that may come out of this process.

e) **Office of Health Care Affordability (OHCA) cost targets.** OHCA was established in 2022 in response to widespread cost-related access challenges across California. According to the California Health Care Foundation, over half of Californians say they skip or delay health care due to costs. OHCA collects, analyzes, and publicly reports data on total health care expenditures and enforces spending targets. OHCA's spending targets are intended to reduce excess spending and slow health care spending growth. In April of 2024, OHCA approved a statewide cost growth target of 3.5% starting in 2025 and phasing down to 3% by 2029. Health care entities, including health plans, are subject to the statewide spending target and are subject to progressive enforcement if the entity's costs exceed the target. Some entities have raised concerns that new legislative benefit mandates will make it difficult for them to meet the established cost growth target.

   Current law does not explicitly require OHCA to adjust the cost growth targets based on changes to state policy, such as mandates, that may increase spending. However, it does require OHCA to consider state benefit mandates in its development and enforcement of cost growth targets. Specifically, when establishing cost growth target methodology, OHCA is required to review relevant state policy changes impacting covered benefits, provider reimbursement, and costs, among other factors. In addition, in enforcing cost growth targets, OHCA is required to consider factors that contribute to spending in excess of the applicable target, and the extent to which each entity has control over the applicable components of its cost target.

3) **SUPPORT.** Equality California (EQCA), a co-sponsor of this bill, argues that this bill is a critical step forward in California's ongoing fight to end the HIV epidemic and to ensure equitable access to healthcare for all. EQCA states that this bill strengthens existing state law to prohibit health plans and insurers from requiring prior authorization, step therapy, or other protocols designed to delay access to PrEP and PEP medications approved by the FDA or recommended by the CDC. EQCA continues that this bill ensures all health plans and insurers cover PrEP medications without cost-sharing or utilization review and clarifies that long-acting injectable drugs with different durations are not therapeutically equivalent. EQCA notes that with potential federal rollbacks to preventive care requirements and a looming U.S. Supreme Court decision threatening the authority of the U.S. Preventive Services Task Force, California must take decisive action to protect and expand access to these crucial HIV prevention tools.

Insurance Commissioner Ricardo Lara is also co-sponsoring this bill, stating that no one should have to jump through hoops or face financial burdens to access FDA-approved and CDC-recommended treatments that can prevent the spread of HIV/AIDS. The Commissioner continues that by eliminating cost-sharing for these essential medications, we are taking a significant step toward health equity—especially for communities disproportionately impacted by the HIV epidemic. The Commissioner argues this bill is about saving lives, breaking down systemic barriers, and ensuring that all Californians can access the care they need.

4) **OPPOSITION.** The California Association of Health Plans (CAHP) and Association of California Life and Health Insurance Companies (ACLHIC) oppose this bill stating that they support efforts to enhance access to HIV prevention methods but have significant concerns regarding this bill's financial implications on the healthcare system. CAHP and ACLHIC cite the CHBRP analysis which estimates that this bill would increase total premiums paid by employers and enrollees by almost $136 million following full implantation in year two. Additionally, CAHP and ACLHIC cite that enrollees in the Covered California individual market plan would see an increase in premiums of almost $11 million in year two.

5) **PREVIOUS LEGISLATION.**

   a) SB 339 (Weiner) Chapter 1, Statutes of 2024, requires health plans and insurers to cover HIV PrEP and PEP furnished by a pharmacist, including costs for the pharmacist's services and related testing ordered by the pharmacist. Permits a pharmacist to furnish up to a 90-day course of PrEP, or beyond 90-days if specified conditions are met.

   b) SB 427 (Portantino) of 2024 was substantially similar to this bill. SB 427 was held at the Assembly Desk.

   c) SB 159 (Wiener), Chapter 532, Statutes of 2019, permits pharmacists to furnish a 60-day supply of PrEP and PEP; prohibits health plans and insurers from requiring prior authorization or step therapy for PrEP or PEP; requires coverage of pharmacist-prescribed PrEP and PEP; and, permits Medi-Cal reimbursement for pharmacists prescribing PrEP and PEP.

REGISTERED SUPPORT / OPPOSITION:

Support

APLA Health (co-sponsor)
Equality California (co-sponsor)
Los Angeles LGBT Center (co-sponsor)
San Francisco Aids Foundation (co-sponsor)
AIDS Healthcare Foundation
AltaMed Health Services Corporation
American College of Obstetricians & Gynecologists - District IX
API Equality-LA
Asian Americans Advancing Justice-southern California
Buen Vecino
California Legislative LGBTQ Caucus
California LGBTQ Health and Human Services Network

California Life Sciences Association
California Nurses Association
California Pharmacists Association
California Physicians Alliance
CFT- a Union of Educators & Classified Professionals, AFT, AFL-CIO
City of Long Beach
City of San Jose
Clinica Monseñor Oscar A. Romero
Coachman Moore & Associates, Inc.
Community Clinic Association of Los Angeles County (CCALAC)
County Health Executives Association of California (CHEAC)
Courage California
El/La Para Translatinas
End the Epidemics: Californians Mobilizing to End HIV, Viral Hepatitis, STIs, and Overdose
Essential Access Health
Glide
Insurance Commissioner Ricardo Lara / California Department of Insurance
LGBTQ+ Inclusivity, Visibility, and Empowerment (LIVE)
Long Beach Forward
Northeast Valley Health Corporation
PFLAG Los Angeles
PFLAG San Jose/Peninsula
Pride At the Pier
Rainbow Families Action Bay Area
Sacramento LGBT Community Center
The Translatin@ Coalition
The Wall Las Memorias Project
Venice Family Clinic
Viiv Healthcare
Youth Leadership Institute

Opposition

Association of California Life & Health Insurance Companies
California Association of Health Plans

Analysis Prepared by: Riana King / HEALTH / (916) 319-2097

Date of Hearing: April 29, 2025

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 577 (Wilson) – As Amended April 21, 2025

SUBJECT: Health care coverage: antisteering.

SUMMARY: Prohibits a health care service plan (health plan), health insurer, or pharmacy benefit manager (PBM) from engaging in specified steering practices, including requiring an enrollee or insured to use specific settings for the administration of injected or infused medication. Specifically, **this bill**:

1) Prohibits a health plan contract or health insurance policy issued, amended, or renewed on or after January 1 2026, or a PBM from doing any of the following:

    a) Requiring an enrollee or insured to self-administer an injected or infused prescription medication if a health care provider determines it is clinically appropriate for the medication to be administered by a health care provider in a physician's office, clinic, or infusion center;

    b) Requiring an enrollee or insured to use a specific health care provider, external infusion center, or home infusion pharmacy for administration of an injected or infused medication, if their current health care provider determines it is clinically appropriate for the medication to be administered by their current health care provider in a physician's office, clinic, or infusion center;

    c) Requiring an enrollee or insured, in order to receive coverage under the plan or insurer, to use a mail order pharmacy to furnish a health care provider, enrollee, or insured with an injected or infused prescription medication for subsequent administration in a physician's office, clinic, or infusion center;

    d) Imposing upon an enrollee any cost-sharing requirement relating to injected or infused prescription medication furnished by a health care provider for administration in a physician's office, clinic, or infusion center that is greater, or more restrictive, than what would otherwise be imposed if a mail order pharmacy furnished the injected or infused prescription drugs to the health care provider, enrollee, or insured;

    e) Refusing to authorize, approve, or pay a participating health care provider for providing covered injected or infused prescription medications and related services to enrollees or insured, if the injected or infused prescription medication would otherwise be covered;

    f) Requiring an enrollee or insured to use a retail pharmacy for dispensing prescription oral medications, if the health care provider determines it is clinically appropriate for the medication to be dispensed by a different pharmacy or by the prescriber;

    g) Reimbursing at a lesser amount a prescription oral medication dispensed by a physician than the amount that would otherwise be reimbursed if the same medication was dispensed by the plan, insurer, or PBMs chosen pharmacy; and,

h) Imposing any requirements, conditions, or exclusions that discriminate against a physician in connection with dispensing prescription oral medications. Specifies that discrimination prohibited by this bill includes, but is not limited to, any of the following:

i) Including terms and conditions in a contract with a physician based on the physician dispensing prescription oral medications, including, but not limited to, either of the following:

(1) Terms and conditions to preemptively dissuade or discourage the physician from dispensing prescription oral medications; or,

(2) Terms and conditions included because of, or in response to, a physician dispensing prescription oral medications;

ii) Refusing to contract with or terminating a contract with a physician on the basis of the physician dispensing prescription oral medications; or,

iii) Retaliation against a physician based on the physician's exercise of any right or remedy under this bill.

2) Specifies that the provisions of this bill do not prohibit or interfere with compliance with federal and state law, including registration with the United States Drug Enforcement Administration as required to dispense controlled substances.

3) Defines "PBM" as a person, business, or other entity that, pursuant to a contract with a health care service plan, manages the prescription drug coverage provided by the health care service 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.

EXISTING LAW:

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

2) Establishes the Board of Pharmacy within the Department of Consumer Affairs to administer and enforce the Pharmacy Law. [Business and Professions Code (BPC) §§ 4000 - 4427.8]

3) Prohibits a health plan contract from requiring or allowing a health care service provider (but not other providers such as health facilities, hospices, or surgical centers) to assume or be at any financial risk for any specified covered injectable medications and adult vaccines that are administered in the office of a physician and surgeon or prescribed by a physician and surgeon for self-administration by the patient. Requires these items to be reimbursed on a fee-for-service basis at the negotiated contract rate or through an alternate funding mechanism mutually agreed to by the health plan and the health care service provider, subject to any applicable copayment or deductible, by the health plan. [HSC § 1375.8]

4) Permits a health care service provider to assume financial risk for the items described in 3) above after making the request in writing at the time of negotiating an initial contract or renewing a contract with a health plan. Prohibits a health plan from requesting or requiring as a condition of the contract agreement a health care service provider to assume the financial risk for any of those items. [HSC § 1375.8]

5) Defines a "PBM" in the Knox-Keene Act to mean 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. Excludes from this definition a health plan licensed under the Knox-Keene Act or any individual employee of a health plan its contracted provider performing the above-described services. [HSC § 1385.001]

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

COMMENTS:

1) **PURPOSE OF THIS BILL.** According to the author, PBMs, health plans and insurers have begun to institute policies which take the in-office administration of physician administered drugs out of the hands of patients' doctors, and into their own vertically-integrated pharmacies and infusion centers, in an effort to increase their profits at the expense of patients. The author states that these policies effectively prevent patients from receiving drugs directly from their physician—such as requiring cancer patients to go to an infusion center—as opposed to receiving chemotherapy infusions in their own physician's office. The author continues that PBMs often require patients to receive oral drugs through the PBM-owned mail-order pharmacies. The author argues that these policies prevent physicians from dispensing oral drugs to their patients, such as when a physician dispenses anti-nauseant medication to their patient prior to administering an infusion. The author continues that unfortunately, there are currently no laws to prevent PBMs from engaging in patient steering practices, and many of the other anti-competitive practices they deploy, since there is a lack of regulatory oversight of PBMs.

2) **BACKGROUND.**

   a) **Patient steering.** Patient steering is the practice of directing patients to certain preferred pharmacies or providers in a network. Steering has become a particular point of focus in the delivery of pharmacy benefits. A January 2025 interim Federal Trade Commission (FTC) report entitled "*Specialty Generic Drugs: A Growing Profit Center for Vertically Integrated PBMs"* identified specialty prescription steering as a key mechanism through which PBMs, and the health plans they are integrated with, direct patients to their owned or affiliated pharmacies and entities. The FTC reported that members of commercial health plans managed by the Big 3 PBMs filled a significantly larger proportion of their high markup specialty generic drug prescriptions at PBM-affiliated pharmacies, which suggests that the Big 3 PBMs may be steering these prescriptions to their own affiliated pharmacies (and away from unaffiliated pharmacies). The FTC further noted that documents produced by PBMs showed various discussions on "optimization levers" that may be used to steer patients to their affiliated pharmacies, as well as strategies to "push

to retail" prescriptions on "low/no margin drugs" and "effectively block" the dispensing of these drugs at their affiliated pharmacies.

b) **White & brown bagging.** The National Association of Pharmacy Boards (NAPB) describes "white bagging" as the distribution of patient-specific medications from a pharmacy, typically a specialty pharmacy, to the physician's office, hospital, or clinic for administration. It is often used in oncology practices to obtain costly injectable medications that are distributed by specialty pharmacies and may not be available in all non-specialty pharmacies. "Brown bagging" is the dispensing of medication from a pharmacy (typically a specialty pharmacy) directly to a patient, who then transports the medications to the physician's office for administration. In a 2018 report on these topics, the NABP indicates that as the specialty pharmacy model becomes more prevalent more patient care will be subject to white and brown bagging under mandates by third party payers. The NAPB concluded that there is a legitimate patient protection issue when a specialty drug is distributed to an entity other than the patient.

   As part of their 2025 Sunset Oversight Review Report, the California Board of Pharmacy (BoP) discussed payer activities that negatively impact patient access. In 2021, the BoP convened an informational meeting to discuss the practice of white bagging. The BoP reported that during that meeting they learned about many of the patient safety concerns stemming from this practice, including challenges in coordinating care and delays in therapy. Many of the patients requiring infusion have serious medical conditions such as cancer where delays in therapy to result in disease progression. The BoP noted that they do not have the current authority to prevent this payer driven practice, although they have suggested statutory changes to rein in the practice.

c) **Consumer co-pay caps.** AB 948 (Berman), Chapter 820, Statutes of 2023, made permanent a $250 co-pay cap for a 30-day supply of a prescription. Before the $250 cap, Californians with serious and chronic conditions like cancer, HIV/AIDS, multiple sclerosis and lupus were particularly vulnerable to high out-of-pocket costs because more expensive specialty drugs were often put on the highest tier of the formulary, costing thousands of dollars.

   While this $250 co-pay cap has been made permanent in state law, it is important to note that the cap only applies to pharmacy benefits, which in the context of this bill typically covers self-injected or self-administered medications. Medical benefits, which cover drugs administered by a health care provider, are not subject to the $250 co-pay cap.

3) **SUPPORT.** The Association of Northern California Oncologists (ANCO), the Medical Oncology Association of Southern California (MOASC), and the California Rheumatology Alliance (CRA) are sponsoring this bill, stating that California's patients and their doctors have been experiencing a growing trend utilized by health plans/insurers and PBMs which prevent patients from receiving drugs directly from their physician, such as requiring cancer patients to go to an infusion center, as opposed to receiving chemotherapy infusions in their own physician's office. The sponsors continue that these entities prevent physicians from obtaining and dispensing drugs to their patients, such as when an oncologist dispenses anti-nausea medication to their patient prior to administering chemotherapy or rheumatology patients with chronic diseases are forced to have their drugs administered at an infusion center by the health plan or PBM. The sponsors argue that policies which prevent physicians

from administering and dispensing drugs from their own inventory directly risk patient outcomes and safety by interfering with the ability to make same-day treatment adjustments. Furthermore, the sponsors note that forcing patients to travel to infusion centers to receive treatments risks patient safety and health outcomes since their physician is unable to monitor their reaction to the treatment. The sponsors continue that health plans that own PBMs and pharmacies are implementing these types of reimbursement policies to ensure that their own vertically integrated pharmacies and infusion centers receive their reimbursement dollars, keeping all payments within a tight loop for the parent company. The sponsors contend that these policies do not benefit the patient or the community physicians who provide care in underserved areas, such as rural communities.

4) **OPPOSITION.** The California Association of Health Plans (CAHP), Association of California Life and Health Insurance Companies (ACLHIC), and America's Health Insurance Plans (AHIP) oppose this bill, contending that it restricts health plans' ability to hold down drug costs for patients and purchasers of health care. The opposition states that pharmacy costs now represent over 24 cents out of every dollar of premium spent on health care. The opponents continue that health plans are constantly fighting for patients by developing innovative solutions to make prescription drugs more affordable. The opposition notes that one of these solutions is leveraging the use of lower-cost pharmacies – called specialty pharmacies – to safely distribute physician-administered drugs (sometimes referred to by providers as "white bagging" or "brown bagging"). The opposition argues that high drug costs are especially problematic with physician-administered drugs, where the problem of high manufacturer prices is compounded by exorbitant mark-ups by hospitals and physician' offices. An AHIP study analyzed the cost of ten drugs that are commonly and safely delivered through a specialty pharmacy for provider administration. For these ten drugs, the study found that on average, hospitals charged double the price (118% more) for the same drugs compared to specialty pharmacies while physician offices charged an average of 23% more than specialty pharmacies. The opponents further argue that specialty pharmacies protect patient safety and offer greater value and affordability. CAHP, ACLHIC, and AHIP conclude that this bill will increase the financial burden on purchasers of health care and ultimately, will raise health care costs for all residents.

5) **PREVIOUS LEGISLATION.** SB 958 (Limon) would have restricted the ability of health plans/insurers, or their designated medical groups or PBMs, from requiring or incentivizing patients to have infused or injected medications supplied by a vendor to the patient, or to the patient's physician office, clinic, infusion center, or hospital outpatient department, rather than maintained at the location where the infused or injected medication will be administered. SB 958 was not set for a hearing in the Assembly Health Committee.

6) **PROPOSED AMENDMENTS.** The committee and author have agreed on amendments to do the following:

   a) Clarify that the provisions of this bill apply only to in-network providers, contracted services, and covered prescriptions;

   b) Require a health care provider to determine that it is medically necessary, as defined in existing law, in order to directly administer the injected or infused medication or send a patient to a specified pharmacy or facility, if such administration, facility or pharmacy is different than where the health plan, insurer, or PBM has directed the patient;

c) Require a health care provider, physician's office, clinic, or infusion center to obtain consent from the patient and disclose a good faith estimate of the enrollee's applicable cost-sharing amount in order to directly administer the injected or infused medication or send a patient to a specified facility or pharmacy, if such administration, facility, or pharmacy is different than where the health plan, insurer, or PBM has directed the patient;

d) Clarify that all dispensing must be complaint with existing Business and Professions Code requirements;

e) Clarify that the provisions of this bill do not apply to hospital outpatient facilities; and,

f) Align the definition of PBM with the existing definition in current law.

REGISTERED SUPPORT / OPPOSITION:

Support

Association of Northern California Oncologists (co-sponsor)
California Rheumatology Alliance (co-sponsor)
Medical Oncology Association of Southern California (co-sponsor)
American College of Obstetricians & Gynecologists - District IX
American Diabetes Association
Association for Clinical Oncology
California Chronic Care Coalition
California Medical Association (CMA)
California Podiatric Medical Association
California Retired Teachers Association
Center for Cancer and Blood Disorders
Central Coast Oncology & Hematology
Hemophilia Council of California
Infusion Access Foundation
National Infusion Center Association (NICA)
One individual

Opposition

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

Analysis Prepared by: Riana King / HEALTH / (916) 319-2097

Date of Hearing: April 29, 2025

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 585 (Patterson) – As Introduced February 12, 2025

SUBJECT: Electronic death registration system.

SUMMARY: Requires the State Registrar to use updated technology, including computer and mobile telephone applications, to upgrade its internet-based electronic death registration system (EDRS) for the creation, storage, and transfer of death registration information. Requires that specified individuals, including a physician, medical examiner, and local registrar, have the ability to access the electronic death registration system in addition to the individuals currently responsible for completing a certificate of death.

EXISTING LAW:

1) Requires that each death be registered with the local registrar of births and deaths in the district in which the death was officially pronounced or the body was found. [Health and Safety Code (HSC) § 102775]

2) Requires the State Department of Public Health (DPH) to implement an internet-based electronic death registration system for the creation, storage, and transfer of death registration information. [HSC § 102778]

3) Authorizes the State Registrar, at their discretion, to incorporate computer or telephone facsimile technology, or both, in the statewide program of death and fetal death registration, including, but not limited to, the issuing of permits for disposition of human remains. [HSC § 102785]

4) Allows local districts to file certificates of death and fetal death manually within the local registration districts. [HSC § 102785]

5) Requires a funeral director, or person acting in lieu thereof, to prepare the certificate and register it with the local registrar. [HSC § 102780]

6) Requires the funeral director to obtain the required information other than medical and health section data from the person or source best qualified to supply this information. [HSC § 102790]

7) Requires that the medical and health section data and the time of death be completed and attested to by the physician and surgeon last in attendance or, in the case of a patient in a skilled nursing or intermediate care facility, by the physician and surgeon last in attendance, by a licensed physician assistant meeting certain qualifications. Requires the coroner to complete the medical and health section data and certify and attest to these facts in certain cases. [HSC § 102795]

8) Requires DPH to access data within the EDRS to compile a report on veteran suicide in California. [HSC § 102791]

9) Requires DPH to access data within the EDRS to compile a report on veteran drug overdose deaths in California. [HSC § 102792]

10) Requires the medical and health section data and the physician's or coroner's certification to be completed by the attending physician within 15 hours after the death, or by the coroner within three days after examination of the body. Requires the physician within 15 hours after the death to deposit the certificate at the place of death, or deliver it to the attending funeral director at his or her place of business or at the office of the physician. [HSC § 102800]

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

COMMENTS:

1) **PURPOSE OF THIS BILL.** According to the author, after 20 years without updates, this bill will modernize the electronic death registration system by incorporating mobile and computer applications and expanding access to additional professionals, such as physicians, medical examiners, and local registrars, to enhance efficiency and accuracy.

2) **BACKGROUND.**

   a) **Background on EDRS.** The State Registrar (SR) is responsible for registering each live birth, death, fetal death, and marriage that occurs in California, and for providing certified copies of vital records to the public. State law requires the State Registrar to permanently preserve vital records in a systematic manner and to prepare and maintain a comprehensive and continuous index of all registered certificates.

   The California Integrated Vital Records System (Cal-IVRS) includes the Electronic Birth Registration System (EBRS), the Electronic Death Registration System (EDRS), and the Vital Records Business Intelligence System (VRBIS).

   EBRS and EDRS are secure, web-based electronic birth and death registration databases that enable record preparers to enter certificate data into the registration database and electronically submit completed records to the local registrar to be registered. Once records are registered in EBRS and EDRS, record data are transmitted to VRBIS. VRBIS is a secure, web-based electronic solution for the SR to store California's vital records data and to permit local health departments and others to access such data for purposes allowed under California statute, such as epidemiologic analysis, surveillance, and program evaluation.

   The University of California, San Diego (UCSD) is contracted by the DPH Center for Health Statistics and Informatics (CHSI) to provide regular maintenance and operations functions and scheduled system enhancements for functionality and efficiency to Cal-IVRS as defined in an Inter-Agency Agreement (IAA). The CHSI Informatics Branch-Cal-IVRS Section (IBCS) collaborates with UCSD on Cal-IVRS maintenance and enhancement activities including management of versioning schedules, facilitation of requirements gathering, coordination of CHSI and stakeholder User Acceptance Testing (UAT), and assisting with training, communications, and outreach.

   In a recent press release by UCSD announcing the renewal of the contract for Cal-IVRS through June 2027, UCSD notes that Cal-IVRS brings the birth, death, and fetal death

vital records under one umbrella. The system facilitates the secure submission and processing of vital records by local registrars, hospitals, and other entities involved in vital statistics.

Cal-IVRS platform is used for data collection and legal certificate issuance for approximately 500,000 births, 240,000 deaths, and 5,000 fetal deaths annually in California. Hosted at UC San Diego Health's data center and operated by the UC San Diego Cal-IVRS team, the system boasts 99.98% uptime and serves 6,000 daily users across 61 registration districts, 58 coroner offices, 450 hospitals, and over 1,000 funeral homes in California. Around 80,000 physicians are able to access the remote attestation modes—Fax and Voice—for the purpose of reviewing and attesting certificates.

b) Recent Updates to Cal-IVRS. In recent years, legislation has been enacted mandating changes to Cal-IVRS. Some examples include AB 959 (Chiu, Chapter 565, Statutes of 2015) requiring the addition of sexual orientation and gender identity data collection; AB 1726 (Bonta, Chapter 607, Statutes of 2016) requiring the addition of new Asian and Pacific Islander race categories; AB 218 (Ward, Chapter 577, Statutes of 2021) requiring the collection of sex at birth, and AB 2176 (Wood, Chapter 34, Statutes of 2022) changing the requirement for local registration of births from 10 to 21 days. These legislative changes often result in required changes to vital records certificate templates, Cal-IVRS system user interfaces, user and reference documentation, multiple data file modifications including files shared with California counties and researchers as well as mandated files shared with the National Center for Health Statistics and the Social Security Administration, and frequently require user training and outreach.

c) What does this bill do? This bill requires, in addition to the individuals currently responsible for completing a certificate of death and the required contents in existing law, EDRS to be accessible by health care providers, including physicians, medical examiners, and local registrars. This bill would also require DPH to use upgraded technology, including computer and mobile applications, to upgrade EDRS.

d) The EDRS process. According to information provided by the California Funeral Directors Association (CDFA), the sponsor of the bill, the current system requires the funeral director to fax a worksheet to the doctor to establish the cause of death even before beginning the EDRS process. Afterward, the funeral director begins the EDRS process by sending the decedent's vital statistics to the local department of public health. The funeral director cannot fill out the cause of death until the doctor completes and returns a worksheet to delineate the cause of the death. The sponsor states that currently, the doctor cannot insert the cause of death directly into EDRS, they may only attest to it once the funeral director has completed it. Once the funeral director completes the death certificate and the doctor attests to it, the funeral director submits it to the local department of public health for acceptance. If the cause of death is not accepted, the funeral director must go back to the doctor to more clearly delineate a cause of death. Errors may occur when a funeral director misinterprets what the doctor put on the aforementioned worksheet, contributing to delays. The sponsor continues that with the funeral director acting as a conduit, the doctor and registrar will agree on the cause of death. Once completed, the doctor may sign it electronically. Afterward, the funeral director may provide copies of death certificates to the family for use in submitting

claims and closing out accounts and obtain a Disposition Permit allowing the disposition of the body and funeral services to take place.

CDFA highlights that while physicians are able to access the remote attestation modes within EDRS, they are not able to directly fill in the cause of death. The sponsor contends that this bill would allow the physician immediate access to EDRS without the funeral director acting as an intermediary, making the EDRS process faster and more efficient.

According to information provided by DPH, medical examiners, coroners, hospital staff (including physicians) and local registrar staff currently have the ability to work directly in the Electronic Death Registration System (EDRS). Medical examiners, coroners and physicians are able to enter causes of death directly in EDRS if they have one of three types of user accounts to input cause of death data: Funeral home user; Hospital user; or, medical examiner/coroner (MEC) user.

DPH notes that physicians may request access to EDRS as a "hospital user." A "hospital user" account allows the user to initiate a record to enter personal and health information about a decedent including establishing the facts of a death. The "hospital user" account does not allow for attestation. The attestation process for physicians is performed via fax and voice methods, which is outside the system. Physicians are not set up to attest within EDRS electronically nor is there a statutory mandate for physicians or hospitals to start the record. DPH notes that often, hospitals leave it up to the funeral homes to do so. DPH continues that while medical examiners and coroners (MECs) have access to EDRS and attest to the death through the system, physicians cannot attest to a death in EDRS. DPH notes that physicians currently go through funeral directors or hospital staff to provide causes of death. DPH continues that having access to EDRS would not change the way a physician would be able to attest to the record. Physicians would still only be able to complete attestation via voice or fax.

e) **Upgraded Technology.** This bill requires DPH to use upgraded technology, including computer and mobile telephone applications, to update EDRS. DPH notes that it is in the process of continuing efforts of updating and improving EDRS over the next few years. Some of these planned updates include: reducing the number of steps required for state registration; adding new front-end validations of data entered in the system; and, adding a user notification system. DPH first transitioned from a paper death registration workflow to an electronic registration process in 2005. Since then, DPH has made continuous updates to the system including a major upgrade of EDRS in 2021. This version of EDRS modernized the user interface and infrastructure of the platform to bring it into alignment with the more up-to-date birth registration system.

f) **Importance of timely access to death certificates.** Death certificates are official documents that legally establish the occurrence of death and record the details surrounding an individual's death within the state. According to CA.gov, a certified copy of a death certificate can typically be used to obtain death benefits, claim insurance proceeds, notify social security, and other legal purposes. Death certificates are also used as a source of state and national mortality statistics used to understand trends of disease and mortality. For instance, recently enacted legislation requires DPH to access EDRS data to report on veteran suicide and veteran drug overdose in California.

3) **SUPPORT.** CDFA is the sponsor of the bill and states that since the implementation of EDRS in 2005 by DPH, EDRS has remained unchanged for 20 years. CDFA continues that other states with similar systems have upgraded to new systems such as Washington and New York. CDFA notes that the current system requires funeral directors to fax a worksheet to a physician to establish cause of death even before EDRS is touched. CDFA states that there is no regulation on how to get the information from the physician. CDFA states that delays in the system mean that the families of the deceased individual cannot have their services until this process is completed. CDFA contends that further delays in the system obviously results in greater grief for the families. CDFA states that this bill allows physicians, medical examiners, and local registrars to access EDRS along with the individuals currently responsible for completing a certificate of death. CDFA further notes that this bill allows EDRS to be more efficient, faster, with less errors for everyone involved by allowing the physician to submit the cause of death directly to the health registrar though immediate access to EDRS. CDFA further states that this bill updates technology used by CA-EDRS as technology improves. CDFA continues that by allowing physicians to submit the cause of death directly to CA-EDRS, there is no need for funeral directors to act as an intermediary. This is a tremendous burden taken off funeral directors and avoids misinterpretation between physicians and directors. CDFA concludes that this bill is a commonsense bill to update an out-of-date system.

4) **RELATED LEGISLATION.** AB 583 (Pellerin) authorizes the medical and health section data and the time of death on a death certificate to be completed and attested to by a licensed nurse practitioner. AB 583 passed the Assembly Health Committee on April 1, 2025 with a vote of 15-0.

5) **PREVIOUS LEGISLATION.**

   a) AB 1462 (Patterson), Chapter 844, Statutes of 2023 requires DPH to access data within EDRS to compile a report on veteran drug overdose deaths in California. Requires the report to include, but not be limited to, information on the ages, sexes, races or ethnicities, counties of residence, and drug or drugs causing overdose deaths of veterans. Requires DPH to annually provide the report to the Legislature and the Department of Veterans Affairs by March 15 of each year.

   b) AB 2176 changes the requirement for local registration of births from 10 to 21 days.

   c) AB 2436 (Bauer-Kahan), Chapter 966, Statutes of 2022 requires the certificate of death to include the current first and middle names, birth last names, and the birthplaces of the parents, without reference to the parents' gendered relationship to the decedent. Requires the SR to electronically capture information on the parents' relationship to the decedent and any additional last names used by the parents, which would not be transcribed onto the actual hard copy of the death certificate.

   d) AB 218 (Ward), Chapter 577, Statutes of 2021 allows a person to obtain an amendment to the following vital records, to reflect the person's change of gender and sex identifier to female, male, or nonbinary; marriage license and certificate; confidential marriage license and certificate; birth certificate for their minor or adult child.

   e) AB 3371 (Committee on Veterans Affairs), Chapter 77, Statutes of 2020 requires DPH to access data within the EDRS to compile a report on veteran suicide in California.

Requires the report to include, but not be limited to, information on the ages, sexes, races or ethnicities, counties of residence, and methods of suicide of veterans. Requires DPH to annually provide the report to the Legislature and the Department of Veterans Affairs by March 15 of each year.

f) AB 1726 (Bonta), Chapter 607, Statutes of 2016 requires DPH to use the additional separate collection categories and other tabulations for specified Asian groups and Pacific Islander groups.

g) AB 959 (Chiu), Chapter 565, Statutes of 2015 requires DPH, the Department of Health Care Services, the Department of Social Services, and the Department of Aging to include sexual orientation and gender identity data when collecting client demographic data.

6) **POLICY COMMENT**. This bill seeks to provide healthcare providers, including physicians, medical examiners, and local registrars access to EDRS. DPH notes that medical examiners, physicians, and local registrars are able access EDRS directly. Of key concern to the author and sponsor is the ability for a physician to enter the cause of death directly into EDRS, rather than going through the funeral director, which appears to be allowable under a hospital user account. The author and sponsor may wish to more clearly identify what barriers to access EDRS exist for medical examiners, physicians, and local registrars and to work with DPH to determine the best course of action to address these barriers. The author may also wish to specify the reference to health care providers and align the definition to refer to individuals who are authorized to complete the medical and health section data and time of death, as is specified in HSC § 102795.

REGISTERED SUPPORT / OPPOSITION:

Support

California Funeral Directors Association

Opposition

None on file

Analysis Prepared by: Eliza Brooks / HEALTH / (916) 319-2097

Date of Hearing: April 29, 2025

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 682 (Ortega) – As Introduced February 14, 2025

SUBJECT: Health care coverage reporting.

SUMMARY: Requires a health plan or health insurer, as part of existing reporting to the Department of Managed Health Care (DMHC) and Department of Insurance (CDI), to include claim related information. Requires DMHC and CDI to publish monthly claims denial information for each plan or insurer. Specifically, **this bill**:

1) Requires health plans or health insurers, as part of financial statements reported to DMHC or annual reporting to CDI, to include the following information for each month:
    a) The number of claims processed or adjudicated;
    b) The number of claims denied or partially denied;
    c) The total cost of claims denied or partially denied;
    d) The number of in-network claims denied or partially denied;
    e) The number of prior authorization requests denied or partially denied;
    f) The number of claims denied or partially denied, disaggregated by each of the following reasons:
        i) Out-of-network provider;
        ii) Excluded service;
        iii) Lack of prior authorization or referral;
        iv) Medical necessity reasons;
        v) Experimental or investigational treatment;
        vi) Lack of efficacy;
        vii) Medical records not provided or insufficient information;
        viii) Patient ineligibility or coverage rule;
        ix) Lack of timely filing; and,
        x) Any other reason DMHC or CDI prescribe.
    g) The number of internal appeals or grievances filed or processed;

h) The number of claims denied or partially denied that were overturned through internal appeals or grievances processes;

i) The number of external appeals or grievances filed;

j) The number of claims denied or partially denied that were overturned through external appeals or grievances processes; and,

k) The number of claims denied or partially denied that at any point were processed, adjudicated, or reviewed with artificial intelligence or other predictive algorithms.

2) Requires DMHC and CDI to publish monthly claims denial information to their websites.

EXISTING LAW:

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

2) Requires health plans to submit financial statements to DMHC at specified times. Requires health insurers to annually report specified information to CDI. [HSC § 1384 and INS § 10127.19]

3) Requires the criteria or guidelines used by health plans and insurers, or any entities with which plans or insurers contract for utilization review (UR) or utilization management (UM) functions, to determine whether to authorize, modify, or deny health care services to:

a) Be developed with involvement from actively practicing health care providers;

b) Be consistent with sound clinical principles and processes;

c) Be evaluated, and updated if necessary, at least annually;

d) If used as the basis of a decision to modify, delay, or deny services in a specified case under review, be disclosed to the provider and the enrollee or insured in that specified case; and,

e) Be available to the public upon request. [HSC § 1363.5 and INS § 10123.135]

4) Requires health plans to demonstrate that medical decisions are rendered by qualified medical providers, unhindered by fiscal and administrative management. [HSC § 1367]

5) Requires health plans and disability insurers and any contracted entity that performs UR or UM functions, prospectively, retrospectively, or concurrently, based on medical necessity requests to comply with specified requirements. [HSC § 1367.01 and INS § 10123.135]

6) Prohibits any individual, other than a licensed physician or a licensed health care professional who is competent to evaluate the specific clinical issues involved in the health care services requested by the provider, from denying or modifying requests for authorization of health care services for an enrollee or insured for reasons of medical necessity. Requires the decision to be communicated to the provider within 24 hours of the decision, and the enrollee

(in writing) within two business days of the decision. Prohibits, in the case of concurrent review, discontinuance of care until the treating provider has been notified and has agreed to a care plan that is appropriate for the medical needs of the patient. [HSC § 1367.01 and INS § 10123.135]

7) Requires, if a health plan or health insurer that provides coverage for prescription drugs or a contracted physicians group fails to respond to a prior authorization, or step therapy exception request, as specified, within 72 hours for nonurgent requests, and within 24 hours if exigent circumstances exist, upon the receipt of a completed request form, that the request be deemed granted. [HSC § 1367.241 and INS § 10123.191]

8) Allows for appeal of a denial of an exception request for coverage of a nonformulary drug, prior authorization request, or step therapy exception request by filing an internal appeal pursuant to federal law and any subsequent rules or regulations issued thereunder. [INS § 10123.201]

9) Establishes, in DMHC and CDI, the Independent Medical Review System (IMR) which reviews disputed health care services that a plan, or one of its contracting entities, or insurer determines is not medically necessary or is experimental or investigational. [HSC §§ 1374.30 - 1374.36 and INS § 10169]

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

COMMENTS:

1) **PURPOSE OF THIS BILL.** According to the author, the health insurance system should provide relief, security, and fairness, not confusion, frustration, and denial. Yet the author argues that today, Californians face a bureaucratic labyrinth where unnecessarily complex processes discourage patients from pursuing the care they need. The author continues that too often insurance claim denials rob patients of life-saving treatments and timely healthcare. The author states that this bill mandates transparency and accountability. The author continues that by publicly disclosing detailed claim denial data, including reasons, outcomes of appeals, and frequency of denials, this bill empowers consumers to make informed choices and pressures insurance companies to compete fairly on quality of service, not just premiums and profit margins. The author argues that by providing data on the issue of claim denials, this bill would also empower lawmakers and stakeholders to create targeted interventions and sound public policy. The author concludes that this bill marks a vital advancement toward a healthcare system that prioritizes patient health, restores trust, and compels insurers to honor their commitments to patients.

2) **BACKGROUND.** UM and UR are processes used by health plans to evaluate and manage the use of health care services. UR can occur prospectively, retrospectively, or concurrently and a plan can approve, modify, delay or deny in whole or in part a request based on its medical necessity. Prior authorization is a UR technique used by health plans that requires patients to obtain approval of a service or medication before care is provided. Prior authorization is intended to allow plans to evaluate whether care that has been prescribed is medically necessary for purposes of coverage. Concurrent review occurs throughout the course of a patient's treatment. Concurrent review is intended to enable a plan to scrutinize the necessity for the plan, level, and setting of care while care is being delivered. Retrospective review occurs after care was delivered and after the bill for that care was

submitted. Retrospective review seeks to confirm that the care that was delivered was appropriate and provided at the most efficient and effective level.

a) **Overall impact of prior authorization.** Across state-regulated commercial plans and policies, 100% of enrollees are subject to some sort of prior authorization in their benefits. In 2023, the California Health Benefits Review Program (CHBRP) published a report to help the Legislature better understand the ways in which prior authorization is used in California. CHBRP noted that prior authorization is an imperfect instrument that's utilized in a myriad of ways. This poses a challenge for policymakers, payers, patients, and providers since prior authorization is generally intended to decrease costs and waste, but it may also contribute to delays in treatment and additional barriers to care. Currently, evidence is limited as to the extent to which health insurance uses prior authorization and its impact on the performance of the health care system, patient access to appropriate care, and the health and financial interests of the general public. Despite the limited evidence, there is clear frustration from both patients and providers regarding prior authorization practices. According to CHBRP, complaints range from the time required to complete the initial authorization request and pursue denials, to delays in care, to a general lack of transparency regarding the process and criteria used to evaluate prior authorization requests. CHBRP further notes that people with disabilities, younger patients, African Americans, and people with lower incomes are more likely to report administrative burdens, including delays in care, due to prior authorization.

b) **Claim denials and grievance and appeals under California law.** Under state law, if an enrollee's health plan denies, changes, or delays a request for medical services, denies payment for emergency treatment or refuses to cover experimental or investigational treatment for a serious medical condition, an enrollee can apply for an IMR. Before filing an IMR with the regulator, enrollees are first required to file a grievance with the health plan (absent an emergency). Once an enrollee has participated in the 30-day process with the health plan, if the issue has not been resolved or an enrollee is not satisfied with the decision, an enrollee can proceed with filing an IMR. According to CHBRP, a sizable share of prior authorization denials were overturned upon appeal, ranging from 40% to 82% of denials being overturned. This is consistent with overall appeals across the state. According to 2023 data, 72% of appeals made to DMHC resulted in a denial being reversed.

3) **SUPPORT.** The California Nurses Association (CNA), sponsor of this bill, states that by shining a light on harmful denial practices by health insurers, this bill would establish common sense requirements on the collection and reporting of information on the extent and reasoning behind health insurance denials. CNA continues that while patients and doctors report that health insurance denials are steadily on the rise, there are little to no requirements under state or federal law that insurers disclose and regulators publish data on health insurance denials. CNA notes that this bill would restore the public availability of information regarding the number of health insurance denials, which had been previously reported by DMHC, and would additionally require more robust reporting on the reasons why claims are denied, the time for appeals and denials to be processed, and other characteristics of denials. CNA argues that public transparency on health insurance denials is necessary for patients, researchers, and regulators to better understand the scope of the problem and to take well-informed action to address delays and denials in health care.

4) **SUPPORT IF AMENDED.** The California Chapter of the American College of Emergency Physicians (CACEP) would support this bill if it is amended to require the reporting of unpaid claims. CACEP states that in the last five years, there has been an increase in the non-payment of emergency claims. CACEP continues that health plans may only deny reimbursement for emergency services if the health care service plan had a good faith belief that the emergency services and care were never performed or when the enrollee reasonably should have known that an emergency did not exist. CACEP argues that existing law does not allow plans to simply not pay a claim when the service was performed, yet plans have been skirting that law. CACEP concludes that adding unpaid claims to the required reporting list, would allow for a greater assessment of the prevalence of this emerging issue.

   The California Optometric Association (COA) would also support this bill if amended to apply the bill to specialized health care service plans. COA states that while the Health and Safety Code provisions of this bill applies to "a plan or other person subject to this chapter" and therefore would apply to specialized health care service plans, the Insurance Code sections do not apply to all health insurers. COA requests that the exclusion in Insurance Code be deleted to require the reporting of vision only insurers.

5) **RELATED LEGISLATION.** SB 363 (Wiener) would require health plans and insurers to annually report to their regulator their total number of claims processed and treatment denials or modifications. SB 363 would make health plans and insurers liable for penalties for each independent medical review that is resolved in favor of the consumer in excess of 40% or for each failure to report a treatment denial or modification. SB 363 is currently pending in the Senate Appropriations Committee.

REGISTERED SUPPORT / OPPOSITION:

Support

California Nurses Association (sponsor)
California Chapter American College of Cardiology
California Hospital Association
California Society of Plastic Surgeons
Steinberg Institute
United Hospital Association

Opposition

None on file

Analysis Prepared by: Riana King / HEALTH / (916) 319-2097

Date of Hearing: April 29, 2025

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 725 (Solache) – As Introduced February 18, 2025

SUBJECT: Source plasma donation.

SUMMARY: Authorizes a person to operate a source plasma donation center for the purpose of collecting source plasma, as defined. Authorizes a source plasma donation center to offer payment to a donor of money or other valuable consideration. Requires the operator of a source plasma donation center to obtain a license from the State Department of Public Health (DPH), as specified. Authorizes DPH to regulate source plasma donation centers, including to inspect the property or records of the center and to suspend or revoke a license for violation of specified law or regulation. Authorizes DPH to promulgate any regulations it deems necessary to implement the bill's provisions. Specifically, **this bill**:

Donations

1) Authorizes, notwithstanding any other provision of law, a person to operate a source plasma donation center for the purpose of collecting source plasma if they are licensed under this bill and the source plasma is collected in accordance with this bill.

2) Exempts a source plasma donation center that is licensed pursuant to this bill is exempt from licensure as described in existing law 3) below.

3) Authorizes a source plasma donation center to offer payment to a donor of money or any other valuable consideration that can be converted to money by the recipient in return for the donation of source plasma.

4) Requires a source plasma donation center to require a donor of source plasma who receives payment in exchange for the donation of source plasma to provide photographic driver's license or other photographic identification that is issued by the Department of Motor Vehicles, or other acceptable identification issued by any other state or federal government agency, or tribal government, as specified in regulation.

5) Requires, before a donor donates source plasma for the first time, a source plasma donation center to do all of the following:

    a) Require the donor to complete a donor history questionnaire recognized by the United States Food and Drug Administration;

    b) Advise the donor of the risks and hazards of plasmapheresis and obtain informed consent from the donor;

    c) Notify the donor in writing and obtain a written statement confirming the notification that each donation will be tested for evidence of relevant transfusion-transmitted infections;

    d) Notify the donor in writing that the test results may result in the donor being deferred from future donations and being placed on the National Donor Deferral Registry; and,

e) Require a registered nurse to conduct a donor screening examination of the donor.

6) Requires a source plasma donation center to prominently display at each of its donation sites a notice that provides the addresses and telephone numbers of sites, within the proximate area of the source plasma donation center, where anonymous HIV antibody testing provided pursuant to existing law may be administered without charge.

7) Prohibits, notwithstanding any other provision of law, civil liability or criminal sanction from being imposed for disclosure of test results to a local health officer if the disclosure is necessary to locate and notify a plasma donor of a reactive result to HIV antibody testing if reasonable efforts by the source plasma donation center to locate the donor have failed.

8) Requires, upon completion of the local health officer's efforts to locate and notify a source plasma donor of a reactive result to HIV antibody testing, all records obtained from the source plasma donation center pursuant to this subdivision, or maintained pursuant to this subdivision, including, but not limited to, any individual identifying information or test results, to be expunged by the local health officer.

9) Prohibits, notwithstanding existing law 8) below, or any other provision of law, any public entity or any private source plasma donation center from being liable for an inadvertent, accidental, or otherwise unintentional disclosure of the results of an HIV test.

10) Provides that a "public entity" includes, but is not limited to, any publicly owned or operated source plasma donation center, local health officer, and DPH.

11) Prohibits DPH or any source plasma donation center, including a source plasma donation center owned or operated by a public entity or a local health officer, from being held liable for any damage resulting from the disclosure of test results obtained pursuant to 6) above.

12) Provides that the procurement, processing, distribution, or use of source plasma is the provision of a service by a person, firm, or corporation rather than a sale of source plasma.

Administration of Source Plasma Donation Centers

13) Authorizes, notwithstanding any other law, personnel who are explicitly authorized by the source plasma donation center and who meet the education, training, and competency standards of the source plasma donation center to obtain a predonation health history and perform predonation screening, including nondiagnostic general health assessments for which blood collection is performed by skin puncture.

14) Requires when unlicensed personnel perform the duties described in 13) above, the review of work required by federal regulations described in 27) and 28) of existing law below to be performed by a staff member who is a licensed health care professional.

15) Requires, notwithstanding any other law, a licensed clinical laboratory bioanalyst, a licensed clinical laboratory technologist, a registered clinical laboratory technologist trainee, a licensed vocational nurse, a registered nurse, a blood donor phlebotomist, as defined by the American Association of Blood Banks, or a source plasma donor phlebotomist may perform skin puncture and venipuncture for the purposes of collecting human source plasma.

16) Requires the actions described in 13) and 15) above to be performed under both of the following conditions:

    a) In a source plasma donation center licensed pursuant to this chapter and according to standard operating procedures approved by the United States Food and Drug Administration.

    b) Under the general supervision of a licensed physician and surgeon. Requires the licensing and registration to be pursuant to the Business and Professions Code.

    c) Authorizes, notwithstanding 14) above, source plasma to be collected at a source plasma donation center when a physician or surgeon is not physically present on the premises. Authorizes the physician and surgeon to delegate the general supervision duties to a registered nurse, but requires the physician and surgeon to remain responsible for ensuring that all those duties and responsibilities are properly performed.

17) Requires a source plasma donation center to have a medical director.

18) Requires, notwithstanding any other provision of law, the medical director to meet the definition in 47) b) below and be designated in the source plasma donation center license as the medical director.

19) Authorizes, notwithstanding any other provision of law, a source plasma donation center to employ a person to perform total protein tests using a digital refractometer pursuant to 19) of existing law below.

20) Exempts, notwithstanding any other provision of law, a source plasma donation center performing only a total protein test using a digital total protein refractometer classified as a moderate complexity test and performing no other test of a moderate or high complexity classification under the Clinical Laboratory Improvement Amendments in 29) of existing law below from licensure as a clinical laboratory.

21) Authorizes, notwithstanding any other provision of law, a person who has attained the age of 18 to consent to the donation of their source plasma and to the penetration of tissue necessary to accomplish a source plasma donation, and a licensed source plasma donation center may accept the donation and compensate the donor for the donation pursuant to 3) above.

22) Provides this bill does not repeal or in any manner affect any provision of the Business and Professions Code (BPC) relating to the practice of medicine.

Licenses

23) Requires DPH develop a form for the application for a source plasma donation center license issued pursuant to this chapter. Requires the form to contain, at a minimum, all of the following:

    a) The name and address of the person owning the place, establishment, or institution in which source plasma donation or production is planned;

    b) The name and address of the medical director who will be in charge of the production of source plasma;

c) A full description of the building, its location, facilities, equipment, and apparatus to be used in source plasma production;

d) The name and address of each source plasma donation center operated by the applicant within this state; and,

e) Any additional information as DPH may require by regulation.

24) Requires, if DPH does not, within 60 days after the filing of the application, issue a license, DPH to state the specific grounds and reasons for its refusal in writing and serve a copy upon the applicant. Requires, if DPH does not issue its written refusal of the application for the license within this period, the application to be deemed approved and a license issued following expiration of the 60-day application review period. Authorizes the notice of refusal to be served by registered mail addressed to the applicant at their last known address.

25) Provides that a license is subject to revocation of the license if there is a change of address, ownership, or the person in charge of source plasma production.

26) Authorizes a licensee to request an amendment of an existing license for a change of medical director of the source plasma donation center if the request is submitted within 30 days of the change of address, ownership, or the person in charge and the proposed change is in compliance with all the provisions of this chapter.

27) Requires, in the event the medical director of a source plasma donation center disassociates from the licensed source plasma donation center, the licensee to, within 24 hours of the date of the disassociation, notify DPH in writing of the disassociation.

28) Requires the licensee replace the medical director within 45 days.

29) Requires, in order to replace the medical director, the licensee to file an application for amendment of the existing license in the manner prescribed by DPH designating the new medical director.

30) Requires, upon failure of the licensee to submit an application to DPH naming the new medical director within 45 days of the disassociation date of the former medical director, the license for the source plasma donation center to be automatically revoked.

31) Authorizes a new license to be secured for a new location, owner, or person in charge prior to the actual change if the contemplated change is in compliance with all the provisions of this chapter and relevant regulations.

32) Authorizes license to be denied for any reason applicable to the revocation and suspension of licenses.

33) Requires proceedings for the denial of a license or a license amendment to be conducted in accordance with 7) of existing law below.

34) Requires each application for a license, a license amendment, or a license renewal pursuant to this chapter to be accompanied by a fee determined by the director in regulation and in an amount sufficient to cover the reasonable cost of administering this chapter, but not to exceed those costs, as specified pursuant to Section 1633.4.

35) Requires DPH to receive and account for all moneys received pursuant to this chapter and deposit them with the State Treasurer for deposit in the Clinical Laboratory Improvement Fund established pursuant to 14) of existing law below.

36) Requires all funds received pursuant to this chapter to, be expended to administer this chapter, upon appropriation by the Legislature.

37) Requires each license issued under this chapter to expire 24 months from the date of its issuance. Application for renewal of license accompanied by the fee to be filed with DPH not less than 10 days prior to its expiration. Requires failure to make a timely renewal to result in expiration of the license.

38) Clarifies that source plasma collection centers are not blood bank depositories pursuant to 15) of existing law below.

Enforcement

39) Requires DPH to implement the provisions of this bill.

40) Authorizes, in order to carry out this chapter, a duly authorized representative of the DPH to do any of the following:

    a) Enter or inspect on an announced or unannounced basis any building, premise, equipment, materials, records, or information at any reasonable time to secure compliance with, or prevent a violation of, this bill or the regulations adopted pursuant to this bill.

    b) Inspect, photograph, or copy any records, reports, test results, test specimens, or other information related to the requirements of this chapter or the regulations adopted pursuant to this chapter.

    c) Secure any sample, photograph, or other evidence from any building or premise for the purpose of enforcing this chapter or the regulations adopted pursuant to this bill.

41) Requires a license to be suspended or revoked by DPH for the violation of any provision of this bill, or of any rule or regulation made by DPH adopted pursuant to this chapter. The proceedings shall be conducted in accordance with 7) of existing law below.

42) Authorizes a district or city attorney to prosecute a violation of this chapter upon evidence of a violation within their respective jurisdictions submitted by DPH.

43) States the intent of the Legislature that this chapter does not conflict with the Sherman Food, Drug, and Cosmetic Law. All provisions of that division to apply to source plasma within the meaning of this bill.

44) States that this bill does not apply to products of either of the following:

    a) A laboratory licensed by the Public Health Service, Department of Health and Human Services.

b) A laboratory licensed by the Animal and Plant Health Inspection Service, United States Department of Agriculture.

45) Provides that the violation of any provision of this bill is a misdemeanor punishable by a fine of not less than one hundred dollars ($100) nor more than one thousand dollars ($1,000), or by imprisonment for not more than 30 days, or by both.

46) Authorizes DPH may promulgate any regulations it deems necessary to implement this chapter.

Definitions

47) Defines the following for purposes of the bill:

a) "Department" to mean DPH.

b) "Medical director" to mean the California licensed physician and surgeon designated by the licensee to direct and control personnel and relevant procedures concerning the determination of donor eligibility, collection of source plasma, the immunization of a donor, and the return of red blood cells or other blood components to the donor during collection of source plasma by plasmapheresis.

c) "National Donor Deferral Registry" to mean the database of deferred plasma donors in North America owned by the Plasma Protein Therapeutics Association.

d) "Person" to mean any individual, blood bank, source plasma donation center, hospital, firm, corporation, or any other entity.

e) "Plasmapheresis" to mean a procedure in which, during a single visit to a source plasma donation center, blood is removed from a donor, the plasma separated from the formed elements, and at least the red blood cells are returned to the donor.

f) "Source plasma" to mean the fluid portion of human blood collected by plasmapheresis that is intended as source material for further manufacturing use. Specifies that "Source plasma" does not mean single donor plasma products intended for intravenous use.

g) "Source plasma donation center" to mean a facility, other than a licensed blood bank, where source plasma is collected by plasmapheresis.

h) "Source plasma donor phlebotomist" to mean a suitably qualified individual who has received appropriate training on venipuncture, blood sample collection, and collection of source plasma via automated plasmapheresis which has been approved by the medical director of the donation center.

Fees

48) Requires source plasma donation centers to pay fees to the Clinical Laboratory Improvement Fund, which is established within the State Treasury.

EXISTING LAW:

State Law

1) Defines "blood bank" to mean any place where human whole blood, and human whole blood derivatives specified by regulation, are collected, prepared, tested, processed, or stored, or from which human whole blood or human whole blood derivatives specified by regulation are distributed. [Health and Safety Code (HSC) § 1600.2]

2) Defines "blood collection center" to mean a stationary auxiliary to a blood bank which is designed, equipped, and staffed to procure human whole blood or blood components which are to be transported to the blood bank for processing, storing, and distribution. [HSC § 1600.21]

3) Provides for the licensure of the place, establish, or establishment in which biologics production is planned and requires the application for licenses to contain at least the following:

    a) The name and address of the person owning the place, establishment, or institution in which biologics production is planned;

    b) The name and address of the person to be in charge of biologics production;

    c) The types of biologics to be produced;

    d) A full description of the building, its location, facilities, equipment, and apparatus to be used in biologics production;

    e) The name and address of each blood collection center operated by the applicant and whether the applicant operates any mobile units; and,

    f) Any additional information as the department may require. [HSC § 1613]

4) Requires, if DPH does not within 60 days after the filing of the application issue a license, it shall state the grounds and reasons for its refusal in writing, serving a copy upon the applicant. Authorizes the notice to be served by registered mail addressed to the applicant at their last known address. [HSC § 1614]

5) Requires a license to be automatically revoked when there is a change of address, ownership, or person in charge of biologics production. Authorizes a new license to be secured for the new location, owner, or person in charge prior to the actual change if the contemplated change is in compliance with all the provisions of this chapter and regulations pertaining thereto. [HSC § 1615]

6) Requires proceedings for denial of license to be conducted in accordance with existing law below. [HSC § 1615]

7) Establishes, notwithstanding any other provision of law, procedures for proceedings that take place, whenever DPH is authorized or required by statute, regulation, due process, or a contract, to conduct an adjudicative hearing leading to a final decision of the director or DPH, as specified. [HSC § 100171]

8) Prohibits an individual from being compelled in any state, county, city, or other local civil, criminal, administrative, legislative, or other proceedings to identify or provide identifying characteristics that would identify any individual who is the subject of an HIV test, as specified. [HSC § 120975]

9) Requires the director of DPH to, in order to protect the public health and in order to make blood and blood components safe for transfusion, to designate counties that are required to establish alternative testing sites, within the funds available. Authorizes, when designating a county, the director to consider whether the county contains a permanent operational blood bank. Requires all alternative test sites to be under the supervision of a physician and surgeon or be a clinic or health facility licensed by DPH, as provided. [HSC § 120895]

10) Requires each county, designated by the director, to make testing for the presence of antibodies of the causative agent of acquired immune deficiency syndrome (AIDS) available within its jurisdiction without charge, in an accessible manner. Requires the tests to be made available by the county on an anonymous basis through use of a coded system with no linking of individual identity with the test request or results. Requires the number and location of sites in each county designated by the director to be approved by the director. The test shall be made available by the county either directly or by contract with a physician and surgeon or with any clinic or health facility licensed by the department. Prohibits the county and anyone else administering the test from asking for the name, social security number, or any other information that could reveal the identity of the individual who takes the test. Each alternative test site shall make available confidential information and referral services, within the funds available, to individuals who seek testing. Authorizes a county to subcontract with individuals or entities to provide information and referral services. [HSC § 120895]

11) Requires DPH to develop and annually review, and if necessary revise, a standardized written summary which explains the advantages, disadvantages, risks, and descriptions of autologous blood, and directed and nondirected homologous blood from volunteer donors. [HSC § 1645]

12) Requires a person engaged in the production of human whole blood or human whole blood derivatives to be licensed by the state, and requires licensed blood banks and blood transfusion services to meet specified standards. [HSC § 1600, *et. seq*]

13) Authorizes DPH to establish and require compliance with additional requirements, as specified. [HSC § 1602.5]

14) Establishes the Clinical Laboratory Improvement Fund and requires specified fees collected from the licensing and regulation of blood banks and blood transfusion services to be deposited in the fund, available upon appropriation, for the purpose of regulating blood banks and blood transfusion services. [Business and Professions Code (BPC) § 1302]

15) Requires specified establishments that receive specified human whole blood and derivatives to be considered blood bank depositories and require specified procedures on blood for transfusion to be the sole responsibility of the blood bank depository. [HSC § 1605]

16) Defines “clinical laboratory bioanalyst” or “bioanalyst” means a person licensed to engage in clinical laboratory practice and direction of a clinical laboratory, as provided. [BPC § 1203]

17) Defines a "vocational nurse", to mean a person who has met all the legal requirements for a license as a vocational nurse in this state and who for compensation or personal profit engages in vocational nursing, as provided. [BPC § 2859]

18) Defines "the practice of nursing" to mean those functions, including basic health care, that help people cope with difficulties in daily living that are associated with their actual or potential health or illness problems or the treatment thereof, and that require a substantial amount of scientific knowledge or technical skill, as specified. [BPC § 2725]

19) Authorizes a person to perform a total protein test using a digital refractometer in a licensed plasma collection center if DPH as part of its routine, fee-supported inspection of the licensed plasma collection center, as specified, determines that the person has earned a high school diploma or equivalent as determined by the federal Centers for Medicare and Medicaid Services and the person has training sufficient to determine that the individual has the required skills and abilities, as provided. [BPC § 1246.7]

20) Requires blood bank or plasma center shall require as identification either a photographic driver's license or other photographic identification that is issued by the Department of Motor Vehicles, as specified, from all donors of human whole blood or blood components who receive payment in return for the donation of that blood or blood components. [HSC § 1603.2]

21) Defines "payment" means the transfer by a blood bank or plasma center to any person of money or any other valuable consideration that can be converted to money by the recipient, except that payment does not include any of the following: Cancellation or refund of the nonreplacement fees or related blood or blood components transfusion charges; blood assurance benefits to a person as a result of a blood or blood components donation to a donor club or blood assurance program; and, time away from employment granted by an employer to an employee in order to donate blood or blood components. [*Ibid*.]

22) Requires, before donation of blood or blood components, a donor to be notified in writing of, and to have signed a written statement confirming the notification of, all of the following:

    a) That the blood or blood components is required to be tested for evidence of antibodies to HIV;

    b) That the donor is required to be notified of the test results, as specified;

    c) That the donor blood or blood component that is found to have the antibodies is prohibited from being used for transfusion;

    d) That blood or blood components is prohibited from being donated for transfusion purposes by a person if the person may have reason to believe that he or she has been exposed to HIV or AIDS;

    e) That the donor is required to complete a health screening questionnaire to assist in the determination as to whether he or she may have been exposed to HIV or AIDS. [HSC § 1603.3]

23) Requires a blood bank or plasma center to incorporate voluntary means of self-deferral for donors. Authorizes the means of self-deferral to include, but not be limited to, a form with checkoff boxes specifying that the blood or blood components are for research or test purposes only and a telephone callback system for donors to use in order to inform the blood bank or plasma center that blood or blood components donated should not be used for transfusion. Requires the blood bank or plasma center to inform the donor, in a manner that is understandable to the donor, that the self-deferral process is available and should be used if the donor has reason to believe that he or she is infected with HIV. [HSC § 1604.6]

24) Establishes the Sherman Food, Drug, and Cosmetic Law governs the safety, effectiveness, manufacturing and labeling of food, drugs, medical devices, and cosmetics. [HSC § 109875, *et seq.*]

25) Prohibits, except as specified, blood or blood components from being used in vivo for humans in this state, unless the blood or blood components have been testing and found nonreactive for HIV or blood or blood components are used for research or vaccination programs pursuant to an informed consent. [HSC § 1603.1]

26) Requires blood banks and plasma centers requires to make laboratory tests of all human whole blood and blood components received to detect the presence of viral hepatitis and HIV in the manner specified in 22) above. Requires, if the blood bank or plasma center finds the presence of viral hepatitis, or an antigen thereof, in the blood or blood components tested, the blood bank or plasma center to report that finding, the date of the human whole blood or blood components donation, the name, address, and social security number of the person who donated the blood or blood components, and the name and address of the blood bank or plasma center that received the human whole blood or blood components from the person and any additional information required by DPH to the local health officer within 72 hours of the confirmation of the presence of viral hepatitis, or an antigen thereof, in the blood or blood components tested. [*Ibid.*]

Federal Law

27) Establishes requirements for the collection, processing, compatibility testing, storage, distribution of blood and blood components, as provided. [Title 21, Code of Federal Regulations (CFR) § 606]

28) Establishes the minimum current good manufacturing practice requirements for the preparation of drug products for administration to humans or animals. [Title 21, CFR § 211]

29) Establishes the Clinical Laboratory Improvement Amendments (CLIA) which include federal standards applicable to all United States facilities or sites that test human specimens for health assessment or to diagnose, prevent, or treat disease, as provided. [Title 42, United States Code § 263a]

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

COMMENTS:

1) **PURPOSE OF THIS BILL.** According to the author, the regulatory framework surrounding source plasma donation centers has not been updated since the 1990s despite significant

advancement in donation methods. The author continues that as a result, regulations no longer reflect current technology, creating unnecessary burdens in the way of patient care. The author states that these outdated laws restrict the availability of source plasma, which is necessary for producing plasma-derived therapies. The author continues that these therapies are essential for treating hundreds of thousands of people with rare and severe health conditions and are vital in critical-care settings. The author states that this bill aims to streamline the licensing process for source plasma donation centers and update current law to reflect current practice. The author concludes that ensuring that California can keep its place on the cutting-edge of developing and manufacturing life-saving treatments for patients across the state and around the world.

2) BACKGROUND.

a) What is plasma? According to Stanford Medicine Children's Health, plasma is the largest component of blood, making up about 55% of its content. Plasma carries water, salts and enzymes. Plasma also contains important components including antibodies, clotting factors, and the proteins albumin and fibrinogen. The main role of plasma is to take nutrients, hormones, and proteins to the parts of the body that need it. Cells also put their waste products into the plasma. The plasma then helps remove this waste from the body. Blood plasma also carries all parts of the blood through the circulatory system.

b) Therapeutic Uses of Plasma. According the University of Rochester, when individuals donate blood, healthcare providers can separate different components of the plasma, which can be concentrated into various products. These products are then used as treatments that can help save the lives of people suffering from burns, shock, trauma, and other medical emergencies. According to information provided by the sponsors, the use of medicine made from plasma is expected to continue to increase due to a growing number of diagnoses, easier access to care, and improved coverage of medicines. Use of plasma-derived therapies to treat primary immune deficiencies increased in the E.U. by 42% and in the U.S. by 67% from 2014 to 2020.

For instance, immune globulins (IGs) are gamma globulins purified from the plasma of human donors, containing primarily immune globulin G (IgG) as well as trace amounts of immune globulin A (IgA) and immune globulin M (IgM). IG products were first used in 1952 to treat immune deficiencies and later became an important treatment option in a variety of immune-related and inflammatory disease. A descriptive study titled, "*Assessment of Immune Globulin Utilization in Commercially insured and Medicare Populations*", reviewed temporal trends in IG use from 2009 to 2019 and found substantial increase in IG administrations overall, reflecting both an increase in individuals receiving IG and an increase in average annual administrations and dose per recipient.

c) How are source plasma donation centers currently regulated in California? DPH's Laboratory Field Services Biologics Program is responsible for license application review, approval, renewal, survey and investigation of: community blood banks and collection centers; hospital blood banks; blood and blood components collection centers; cord blood banks and collection entities; plasma collection centers; and, biologics processing and/or storage facilities.

Currently, source plasma donation centers are regulated as plasma collection centers. According to information provided by DPH, plasma collection centers operate under a blood bank license and a clinical laboratory license, both valid for one year.

Blood bank licensees must apply for a renewal of the license not less than 10 days prior to the license expiration date. Blood bank renewal applications require completing two forms and paying the fee. Clinical laboratory licensees have up to 60 days after the license expires to apply for renewal. The clinical laboratory license requires four to five forms and paying the fee. The renewal process looks for changes in personnel and operations. Some changes may require additional review or submission of documentation to ensure compliance with the law. If the facility simply maintains the operations which it was originally approved for, the renewal review is quick and straightforward. Plasma centers, due to their use of clinical laboratory testing, are subject to the federal CLIA requirement to hold a CLIA certificate. The CLIA certificate is valid for two years.

d) **How would this bill change how source plasma donation centers are regulated?** This bill creates a separate licensure category for source plasma donation centers. Further, this bill seems to seek alignment between the state license duration with that of the federal CLIA certificate.

Current law requires DPH, if DPH does not within 60 days after the filing of an application for a blood bank license issue the license, to state the grounds for its refusal in writing and serve a copy to the applicant. According to information provided by DPH, applications are reviewed within a few weeks for completeness. DPH verifies whether all required forms and documents have been submitted, are accurate, and meet state requirements. A more comprehensive review of the technical aspects of the application may take longer. In both cases, the applicant is informed if any forms are filled out incorrectly, required documents are missing, or additional information is required. Applicants are given several opportunities to rectify the application before it is considered abandoned, at which point they will need to reapply. Resolving a deficient application may take many months depending on the responsiveness of the applicant and DPH's caseload.

Denial of an application must be conducted according to existing law. Applicants denied a license have the right to appeal. This process involves a hearing in an administrative court and can take three years or more to resolve.

Existing law does not require the license to be automatically granted at the end of the 60 day period, whereas this bill does.

In terms of revocation, existing law states that a blood bank's license is required to be shall be automatically revoked when there is a change of address, ownership, or person in charge of biologics production. However, a new license may be secured for the new location, owner, or person in charge prior to the actual change if the contemplated change is in compliance with all the provisions of this chapter and regulations pertaining thereto.

Per regulations, the license is issued to individuals and requires that the building be ready for operations, and for the operation to be supervised by a competent person. Modifications in ownership or directorship directly impact the issuance of the license. According to information provided by DPH, when a new director is appointed, it requires

significant attention to whether a qualified individual will effectively oversee the health and safety of both donors and recipients. Additionally, relocating the facility prompts thorough assessment about the new site's adequacy of preparedness to sustain operations. Given the stringent regulations governing blood banks, aimed at safeguarding donor health and ensuring product safety, any change in the licensed individual providing the oversight would render the license invalid.

If DPH has concerns about the facility or its operations, it is the director and owners of the plasma collection center who are responsible for addressing them and DPH must have knowledge of the individuals on file.

Current law is strict, providing for automatic revocation when there is a change in ownership due to the consequences of improper processing or handling of the blood or blood products. This bill allows a source plasma donation center licensee to notify DPH within 24 hours of the disassociation and gives the center a 45-day deadline to file an amendment of the existing license in the manner described by the DPH designating the new medical director. Under this bill, if the source plasma donation center fails to designate a new medical director within 45 days, the license is to be automatically revoked.

In terms of the requirements for the medical director, state regulations require a blood bank to be under the direction of a physician and surgeon duly licensed by the State of California, and who shall have a minimum of six months experience in blood bank methods, transfusion principles, and transfusion practices, satisfactory to the department. State regulations define a blood bank as "a medical facility designed, equipped, and staffed to procure, to process, to store, or to distribute human whole blood or blood derivatives for transfusion purposes. The Plasma Protein Therapeutics Association (PPTA), the sponsor of this bill, contends that despite the fact that source plasma donation centers do not meet the definition of a blood bank (in that they do not collect whole blood or blood derivatives for transfusion purposes), they are currently being held to the experience requirements found in state regulations.

This bill defines the medical director for purposes of this bill to be a California licensed physician and surgeon designated by the licensee to direct and control personnel and relevant procedures concerning the determination of donor eligibility, collection of source plasma, the immunization of a donor, and the return of red blood cells or other blood components to the donor during collection of source plasma by plasmapheresis.

Currently, source plasma donation centers are required to hold a state clinical laboratory license. This bill exempts a source plasma donation center from licensure as a clinical laboratory if a source plasma donation center performing only a total protein test using a digital total protein refractometer classified as a moderate complexity test and performing no other test of a moderate or high complexity classification under CLIA.

e) **National Donor Deferral Registry.** This bill requires the licensed source plasma donation center to notify the donor in writing that test results from testing of transfusion-transmitted infections (which may include HIV, Hepatitis B or HBV, and Hepatitis C or HCV) may result in the donor being deferred from future donations and being placed on the National Donor Deferral Registry. The National Donor Deferral Registry is owned by the PPTA, the sponsor of this bill. According to PPTA, the NDDR is a database of donors

who test reactive for the viral agents for HIV, HBV, and HCV and are permanently prohibited from donating plasma at participating licensed and industry-certified centers in the U.S. and Canada. PPTA states that it is one of the voluntary, self-regulating initiatives taken by the plasma collection industry and is an important component of the industry-driven safety measures that help ensure the safety of the final therapies.

f) **Other States.** New York and Connecticut created unique licenses for source plasma donation centers recently. New York requires licensees to renew their licenses every two years, while Connecticut requires a source plasma collection center to biennially apply to renew its license during the 20th month, consistent with what it requires for blood collection facilities and clinical laboratories within the state.

3) **SUPPORT.** PPTA is the sponsor of this bill. PPTA states that this bill creates a separate section of the law in HSC to govern source plasma donation centers, where source plasma is donated for the purpose of manufacturing plasma-derived medicines. Source plasma is used to produce a number of life-saving PDMs that treat rare, chronic and life-threatening conditions. PDMs are used to treat shock, trauma, and burns. PPTA continues that the patient need for PDMs has steadily increased over the years. PPTA states that an expert panel of clinicians concluded it is imperative that the regulatory environment be improved to promote increased plasma donation. PPTA notes that California applies a mix of laws written for other entities (blood banks for transfusion, clinical labs, biologics manufacturers) to govern source plasma donation centers. PPTA continues that some of these laws are from a time when source plasma donation was a manual process. PPTA states the process has been automated since the 1990s. PPTA contends that the requirements for these entities limit source plasma donation because they unnecessarily require source plasma donation centers to meet requirements designed for different entities. PPTA notes that California licenses source plasma donation centers as clinical laboratories and biologics manufacturers. As a result, some PPTA members report they are audited three times by DPH and often by different people. PPTA concludes by stating that creating a unique licensure and legal category for source plasma donation centers could help streamline the DPH's inspections, audits, and resources.

4) **RELATED LEGISLATION.** ACR 43 (Pacheco) proclaims the month of March 2025 "Bleeding Disorders Awareness Month" in California and makes related findings and declarations.

5) **PREVIOUS LEGISLATION.** AB 392 (Nazarian), Chapter 429, Statutes of 2022 extends indefinitely the authorization for licensed plasma collection centers to utilize personnel, including unlicensed personnel, to perform a total protein test using a digital refractometer.

6) **SUGGESTED AMENDMENTS.** In order to provide for a comprehensive review of an applicant for a source plasma donation center license, the Committee may wish to consider to striking the requirement that a license be automatically granted within 60 days. In order to create parity with other blood banks and biologics licensees in the state, the Committee may wish to require renewal annually rather than every two years. The Committee may also wish to amend the bill to correct an incorrect cross-reference to the definition of "medical director" in the bill from HSC § 1631.1 to HSC § 1631. The Committee may also wish to delete an incorrect cross-reference to HSC § 1633.4, which does not exist. The Committee may wish to amend the bill to require, in the event that the medical director dissociates from

the licensed source plasma donation center, the source plasma donation center to identify a substitute medical director who meets the qualifications specified in 47) b) and notify DPH within 24 hours of the dissociation. Moving forward, the author may also wish to consider explicitly requiring testing to detect the presence of transfusion-related diseases such as viral hepatitis and HIV as is required in 25) of existing law.

REGISTERED SUPPORT / OPPOSITION:

Support

Plasma Protein Therapeutics Association (sponsor)
Aiarthritis
Bay Area Cancer Connections
California Chronic Care Coalition
California Life Sciences Association
Center for Inherited Blood Disorders
Grifols, Inc.
Hemophilia Council of California
Jeffrey Modell Foundation
Liver Coalition of San Diego
National Bleeding Disorders Foundation
Patient Advocates United in San Diego County
Rare Disease Access Coalition
Takeda Pharmaceuticals America

Opposition

None on file

Analysis Prepared by: Eliza Brooks / HEALTH / (916) 319-2097

Date of Hearing: April 29, 2025

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 849 (Soria) – As Amended April 21, 2025

SUBJECT: Health providers: medical chaperones.

SUMMARY: Requires, as of January 1, 2027, a health care provider that offers a sensitive examination, as defined, to provide notice to patients that a medical chaperone will be made available, upon request, to observe the examination. Specifically, **this bill**:

1) Requires a provider, as defined, that offers a sensitive examination to provide notice to patients that a medical chaperone will be made available upon a patient's request to observe the sensitive examination. Requires the notice to include either of the following:

    a) A hard copy provided to the patient, or their legal guardian, in person at a visit; or,

    b) An electronic transmission, including, but not limited to, a text message or email to the patient or their legal guardian prior to the visit.

2) Grants a patient the right to decline the inclusion of a medical chaperone during the sensitive examination. Specifies that if a patient does not request a medical chaperone, but the provider determines, for any reason, that a medical chaperone must be present, that the provider has the right to decline performing the sensitive examination in the absence of a medical chaperone.

3) Requires a provider that performs a sensitive examination to a patient receiving emergency services and care to, when feasible, inform the patient that a medical chaperone will be made available upon request to observe the sensitive examination.

4) Requires a provider to educate sonographers and clinical and nonclinical staff who may serve as a medical chaperone about appropriate observational and intervention techniques, how to properly drape a patient, the importance of neutrality, and reporting procedures for any inappropriate behaviors observed or communicated by the patient.

5) Requires a provider, if a patient requests a medical chaperone, to document the medical chaperone's presence in the patient's health record.

6) Makes the provisions of this bill operative on January 1, 2027.

7) Defines a "provider" to mean any of the following that delivers or furnishes health care services:

    a) A physician organization;

    b) A health facility, as described in 1) of existing law below;

    c) A clinic conducted, operated, or maintained as an outpatient department of a hospital;

    d) Additional clinics as defined in 2) of existing law below;

e) A specialty clinic, as described in 3) of existing law below;

f) An ambulatory surgical center or accredited outpatient setting;

g) A clinical laboratory licensed or registered with the State Department of Public Health (DPH); and,

h) An imaging facility that employs or contracts with persons that perform mammograms.

EXISTING LAW:

1) Establishes the Department of Public Health (DPH), which, among other functions, licenses and regulates health facilities. Defines a "health facility" to mean a facility, place, or building that is organized, maintained, and operated for the diagnosis, care, prevention, and treatment of human illness, physical or mental, including convalescence and rehabilitation and including care during and after pregnancy, or for any one or more of these purposes, for one or more persons, to which the persons are admitted for a 24-hour stay or longer, and includes the following types:

   a) General Acute Care Hospitals (GACHs), which means a health facility having a duly constituted governing body with overall administrative and professional responsibility and an organized medical staff that provides 24-hour inpatient care, including the following basic services: medical, nursing, surgical, anesthesia, laboratory, radiology, pharmacy, and dietary services;

   b) Acute psychiatric hospital, which means a health facility having a duly constituted governing body with overall administrative and professional responsibility and an organized medical staff that provides 24-hour inpatient care for persons with mental health disorders;

   c) Skilled nursing facility (SNF), which means a health facility that provides skilled nursing care and supportive care to patients whose primary need is for availability of skilled nursing care on an extended basis;

   d) Intermediate care facility (ICF), which means a health facility that provides inpatient care to ambulatory or non-ambulatory patients who have recurring need for skilled nursing supervision and need supportive care, but who do not require availability of continuous skilled nursing care;

   e) ICF/developmentally disabled habilitative, which means a facility with a capacity of four to 15 beds that provides 24-hour personal care, habilitation, developmental, and supportive health services to 15 or fewer persons with developmental disabilities who have intermittent recurring needs for nursing services, but have been certified by a physician and surgeon as not requiring availability of continuous skilled nursing care;

   f) Special hospital, which means a health facility having a duly constituted governing body with overall administrative and professional responsibility and an organized medical or dental staff that provides inpatient or outpatient care in dentistry or maternity (there are currently no licensed special hospitals in California);

g) ICF/developmentally disabled, which means a facility that provides 24-hour personal care, habilitation, developmental, and supportive health services to persons with developmental disabilities whose primary need is for developmental services and who have a recurring but intermittent need for skilled nursing services;

h) ICF/developmentally disabled-nursing, which means a facility with a capacity of four to 15 beds that provides 24-hour personal care, developmental services, and nursing supervision for persons with developmental disabilities who have intermittent recurring needs for skilled nursing care but have been certified by a physician and surgeon as not requiring continuous skilled nursing care;

i) Congregate living health facility, which means a residential home with a capacity of no more than 18 beds, that provides inpatient care, including the following basic services: medical supervision, 24-hour skilled nursing and supportive care, pharmacy, dietary, social, and recreational;

j) Correctional treatment center, which means a health facility operated by the Department of Corrections and Rehabilitation (DCR), the DCR Division of Juvenile Facilities, or a county, city, or city and county law enforcement agency that, as determined by DCR, provides inpatient health services to that portion of the inmate population who do not require a general acute care level of basic services;

k) Nursing facility, which means a health facility that is certified to participate as a provider of care either as a SNF in the federal Medicare Program or Medicaid Program, or both;

l) ICF/developmentally disabled-continuous nursing, which means a homelike facility with a capacity of four to eight, inclusive, beds that provides 24-hour personal care, developmental services, and nursing supervision for persons with developmental disabilities who have continuous needs for skilled nursing care and have been certified by a physician and surgeon as warranting continuous skilled nursing care; and,

m) Hospice facilities. [Health and Safety Code (HSC) § 1250 *et seq.*]

2) Defines specified clinics as follows:

a) A "community clinic" to means a clinic operated by a tax-exempt nonprofit corporation that is supported and maintained in whole or in part by donations, bequests, gifts, grants, government funds or contributions, that may be in the form of money, goods, or services. In a community clinic, any charges to the patient shall be based on the patient's ability to pay, utilizing a sliding fee scale; [HSC § 1204 (a) (1) (A)]

b) A "free clinic" to mean a clinic operated by a tax-exempt, nonprofit corporation supported in whole or in part by voluntary donations, bequests, gifts, grants, government funds or contributions, that may be in the form of money, goods, or services. Specifies that in a free clinic there will be no charges directly to the patient for services rendered or for drugs, medicines, appliances, or apparatuses furnished; and, [HSC § 1204 (a) (1) (B)]

c) A "medical foundation" clinic to mean a clinic operated by a nonprofit corporation exempt from federal income taxation under paragraph (3) of subsection (c) of Section 501 of the Internal Revenue Code of 1954 that conducts medical research and health

education and provides health care to its patients through a group of 40 or more physicians and surgeons, who are independent contractors representing not less than 10 board-certified specialties, and not less than two-thirds of whom practice on a full-time basis at the clinic. [HSC § 1206 (l)]

3) Defines specialty clinics as follows:

   a) A "surgical clinic" to mean a clinic that is not part of a hospital and that provides ambulatory surgical care for patients who remain less than 24 hours. A surgical clinic does not include any place or establishment owned or leased and operated as a clinic or office by one or more physicians or dentists in individual or group practice, regardless of the name used publicly to identify the place or establishment, provided, however, that physicians or dentists may, at their option, apply for licensure;

   b) A "chronic dialysis clinic" to mean a clinic that provides less than 24-hour care for the treatment of patients with end-stage renal disease, including renal dialysis services; and,

   c) A "rehabilitation clinic" means a clinic that, in addition to providing medical services directly, also provides physical rehabilitation services for patients who remain less than 24 hours. Requires rehabilitation clinics to provide at least two of the following rehabilitation services: physical therapy, occupational therapy, social, speech pathology, and audiology services. [HSC § 1204 (b)]

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

COMMENTS:

1) **PURPOSE OF THIS BILL.** According to the author, the medical sector has seen several recent high profile cases across the state of serial sexual abuse in hospitals where medical professionals have preyed on patients under the guise of providing medical care. Many hospitals utilize chaperones during sensitive examinations in an effort to protect patients, but policies can vary widely, and training of chaperones is not always to the highest standard required to protect patients. At Memorial Hospital Los Banos, an ultrasound technician allegedly abused at least ten women over the course of multiple years during sensitive examinations, with many abuses happening either during unchaperoned examinations, after the technician dismissed a chaperone, or with a chaperone present but uninvolved due to receiving no chaperone training.

   The author states that this bill creates a requirement that chaperones be provided for all sensitive ultrasound examinations, unless the patient (and not the technician) opts out. The bill also requires documented training of chaperones on how to identify and intervene to halt any improper actions. The author concludes that through these requirements, this bill provides for patient safety in places of healing, and ensures that the relationship between patients and medical providers is one of trust and transparency during the most vulnerable and sensitive medical examinations.

2) **BACKGROUND.**

   a) Sensitive Exams. According to the University of California Los Angeles Health Center (UCLA Health) any physical exam of the male or female genitals or rectum or female

breasts is considered "sensitive." These include exams of the female breasts, pubic/groin region (for hernia), vulva and vagina, penis and scrotum, and rectum. UCLA Health provides medical chaperones for sensitive exams. Their job is to ensure patient and provider comfort, safety, privacy, security and dignity during these exams or procedures. The chaperone will stand in a location where they can observe what is going on and assist as needed. UCLA protocols note that persons undergoing a sensitive exam should expect: i) An explanation of the exam, including why it is needed, what the provider will do, and what it may feel like; ii) Privacy to undress; iii) A covering (gown or sheet/drape); iv) That the provider should not make sexual remarks, hints or jokes; v) and, that a patient has the right to refuse any portion of an exam or to stop it at any time.

b) **Best Practices for Sensitive Exams.** The American College Health Association (ACHA) recommends every institution have a policy regarding sensitive medical exams to protect patients' safety and minimize risk associated with the performance of these exams. It is ACHA's recommendation that, as part of institutional policy, a chaperone be provided for every sensitive medical examination and procedure.

c) **Medical Mistrust.** Medical mistrust persists and appears to be growing. The public health literature on medical mistrust has largely focused on mistrust among Black and African American populations due to legacies of abuse and mistreatment, such as the infamous Tuskegee Syphilis Study. However, research is now emerging that explores mistrust among various populations and in varying contexts, and the literature now largely emphasizes the role of ongoing, present-day social and economic inequalities in shaping and sustaining mistrust, particularly among populations who experience health disparities. According to a 2021 article published in Behavioral Medicine, *"Whose Responsibility Is It to Dismantle Medical Mistrust? Future Directions for Researchers and Health Care Providers,"* medical mistrust is associated with lower health care utilization and lower health care satisfaction and is thought to negatively affect myriad preventative health practices, particularly among people of color. These include colorectal cancer screening, mammography behaviors, and HPV vaccinations.

3) **SUPPORT IF AMENDED.** SEIU California has a support if amended position on this bill and states that sensitive medical examinations, particularly those involving areas such as the pelvic, breast, and rectal regions, can leave patients feeling vulnerable. The power dynamics inherent in the patient-provider relationship, combined with the physical intimacy of such examinations, present an unfortunate risk of misconduct. SEIU notes that adding a trained medical chaperone as an impartial observer not only enhances patient safety, but also mitigates the risk of misunderstandings or unprofessional behavior during these procedures. While SEIU thinks that this measure is an important step to safeguarding patients from potential abuse, limiting the requirements to only sonographers does not provide protection to those patients who are receiving care from a physician or other provider. The terrifying stories from patients and parents who were abused by Medical Doctors raise the need for trained medical chaperons during all sensitive exams. SEIU urges the author to consider expanding the requirements under the bill to ensure that it covers exams performed by physicians as well.

4) **OPPOSE UNLESS AMENDED.** The California Hospital Association (CHA) is opposed to this bill unless it is amended and states that while CHA appreciates the author's willingness to collaborate to address several concerns, and hospitals fully share the goal of protecting

patients' dignity and safety during intimate examinations, as currently drafted, this bill presents staffing and operational challenges. CHA notes that, every day, hospitals navigate providing patient care while experiencing staffing shortages. Hospitals that currently provide medical chaperones rely on flexibility to offer patients an alternative if a chaperone is unavailable due to staffing limitations. In those instances, hospitals work with the patient to develop a solution that respects the patient's preferences and is operationally feasible. CHA argues that this new staffing requirement would increase costs at a time when affordability remains a top priority, and concludes that with hospitals already under financial strain and bracing for likely Medicare and Medi-Cal cuts, added costs could further jeopardize hospitals' ability to provide access to high-quality care.

5) **OPPOSITION.** The American Association of Clinical Urologists, Inc. (AACU) is opposed to this bill and states that while they do not disagree with the spirit of the measure (patient protection), if passed the bill will present challenges for staffing and workflows in hospitals big and small. AACU notes that chaperones are offered and typically communicated verbally to the patient and some facilities will have a sign posted. According to AACU, the notice requirement, providing both a hard and electronic notification, are duplicative and burdensome. AACU argues that facilities would have to create new forms that go into hospital admissions paperwork and other workflows for electronic notification that increases the administrative burden on an already stressed system. AACU contends that complying with the training requirements and requirement to create a medical chaperone competency report is burdensome and they believe as written the bill is an overreach legislating how urologists practice medicine.

6) **PREVIOUS LEGISLATION.** AB 1030 (Calderon) of 2019 would have required health professionals who are licensed, certified, registered, or otherwise subject to regulation who, acting within the scope of their practice in accordance with standardized protocols where they exist and in conformity with the standard of care for their profession, are authorized to perform pelvic examinations, to provide patients with a pamphlet, created by the Medical Board of California in coordination with specified stakeholders, about appropriate pelvic exams prior to their first pelvic exam with that health professional. AB 1030 died on the Senate inactive file.

7) **POLICY COMMENTS.** As currently drafted this bill applies to many types of health facilities, some of which may not perform sensitive examinations. Moving forward, the author may wish to work with stakeholders to narrow the types of facilities to which this bill applies. The author may also wish to consider requiring facilities to develop best practice policies for sensitive exams.

REGISTERED SUPPORT / OPPOSITION:

Support

None on file

Opposition

American Association of Clinical Urologists, Inc.

Analysis Prepared by: Lara Flynn / HEALTH / (916) 319-2097

Date of Hearing: April 29, 2025

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 886 (Krell) – As Amended April 22, 2025

SUBJECT: Nicotine: cessation.

SUMMARY: Requires the Tobacco Education and Research Oversight Committee (TEROC) to develop and oversee a statewide community education plan to translate, disseminate, and apply research findings from the Tobacco-Related Disease Research Program (TRDRP) related to teenage vaping and nicotine cessation. Requires TEROC to develop a plan to identify and share best practices on effective, developmentally appropriate nicotine cessation strategies for youth, as specified. Requires the State Department of Public Health (DPH) to establish a pilot program in the County of Los Angeles, the County of Sacramento, and the County of Santa Clara to, among other things, implement targeted intervention programs for youth under 21 years of age who are addicted to nicotine and to prioritize developmentally appropriate cessation strategies over traditional nicotine replacement therapies. Specifically, **this bill**:

1) Requires TEROC to develop and oversee a statewide community education plan to translate, disseminate, and apply research findings from the TRDRP related to teenage vaping and nicotine cessation.

2) Requires TEROC to develop a plan to identify and share best practices on effective, developmentally appropriate nicotine cessation strategies for youth. Requires the plan to include, but not be limited to, targeted outreach and education efforts directed at all of the following:

    a) Health care providers and health systems serving youth populations;

    b) Community-based organizations that engage with youth, including, but not limited to, youth experiencing disproportionate tobacco-related harms; and,

    c) Local educational agencies, including school districts and county offices of education.

3) Requires the goal of the statewide plan to be to ensure broad implementation of evidence-based nicotine cessation strategies and interventions tailored to adolescents, recognizing that traditional nicotine replacement therapies have not been deemed appropriate for youth under 21 years of age.

4) Requires DPH, in addition to the statewide plan, to establish a pilot program in the County of Los Angeles, the County of Sacramento, and the County of Santa Clara. Requires the pilot program to do all of the following:

    a) Implement targeted intervention programs for youth under 21 years of age who are addicted to nicotine, using best available research;

    b) Include culturally responsive, youth-centered program models that take into account the unique behavioral, psychological, and social aspects of nicotine addiction in adolescents;

c) Prioritize developmentally appropriate cessation strategies over traditional nicotine replacement therapies; and,

d) Be implemented in collaboration with local health departments and community-based organizations with a demonstrated history of work on nicotine cessation in those regions.

5) Prohibits funding for activities in this bill from being derived from the California Healthcare, Research, and Prevention Tobacco Tax Act of 2016 (Proposition 56) or the Tobacco Tax and Health Protection Act of 1988 (Proposition 99) tobacco tax revenues.

EXISTING LAW:

1) Establishes DPH to, among other functions, to protect the public's health and shape positive health outcomes for individuals, families and communities, including leading statewide and local health programs, services and activities that promote a tobacco free environment. Establishes the California Tobacco Control Branch within DPH, which leads statewide and local health programs, services and activities that promote a tobacco free environment. [Health and Safety Code (HSC) § 131056]

2) Establishes TEROC with overseeing the use of Proposition 99 and Proposition 56 tobacco tax revenues for tobacco control and prevention education and for tobacco-related research. Specifies that in performing this mandate, TEROC will provide advice to DPH, the University of California (UC), and the State Department of Education (DOE) regarding the administration of the Proposition 99 and Proposition 56-funded programs.

3) Requires DPH to establish and develop a program to reduce the availability of "tobacco products," as defined, to persons under 21 years of age through authorized enforcement activities, as specified, pursuant to the Stop Tobacco Access to Kids Enforcement Act (STAKE Act). [Business and Professions Code (BCP) § 22952]

4) Requires all persons engaging in the retail sale of tobacco products to check the identification of tobacco purchasers, to establish the age of the purchaser, if the purchaser reasonably appears to be under 21. [BPC § 22956]

5) Permits an enforcing agency, as specified, to assess civil penalties against any person, firm, or corporation that sells, gives, or in any way furnishes to another person who is under 21 any tobacco product, instrument, or paraphernalia that is designed for the smoking or ingestion of tobacco products, as specified, ranging from $400 to $6,000 for a first, second, third, fourth, or fifth violation within a five-year period. [BPC § 22958]

6) Defines "tobacco product" as a product containing, made, or derived from tobacco or nicotine that is intended for human consumption, as specified, including an electronic device that delivers nicotine or other vaporized liquids to the person inhaling from the device, and any component, part, or accessory of a tobacco product, whether or not sold separately. Prohibits any product approved by the federal Food and Drug Administration (FDA) for sale as a tobacco cessation product or for other therapeutic purposes, as specified, from being deemed a tobacco product. [BPC § 22950.5]

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

COMMENTS:

1) **PURPOSE OF THIS BILL.** According to the author, investing in evidence-based strategies to reduce youth nicotine addiction is essential, given the severe impact of nicotine on adolescent brain development and the lack of FDA-approved nicotine replacement therapies for minors. This bill prioritizes prevention, education, and behavioral interventions designed to curb early addiction and mitigate long-term health consequences of this highly addictive drug. The author concludes that by adopting proven best practices, we can protect young people from lifelong dependence and reduce the broader public health burden of nicotine use.

2) **BACKGROUND.** Cigarette smoking causes more than 480,000 deaths each year in the United States (U.S.), or nearly one in five deaths. Smoking causes more deaths each year than the following causes combined: Human immunodeficiency virus, illegal drug use, alcohol use, motor vehicle injuries, and firearm-related incidents. More than 10 times as many U.S. citizens have died prematurely from cigarette smoking than have died in all the wars fought by the U.S. Smoking causes about 90% (or nine out of 10) of all lung cancer deaths. More women die from lung cancer each year than from breast cancer. Smoking causes about 80% (or eight out of 10) of all deaths from chronic obstructive pulmonary disease. Cigarette smoking increases the risk for death from all causes in men and women. In California, smoking-related health care costs $13.29 billion per year and smoking-related losses in productivity totals $10.35 billion per year.

   a) **Youth vaping data.** According to the 2024 National Youth Tobacco Survey (NYTS), over 1.6 million U.S. kids were current e-cigarette users in 2024. While youth e-cigarette use has declined since its peak in 2019, it remains a serious public health problem. The most recent survey data finds:

      i) Many youth are using these products most days or every day, a sign they are becoming addicted. In 2024, over 40% of high school e-cigarette users vaped on at least 20 days a month, and nearly 30% reported vaping every day;

      ii) Flavored products are driving youth use. Nearly 90% of youth e-cigarette users use flavored products, with fruit, candy/desserts/other sweets, mint and menthol reported as the most popular flavors; and,

      iii) Youth have shifted dramatically to disposable and menthol e-cigarettes, two categories of products that were left on the market under current federal restrictions.

   b) **TEROC.** TEROC is a legislatively mandated advisory committee charged with overseeing the use of Proposition 99 and Proposition 56 tobacco tax revenues for tobacco control and prevention education and for tobacco-related research. In performing this mandate, the Committee provides advice to the DPH, UC, and DOE regarding the administration of the Proposition 99 and Proposition 56-funded programs. TEROC also publishes and periodically updates a state master plan for tobacco control and tobacco-related research, and makes recommendations to the State Legislature for improving Proposition 99 and Proposition 56 -funded tobacco control and tobacco-related research efforts in California.

   c) **TRDRP**. The TRDRP is administered by the UC Office of the President (UCOP), and is one of three state agencies working to eliminate commercial tobacco use and tobacco-

related diseases. TRDRP works with DPH's Tobacco Control Branch and the DOE's Tobacco Use Prevention and Education Program under the guidance of TEROC to ensure collaboration across all sectors of California's tobacco control community. TRDRP is solely funded through the tobacco tax and individual contributions and is administered by the Research Grants Program Office at the UCOP. TRDRP funds both UC campuses and non-UC institutions through a competitive peer review process that distributes funds based on scientific and programmatic merit.

TRDRP disseminates the findings of the research awards in several ways including: (1) grantees are required to describe and execute a plan for community engagement during the course of their award and these plans often involve disseminating scientific information to the public; (2) grantees often publish their results in scientific journals; (3) grantees sometimes describe their results to lay audiences via newspaper editorials, oral presentations at legislative hearings, position papers, social media, and other media channels; (4) TRDRP regularly updates the program website with lay articles summarizing research findings; (5) TRDRP publishes lay articles in a quarterly newsletter that goes to TRDRP grantees, applicants, and other stakeholders; (6) TRDRP hosts webinars and in-person convenings to highlight research findings on a topic of interest.

d) California's flavored tobacco ban. In 2020 the Legislature passed, and Governor Newsom signed, SB 793 (Hill), Chapter 34, Statutes of 2020. The law prohibits a tobacco retailer, or any of its agents or employees from selling, offering for sale, or possessing with the intent to sell or offer for sale, a flavored tobacco product or a tobacco product flavor enhancer. It exempts the sale of Hookah water pipes and flavored shisha tobacco products, pipe tobacco, and premium cigars from the prohibition. Fueled by kid friendly flavors like cotton candy and bubblegum, 3.6 million more middle and high school students started using e-cigarettes in 2018. The disturbing rates of teen e-cigarette use continued to rise in 2019 with the overwhelming majority of youth citing use of popular fruit and menthol or mint flavors and there are now 5.3 million young Americans who use e-cigarettes regularly. SB 793 also included menthol flavor, which was excluded from the original federal Food and Drug Administration (FDA) ban, because, as the author of SB 793 noted during his bill presentation, unless action is taken, an estimated 1.6 million African Americans alive today, who are now under the age of 18, will become regular smokers; and about 500,000 of those will die prematurely from a tobacco-related disease.

e) Tobacco taxes. The California Cigarette and Tobacco Products Tax Law imposes a tax of $2.87 per package of 20 cigarettes. Distributors pay the tax by purchasing tax stamps from the California Department of Tax and Fee Administration, which are then affixed to a cigarette package. While a base tax rate of $0.10 per pack of 20 cigarettes has been in place since 1967, with revenue flowing to the General Fund, the Legislature and voters have adopted four tobacco tax measures directing revenue for specific programs:

i) In 1988, voters approved Proposition 99, which imposed a surtax of $0.25 cents per package, and created an equivalent tax on tobacco products. Proceeds from the tax fund health education, disease research, hospital care, fire prevention, and environmental conservation;

ii) AB 478 (Friedman), Chapter 660, Statutes of 1993, added an excise tax of $0.02 per packet of 20 cigarettes for breast cancer research and early detection services;

iii) In 1998, California voters approved Proposition 10, which imposed an additional surtax of $0.50 per pack, and created a proportionately larger increase in the tax on tobacco products. The revenues are used to fund early childhood development programs, called First 5 programs;

iv) In 2016, voters approved Proposition 56, which imposed an additional surtax of $2 per pack and expanded the definition of "tobacco products" to include e-cigarettes when sold in combination with nicotine for a single price, and liquids containing nicotine used in those products. The additional tax revenues are deposited into the California Healthcare, Research and Prevention Tobacco Tax Act of 2016 Fund, which is used to backfill revenue losses for the above programs that result from reduced consumption due to the increased tax rate; and,

v) SB 395 (Caballero), Chapter 489, Statutes of 2021, enacts the Healthy Outcomes and Prevention Education Act, which imposes the California Electronic Cigarette Excise Tax on the sale of electronic cigarettes, and creates the Health Careers Opportunity Grant Program in the Department of Health Care Access and Information, and directs proceeds of the tax to various purposes.

Because tobacco taxes successfully discourage tobacco use, they are a diminishing source of revenue.

f) Youth Tobacco Cessation Resources. Youth report using a diversity of tobacco products, including cigarettes, e-cigarettes, cigarillos, hookah, smokeless tobacco, and a variety of new and emerging products. Nicotine exposure during youth can harm the developing adolescent brain and can lead to a lifetime of nicotine addiction and tobacco use. Nicotine exposure can also prime the adolescent brain for addiction to other drugs. Helping youth quit using tobacco products is critical for protecting their health now and in the future. DPH's Tobacco Control Branch offers cessation services and resources including flyers, downloadable apps to help youth quit, and automated texting programs.

The FDA has not approved any agents for smoking cessation in patients under the age of 18.

3) SUPPORT. Breathe Southern California is the sponsor of this bill and states that the rapid rise in teen vaping, as evidenced by the 2023 California Youth Tobacco Survey, underscores the urgent need for evidence-based interventions tailored specifically to this age group. Nicotine exposure during adolescence has been shown to impair brain development, increase the likelihood of long-term addiction, and elevate the risk of cardiovascular issues. The sponsor states that this bill addresses this crisis by requiring TEROC within DPH to develop and oversee a statewide community education plan to translate, disseminate, and apply research findings from TRDRP related to youth vaping and nicotine cessation to ensure that available research is getting into the hands of groups that can implement best practices. The sponsor notes that this bill would also require the establishment of research-informed youth nicotine intervention pilot programs in three California counties – Los Angeles, Sacramento, and Santa Clara. The sponsor concludes that by utilizing these evidence-based strategies to

treat and reduce nicotine addiction, this creates a sustainable, statewide framework for youth nicotine cessation.

4) PREVIOUS LEGISLATION.

a) AB 935 (Connolly), Chapter 351, Statutes of 2023, makes provisions of current law prohibiting a tobacco retailer, or any of the tobacco retailer's agents or employees, from selling, offering for sale, or possessing with the intent to sell or offer for sale, a flavored tobacco product or a tobacco product flavor enhancer, punishable by civil penalties in the same manner as the STAKE Act.

b) AB 3218 (Wood), Chapter 849, Statutes of 2024, requires the Attorney General (AG) to establish and maintain on the AG's website, a list of tobacco product brand styles that lack a characterizing flavor, to be known as the Unflavored Tobacco List.

c) SB 793 (Hill) Chapter 34, Statutes of 2020 prohibits a tobacco retailer, or any of the tobacco retailer's agents or employees, from selling, offering for sale, or possessing with the intent to sell or offer for sale a flavored tobacco product or a tobacco product flavor enhancer, as specified.

REGISTERED SUPPORT / OPPOSITION:

Support

Breathe Southern California (sponsor)
American Academy of Pediatrics, California
Center for Environmental Health
Church State Council
Cleanearth4kids.org

Opposition

None on file

Analysis Prepared by: Lara Flynn / HEALTH / (916) 319-2097

Date of Hearing: April 29, 2025

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 916 (Lee) – As Amended March 20, 2025

SUBJECT: Safer Soap Act.

SUMMARY: Prohibits, on and after January 1, 2028, a person from manufacturing, selling, delivering, distributing, or offer for sale, consumer hand soap or body wash that contains a prohibited ingredient, namely benzalkonium chloride (BZK), benzethonium chloride (BZT), or chloroxylenol (PCMX). Requires the Department of Toxic Substances Control (DTSC) to enforce the provisions of this bill. Authorizes the Attorney General (AG), on behalf of DTSC, to bring an action in superior court and requires the court to have jurisdiction upon hearing and for cause shown, to grant a temporary or permanent injunction restraining any person from violating any provision of this bill. Specifically, **this bill**:

Definitions:

1) Defines "body wash" to mean a product that is intended to be used with water, designed for cleansing the human body, and manufactured, sold, or distributed in this state.

2) Defines "hand soap" to mean a product that is intended to be used with water, designed for hand washing by consumers, and manufactured, sold, or distributed in this state.

3) Defines "prohibited ingredient" to mean any of the following substances:

   a) Benzalkonium chloride (BZK);

   b) Benzethonium chloride (BZT); and,

   c) Chloroxylenol (PCMX).

Prohibition of antibacterial soaps and body washes:

4) Prohibits, on and after January 1, 2028, a person from manufacturing, selling, delivering, distributing, or offering for sale into commerce in this state a consumer hand soap or body wash that contains a prohibited ingredient.

5) Exempts from the prohibitions in this bill products intended for use in health care facilities, as defined.

Regulation of antibacterial soaps and body washes:

6) Requires DTSC to, on or before January 1, 2028, adopt regulations to implement, interpret, enforce, or make specific the provisions of this bill.

7) Requires a manufacturer of hand soap or body wash to, on or before July 1, 2028, and in the manner prescribed by DTSC pursuant to the regulations adopted pursuant to this bill, register with DTSC and provide to DTSC all of the following:

a) The name and a description of each hand soap and body wash that it manufactures;

b) The applicable registration charge; and,

c) A statement of compliance certifying that each hand soap and body wash that it manufactures is in compliance with the prohibitions in this bill.

8) Requires a manufacturer, upon request by DTSC, to provide technical documentation to demonstrate compliance with the provisions of this bill, including, but not limited to, analytical test results.

9) Requires DTSC, on or before January 1, 2028, to publish on its internet website a list of accepted testing methods for testing for the presence of prohibited ingredients in hand soap and body wash and appropriate third-party accreditations for laboratories. Authorizes DTSC to update the list of accepted testing methods as necessary.

10) Requires that certifications of compliance and analytical tests demonstrating compliance comply with the accepted testing methods published on DTSC's internet website.

11) Requires DTSC to specify by regulation the manner for manufacturers to register and the amount of the registration charge. Prohibits the registration charge from exceeding DTSC's actual and reasonable costs of implementing the provisions of this bill.

Enforcement:

12) Requires DTSC to issue a notice of violation to a person in violation of the prohibitions in this bill if any of the following occurs:

a) DTSC's testing or a test result submitted to DTSC pursuant to the provisions of this bill indicates that a hand soap or body wash contains a prohibited ingredient;

b) A label on a hand soap or body wash lists a prohibited ingredient as an ingredient; or,

c) DTSC finds a violation of the provisions of this bill or of any regulation adopted pursuant to this bill.

13) Requires a notice of violation to indicate the nature of the violation and authorizes the violation to do any of the following:

a) Assess an administrative or civil penalty against a person or entity in violation of the provisions of this bill; or,

b) Require compliance with the provisions of this bill, including requiring the person to cease the manufacture, sale, or distribution of a hand soap or body wash in this state.

14) Authorizes DTSC to receive reports of alleged violations, including analytical test results, from any person and to verify those alleged reports through its own independent testing, verification, or inspection.

15) Provides that specific provisions of Hazardous Waste Control Law in the Health and Safety Code (HSC) do not apply to the provisions of this bill, except specific provisions about enforcement of misdemeanor violations.

16) Makes a violation of the provisions of this bill is punishable by an administrative or civil penalty.

17) Requires DTSC to determine, on a case-by-case basis, the enforcement mechanism and the amount of any administrative or civil penalty assessed pursuant to the provisions of this bill.

18) Requires the minimum amount of an administrative or civil penalty assessed to be $10,000 for the first and any subsequent violation. Authorizes penalties to be assessed for each violation of a separate provision or, for continuing violations, for each day that the violation continues.

19) Authorizes the court, in assessing the amount of a civil penalty for a violation of the provisions of this bill, to consider all of the following:

    a) The nature and extent of the violation;

    b) The number of violations and the severity of the violations;

    c) The economic effect of the penalty on the violator;

    d) Whether the violator took good faith measures to comply with provisions of this bill and when the measures were taken;

    e) The deterrent effect that the imposition of the penalty would have on both the violator and the regulated community as a whole; and,

    f) Whether there were contributing environmental factors about which a reasonable person knew or should have known.

20) Authorizes the AG, on behalf of DTSC, to bring an action in superior court and requires that the court have jurisdiction upon hearing and for cause shown to grant a temporary or permanent injunction restraining any person from violating any provision of this bill.

21) Requires that a proceeding under provisions of this bill conform to specified injunction provisions of the Code of Civil Procedure, except that DTSC is to be required to allege facts necessary to show or tending to show lack of adequate remedy at law or to show or tending to show irreparable damage or loss.

22) Authorizes the Attorney General to bring actions pursuant to this bill in the name of the people of the state at the request of DTSC.

23) Requires that a prevailing plaintiff bringing an action pursuant to this bill be awarded attorney's fees and costs by the court.

Funding:

24) Requires that penalties collected pursuant to this bill be deposited in the Safer Soap Act Fund, which is hereby created in the State Treasury, to be used by DTSC, upon appropriation by the Legislature, for the purposes of enactment of this bill.

25) Provides that DTSC's duties to initiate, implement, or enforce any requirement of this bill are contingent upon sufficient funds in the Toxic Substances Control Account (TSCA), as determined by the Department of Finance, and an appropriation by the Legislature for the purposes of implementing and enforcing the requirements of this bill.

26) Provides that, upon appropriation by the Legislature, if funds in the TSCA are sufficient to finance the development of the regulations and the startup costs of DTSC's activities pursuant to this bill, funds may be used as a loan by DTSC for DTSC to carry out the provisions of this bill until the Safer Soap Act Fund generates revenues sufficient to fund DTSC's reasonable costs of implementing the provisions of this bill and to reimburse any outstanding loans made from the TSCA used to finance the development of the regulations and the startup costs of DTSC's activities pursuant to the provisions of this bill.

Findings:

27) Makes legislative findings regarding the safety and effectiveness of antimicrobial chemicals in consumer hand soaps and body washes, including that the use of the antimicrobial chemicals benzalkonium chloride, benzethonium chloride, and chloroxylenol in consumer hand soaps and body washes poses significant risks to human health and the environment.

EXISTING LAW:

Federal Law. Establishes the Federal Food, Drug, and Cosmetic Act, which authorizes the federal Food and Drug Administration (FDA) to oversee and regulate the production, sale, and distribution of food, drugs, medical devices, and cosmetics. Authorizes the FDA to mandate drug manufacturers to submit evidence of new drugs' safety and effectiveness before marketing and distribution to the general public. [Title 21, United States Code § 301, *et seq.]*

State Law

1) Prohibits the manufacture or sale of a menstrual product that contains regulated perfluoroalkyl and polyfluoroalkyl substances (PFAS), as defined. [Health and Safety Code (HSC) § 25258.3]

2) Requires DTSC, by January 1, 2029, to adopt regulations to implement, interpret, enforce, or make specific the PFAS prohibition. [HSC § 25258.1]

3) Prohibits, on or after January 1, 2026, the manufacture or sale of any juvenile's feeding, sucking, or teething product that contains any form of bisphenol above a limit determined by DTSC. Authorizes DTSC or the Attorney General to enforce this prohibition and authorizes DTSC to adopt regulations to implement, enforce, interpret, or make specific this prohibition. [HSC § 108940]

4) Prohibits, beginning January 1, 2025, the manufacture or sale of a cosmetic product containing specified intentionally added ingredients, including the quaternary ammonium compound, Quaternium-15. [HSC § 108980(a)(6)]

5) Prohibits, beginning January 1, 2027, the manufacture or sale of a food product for human consumption that contains brominated vegetable oil, potassium bromate, propylparaben, or red dye 3. [HSC § 109025]

6) Prohibits, beginning January 1, 2030, the manufacture or sale of intravenous (IV) solution containers made with intentionally added Di(2-ethylhexyl) phthalate (DEHP). Additionally prohibits, beginning January 1, 2035, the manufacture or sale of IV tubing made with intentionally added DEHP. [HSC § 109052]

7) Requires State Department of Public Health (DPH), in collaboration with the California Environmental Protection Agency, to establish the California Environmental Contaminant Biomonitoring Program. Requires DPH to utilize biological specimens, as appropriate, to identify designated chemicals that are present in the bodies of Californians. [HSC § 105441]

8) Defines "designated chemicals" as those chemicals that are known to, or strongly suspected of, adversely impacting human health or development, based upon scientific, peer-reviewed animal, human, or in vitro studies, and according to certain parameters. [HSC § 105440 (c)]

9) Requires DTSC to adopt regulations to establish a process to identify and prioritize chemicals or chemical ingredients in consumer products that may be considered chemicals of concern, as specified. [HSC § 25252]

10) Requires DTSC to adopt regulations to establish a process to evaluate chemicals of concern in consumer products, and their potential alternatives, to determine how to best limit exposure or to reduce the level of hazard posed by a chemical of concern. [HSC § 25253 (a)]

11) Specifies, but does not limit, regulatory responses that DTSC can take following the completion of an alternatives analysis, ranging from no action, to a prohibition of the chemical in the product. [HSC § 25253]

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

COMMENTS:

1) **PURPOSE OF THIS BILL.** According to the author, for too long, harmful chemicals have been present in consumer hand soaps and body washes despite mounting scientific evidence that they pose significant risks to public health and the environment. The author continues that companies manufacturing antibacterial soaps have had over eight years to prove that these soaps are safe and effective. Yet, the author contends, they continue to profit while failing to provide evidence that antibacterial soaps are more effective than regular soap and water at preventing illness. The author notes that the Centers for Disease Control (CDC) and Prevention and the Food and Drug Administration (FDA) have acknowledged that these chemicals offer no proven health benefits over regular soap and water. The author states that Californians use these products daily, unaware they may contribute to antimicrobial resistance and long-term health concerns. The author concludes that this bill will prioritize

public health and safety by banning the sale of hand soaps and body washes that contain ineffective and potentially dangerous chemicals.

2) BACKGROUND.

a) What makes soap antibacterial? Antibacterial soaps (sometimes called antimicrobial or antiseptic soaps) contain certain active ingredients not found in plain soaps. Those ingredients are added to many consumer products with the intent of reducing or preventing bacterial infection. For nonprescription drugs, antibacterial products generally have the word "antibacterial" on the label and may contain benzalkonium chloride, benzethonium chloride or chloroxylenol. A Drug Facts label on a soap or body wash is a sign a product contains antibacterial ingredients.

b) Are antibacterial cleaning products more effective than regular soap? According to a 2024 FDA publication titled, *"Skip Antibacterial Soap; Use Plain Soap and Water,"* currently there isn't sufficient evidence to show that over-the-counter (OTC) antibacterial soaps are better at preventing illness than washing with plain soap and water. The FDA issued a final rule in 2016 under which 19 active ingredients, including triclosan and triclocarban, can no longer be marketed in nonprescription consumer antiseptic wash products. Those products include liquid, foam, and gel hand soaps; bar soaps; and body washes. The FDA made this determination because manufacturers didn't provide the data necessary to demonstrate that those active ingredients are both safe for daily use over a long period of time and any more effective than plain soap and water in preventing illnesses and the spread of certain infections. The final rule doesn't apply to benzalkonium chloride, benzethonium chloride and chloroxylenol. Those three active ingredients may be used in currently marketed nonprescription consumer antiseptic wash products. Manufacturers are conducting new studies and submitting new safety and effectiveness data for these three active ingredients. The final rule covers only consumer antibacterial soaps and body washes that are used with water. It does not apply to hand sanitizers, hand wipes or antibacterial soaps used in health-care settings, such as hospitals and nursing homes.

c) Concerns about active antibacterial ingredients in consumer products. Benzalkonium chloride and benzenthonium chloride are part of a class of chemicals called quarternary ammonium compounds. According to DTSC's "*Background Document on Quaternary Ammonium Compounds in Cleaning Products and Beauty, Personal Care, and Hygiene Products,*" benzalkonium chloride and benzethonium chloride are the only two QACs authorized for use as antimicrobials in antibacterial soaps and body washes. Exposure to QACs, especially benzylalkyldimethyl ammonium compounds (BAC mixtures), can cause adverse dermal, respiratory, or immune effects in humans. Skin-related issues, such as irritation, sensitization, and dermatitis, have been reported in human studies, particularly with exposure to QACs in personal care products. Work-related asthma has been linked to QAC exposure—especially BAC mixtures. DTSC continues that in a pilot human study, exposure to BAC mixtures was linked to a direct increase in inflammatory response. A growing body of research over the past decade also links certain QACs to reproductive and developmental toxicity, changes to cholesterol and lipid levels, and the failure of cellular mitochondria to function normally.

Chloroxylenol, the third allowable antibacterial active ingredient in cleansing products, is an organohalogen compound. Proponents of the bill argue that most well-studied organohalogens have been found to be harmful to people, ecosystems, and especially to children. According to the United States Environmental Protection Agency (US EPA)'s publication, "*Organohalogen Pollutants and Human Health,"* widespread use of organohalogens have led to global environmental contamination, with human exposures occurring through multiple pathways such as direct skin contact, inhalation, drinking water, and food. US EPA states that exposure to these persistent organic pollutants has been implicated in myriad human health effects, including reproductive, neurological, immunological, endocrine, behavioral, and carcinogenic effects in both wildlife and humans. The US EPA argues, "Based on their use pattern and their persistent chemical properties, it can be predicted that human exposure to these compounds will continue. Hence, understanding human health effects and taking preventive measures for such exposures are necessary."

d) **What does this bill do?** This bill prohibits, on and after January 1, 2028, a person from manufacturing, selling, delivering, distributing, or offering for sale into commerce in this state a consumer hand soap or body wash that contains any of the last three antibacterial active ingredients allowed in these products: benzalkonium chloride, benzethonium chloride, and chloroxylenol. This bill exempts from the prohibitions in this bill antibacterial hand soaps and body washes intended for use in health care facilities, which include hospitals, skilled nursing facilities, intermediate care facilities, congregate living health facilities, correctional treatment centers, and hospice facilities. This bill includes a regulatory and enforcement framework for DTSC to implement the prohibition on the manufacture and sale of antibacterial chemicals in consumer soaps and body washes in the state. Specifically, this bill requires DTSC to, on or before January 1, 2028, adopt regulations to implement, interpret, enforce, or make specific the prohibition. It also requires a manufacturer of hand soap or body wash to, on or before July 1, 2028, and in the manner prescribed by DTSC by regulation, register with DTSC and provide to DTSC specific information regarding their products.

   For enforcement, this bill requires DTSC to issue a notice of violation to a person in violation of the prohibitions in this bill under certain circumstances. It also provides that a violation of the prohibition is punishable by an administrative or civil penalty of $10,000 for the first and any subsequent violation. This bill authorizes penalties to be assessed for each violation of a separate provision or, for continuing violations, for each day that the violation continues. Additionally, this bill authorizes the Attorney General, on behalf of DTSC, to bring an action in superior court.

3) **SUPPORT.** Children Now is the sponsor of this bill and states the U.S. Food and Drug Administration (FDA) issued a final rule banning 19 antimicrobials from consumer antiseptic washes, concluding they were neither safe nor effective. Children Now continues that the agency said there was no data to "demonstrate that there is any additional benefit from the use of these active ingredients in consumer antiseptic wash products compared to non-antibacterial soap and water. However, at the request of manufacturers, the FDA deferred rulemaking for one year on the three other antimicrobials used in antibacterial soaps: benzalkonium chloride (BZK), benzethonium chloride (BZT), and chloroxylenol (PCMX). Children Now continues that the FDA has extended this deferral several more times and has still not reached a decision nearly nine years later. Meanwhile, the evidence of the health

hazards linked to these ingredients (including their possible contribution to antimicrobial resistance) has only gotten stronger. Children Now states that the FDA itself has put out public communications discouraging consumers from using antibacterial hand soap due to these concerns (and lack of demonstrated benefit) as recently as December of 2024. Children Now contends that as the FDA fails to take action, consumers continue to buy soaps with these ingredients (advertised as "antibacterial") thinking they are taking an extra step to protect themselves and their children from viruses and bacteria. In reality, these active ingredients are associated with a wide variety of health harms and can contribute to the rise of antimicrobial resistance. Both the FDA and CDC say that soaps with these chemicals are no more effective in preventing disease than non-antibacterial soap and water and discourages their use due to serious public health and environmental concerns discussed above. Children Now concludes that this bill will safeguard public and ecosystem health and align with our state's leadership in consumer safety.

4) **OPPOSITION.** The American Cleaning Institute is opposed to this bill and states, washing one's hands with soap and water is an easy and effective method for removing germs from the skin, but there are several situations when consumers benefit from the use of antimicrobial products to remain healthy. ACI continues Californians with weakened immune systems depend on antimicrobials to kill bacteria that may remain on the skin after handwashing. ACI continues that consumer antimicrobial products have many applications in the home (such as ensuring home healthcare practitioners have the same hygiene products available to healthcare settings and preventing cross-contamination in food handling at home) as well as in California institutions such as schools, day care centers, and nursing homes. ACI notes that by banning antimicrobial soaps, the food supply chain would be more vulnerable to food borne disease spread. ACI continues that taking away an optional tool with proven effectiveness at fighting bacteria is misguided. ACI notes that DTSC recently initiated its first step in gathering information about the use of these ingredients and will consider a more holistic, and scientifically-sound policy for addressing the chemicals that this bill would ban. ACI contends that without sufficient data, nor a review of the harms that a ban would unleash, the Legislature doesn't have the complete picture of the policy impacts this bill would have. ACI concludes by stating that banning these ingredients would run counter to federal law that considers these as lawfully marketed drugs and preempted from state regulations.

5) **PREVIOUS LEGISLATION.**

   a) AB 2300 (Wilson) Chapter 562, Statutes of 2024 prohibits, beginning January 1, 2030, the manufacture or sale of intravenous (IV) solution containers made with intentionally DEHP. Additionally prohibits, beginning January 1, 2035, the manufacture or sale of IV tubing made with intentionally added DEHP.

   b) AB 2515 (Papan) Chapter 1008, Statutes of 2024 prohibits the manufacture or sale of a menstrual product that contains regulated PFAS, as defined. Further requires DTSC, by January 1, 2029, to adopt regulations to implement, interpret, enforce, or make specific the PFAS prohibition.

   c) SB 1266 (Limón), Chapter 790, Statutes of 2024, revises the existing prohibition on bisphenol A (BPA) in a juvenile bottle or cup to instead prohibit the manufacture or sale of any juvenile's feeding, sucking, or teething product that contains any form of

bisphenol above the practical quantitation limit to be determined by DTSC. Authorizes DTSC to enforce the BPA prohibition and to adopt regulations to implement, enforce, interpret, or make specific the BPA prohibition.

d) AB 347 (Ting), Chapter 932, Statutes of 2024 requires DTSC to enforce and ensure compliance with three existing laws that set limits for PFAS in food packaging, textiles, and juvenile products.

e) AB 418 (Gabriel), Chapter 328, Statutes of 2023) prohibits, beginning January 1, 2027, the manufacture or sale of a food product for human consumption that contains brominated vegetable oil, potassium bromate, propylparaben, or red dye 3.

f) AB 2762 (Muratsuchi), Chapter 314, Statutes of 2020) prohibits, beginning January 1, 2025, the manufacturing or sale of a cosmetic product containing specified intentionally added ingredients, including the QAC, Quaternium-15.

6) **DOUBLE REFERRAL.** This bill is double referred, it passed the Assembly Committee on Environmental Safety and Toxic Materials with a 5-2 vote on March 25, 2025.

REGISTERED SUPPORT / OPPOSITION:

Support

A Voice for Choice Advocacy
Active San Gabriel Valley
Alliance of Nurses for Healthy Environments
American Congress of Obstetricians & Gynecologists - District IX
Breast Cancer Prevention Partners
California Black Health Network
California Nurses for Environmental Health & Justice
California Product Stewardship Council
Children Now
Clean Earth 4 Kids
Clean Water Action
Cleanearth4kids.org
Facts: Families Advocating for Chemical & Toxics Safety
GMO Science
Green Science Policy Institute
Long Beach Alliance for Clean Energy
National Product Stewardship Council
Natural Resources Defense Council (NRDC)
Nontoxic Neighborhoods
Physicians for Social Responsibility - San Francisco Bay Area Chapter
Recolte Energy
Safer Made
San Francisco Baykeeper
Sonoma County Climate Activist Network (SOCOCAN!)
Sonoma Safe Agriculture Safe Schools (Sonoma Sass)
Women's Voices for the Earth
Womens Voices for the Earth

Opposition

American Chemistry Council
American Cleaning Institute
Arxada LLC
California Chamber of Commerce
California Grocers Association
California League of Food Producers
California Manufacturers & Technology Association
California Manufactures & Technology Association
California Restaurant Association
California Retailers Association
California Retailers Association
Consumer Brands Association
Consumer Healthcare Products Association
Household and Commercial Products Association
International Sanitary Supply Association
Personal Care Products Council

Analysis Prepared by: Eliza Brooks / HEALTH / (916) 319-2097

Date of Hearing: April 29, 2025

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 1032 (Harabedian & Rivas) – As Introduced February 20, 2025

SUBJECT: Coverage for behavioral health visits.

SUMMARY: Requires an individual or group health care service plan (health plan) or health insurer to reimburse an eligible enrollee or insured for up to 12 visits per year with a licensed behavioral health (BH) provider if the enrollee or insured is in a county where a local or state emergency has been declared due to wildfires. Contains an urgency clause to ensure that the provisions of this bill go into immediate effect upon enactment. Specifically, **this bill**:

1) Requires an individual or group health plan contract or health insurance policy issued, amended, or renewed on or after January 1, 2026, to reimburse an eligible enrollee or insured for up to 12 visits per year with a licensed BH provider if the enrollee or insured is in a county where a local or state emergency has been declared due to wildfires.

2) Specifies that an enrollee or insured is entitled to the benefits in 1) until one year from the date the local or state emergency is lifted, whichever is later.

3) Requires, for high deductible health plans, that 1) applies only once an enrollee or insured's deductible has been satisfied for the year.

4) Exempts specialized health plans or health insurers from the provisions of this bill.

5) Specifies that this bill does not excuse a health plan or health insurer from complying with existing Mental Health Parity laws.

EXISTING LAW:

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

2) Establishes California's essential health benefits (EHBs) benchmark under the Patient Protection and Affordable Care Act (ACA) as the Kaiser Small Group Health Maintenance Organization, establishes existing California health insurance mandates, and the 10 ACA mandated benefits, including prescription drug coverage. [HSC § 1367.005 and INS § 10112.27]

3) Defines "basic health care services" as all of the following:

   a) Physician services, including consultation and referral;

   b) Hospital inpatient services and ambulatory care services;

   c) Diagnostic laboratory and therapeutic radiologic services;

d) Home health services;

e) Preventive health services;

f) Emergency health care services, including ambulance and ambulance transport services and out-of-area coverage. Basic health care services includes ambulance and ambulance transport services provided through the 911 emergency response system; and,

g) Hospice care, as specified. [HSC § 1345 and INS § 10112.281]

4) Requires every disability insurance policy and health plan that provides hospital, medical, or surgical coverage to provide coverage for medically necessary treatment of mental health (MH) and substance use disorders (SUDs), under the same terms and conditions applied to other medical conditions, as specified. [HSC § 1374.72 and INS § 10144.5]

5) Defines medically necessary treatment of MH or SUD including that the service or product is in accordance with generally accepted standards of MH or SUD care, clinically appropriate in terms of type, frequency, extent, site, and duration. [HSC § 1374.72 and INS § 10144.5]

6) Requires a health plan or insurer that provides hospital, medical, or surgical coverage to base any medical necessity determination or the utilization review (UR) criteria that the plan, and any entity acting on the plan's behalf, applies to determine the medical necessity of health care services and benefits for the diagnosis, prevention, and treatment of MH and SUDs on current generally accepted standards of MH and SUD care, as specified. Requires a health plan or insurer to apply the criteria and guidelines set forth in the most recent versions of treatment criteria developed by the nonprofit professional association for the relevant clinical specialty in conducting UR of all covered health care services and benefits for the diagnosis, prevention, and treatment of MH and SUDs in children, adolescents, and adults. [HSC § 1374.721 and INS § 10144.52]

FISCAL EFFECT: Unknown. This bills has not been analyzed by a fiscal committee.

COMMENTS:

1) **PURPOSE OF THIS BILL.** According to the author, as wildfires continue to devastate our communities, we cannot ignore the lasting emotional toll they take on survivors. The author states that the data is clear—anxiety, depression, and post-traumatic stress disorder (PTSD) are real consequences, and the demand for behavioral health support skyrockets in the aftermath. The author concludes that we must act now to ensure those affected have the behavioral health services they need to heal and rebuild their lives.

2) **BACKGROUND.** California's climate makes it naturally prone to wildfires. The Legislative Analyst's Office released a publication titled, "*Frequently Asked Questions about Wildfires in California*," which highlighted that starting in the spring, much of the state typically experiences low levels of rainfall and increasingly warm conditions. These conditions begin to dry out vegetation, which makes the state increasingly susceptible to wildfires during the summer and early fall—or even later in years when dry conditions persist through the winter. Some areas of the state face a particularly high risk of severe wildfires due to factors such as the type of vegetation present, the local weather patterns, and the forms and features of land surfaces. According to a 2022 study titled, "*Using wildland fire smoke modeling data in*

gerontological health research," between 2007 and 2018, 99.5% of California's population lived in a county with at least one smoke wave, or chronic smoke event. Wildfires have increased in severity over time. Several of the state's largest and most destructive wildfires have occurred in recent years, including the Tubbs Fire (Santa Rosa, 2017), the Camp Fire (Butte County, 2018), the Eaton Fire (Los Angeles, 2025) and the Palisades Fire (Los Angeles, 2025).

a) **Wildfire impact on BH.** Research is emerging regarding the links between severe wildfire incidence and population-wide harm to BH. According to the California Department of Public Health, emotional recovery after a wildfire can be incredibly challenging. The stress of coping with the loss of a home, personal items, pets, livestock and other traumatic events can trigger mood swings, sleep disruption, and cause extreme nervous tension and/or depression. Studies also suggest that even those who do not lose homes can have anxiety, depression or psychological distress for years after a wildfire dies out. Furthermore, both the situational and physical impacts of wildfire exposure can impact a person's BH status. A 2025 study published by researchers at the Harvard T.H. Chan School of Public health found that exposure to fine particle air pollution (PM 2.5) from wildfire smoke was associated with increased visits to emergency departments for mental health conditions.

b) **California Health Benefits Review Program (CHBRP).** CHBRP was created in response to AB 1996 (Thomson), Chapter 795, Statutes of 2002, which 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. 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 to CHBRP's purview.

   i) **Baseline coverage.** CHBRP notes that all enrollees in commercial and California Public Employees' Retirement System (CalPERS) policies captured under this bill have coverage for BH visits regardless of whether or not there is a wildfire. None have coverage that allows them to see any licensed BH provider (contracted with their plan or not) and be reimbursed after the visit. Under this bill, 100% of enrollees would have such coverage. This bill does not expand coverage per se but rather expands access to out-of-network coverage. The enrollee would need to pay for BH visits and then be reimbursed by the insurer, less any cost sharing. This bill would not exceed the definition of EHBs in California.

   ii) **Utilization.** CHBRP estimates that an additional 16,170 people (6,240 utilizing for wildfire-related reasons and 9,930 people with previously unmet needs) would have a total of 194,050 more BH visits (assuming each enrollee receives 12 visits within the first year post-mandate) as a result of this bill.

   iii) **Cost impact.** CHBRP estimates this bill would increase total net annual expenditures by $49,966,000 (0.03%) for enrollees with commercial and CalPERS plans and policies. This is due to an increase of $43,747,000 in total health insurance premiums paid by employers and enrollees, and a $6,219,000 increase in enrollee cost sharing.

iv) **Medical effectiveness.** CHBRP identified a large body of literature demonstrating that psychotherapy and pharmacotherapy treatments are effective for people experiencing PTSD, anxiety, depression, SUD, and sleep disturbances as part of general trauma care. The medical effectiveness review reached the following conclusions for people experiencing general trauma.

(1) For psychotherapy:

(a) There is very strong evidence that psychotherapy is effective at reducing PTSD prevalence and symptoms;

(b) There is strong evidence that psychotherapy is effective at reducing depression prevalence and symptoms;

(c) There is very strong evidence that psychotherapy is effective at reducing anxiety prevalence and symptoms;

(d) There is some evidence that psychotherapy is effective at reducing SUD prevalence and symptoms; and,

(e) There is some evidence that psychotherapy is effective at reducing sleep disturbance prevalence and symptoms.

(2) For pharmacotherapy:

(a) There is strong evidence that pharmacotherapy is effective at reducing PTSD prevalence and symptoms;

(b) There is strong evidence that pharmacotherapy is effective at reducing depression prevalence and symptoms;

(c) There is strong evidence that pharmacotherapy is effective at reducing anxiety prevalence and symptoms;

(d) There is some evidence that pharmacotherapy is effective at reducing SUD prevalence and symptoms; and,

(e) There is strong evidence that pharmacotherapy is effective at reducing sleep disturbance prevalence and symptoms.

CHBRP identified scant literature specific to the effectiveness of psychotherapy and pharmacotherapy treatments for PTSD, anxiety, depression, SUD, and sleep disturbances among people who have experienced natural disasters. Despite the dearth of literature, CHBRP does not have a reason to believe these therapies, which are effective for treating BH conditions generally, would not also be effective for people seeking treatment due to trauma rooted in experience with a natural disaster.

v) **Public health impacts.** CHBRP estimates in the first year after passage, there would be improved BH outcomes among the population of people who reside in a county with a local or state emergency declaration due to wildfires, have a BH need, have the ability to pay out of pocket for out-of-network care, and who ultimately utilize care

and have the cost of BH visits reimbursed. The positive public health outcomes are supported by strong evidence that psychotherapy and pharmacotherapy are medically effective treatments for PTSD, anxiety, and depression; strong evidence that pharmacotherapy is effective at treating sleep disturbances; and some evidence that psychotherapy and pharmacotherapy are effective at treating SUD.

CHBRP has insufficient information to estimate the impact of this bill on disparities by group within the first 12 months after enactment. However, to the extent that this bill would increase access among higher-income people and families who could afford to pay out of pocket before receiving reimbursement, there could be disparate impacts; in such cases, lower-income families might not be able to pay for care upfront before being reimbursed by their plan or policy.

vi) **Long-term impacts.** CHBRP notes that a state emergency declaration due to a wildfire often lasts longer than the initial first few months past the date of the disaster event. Coverage under this bill would go through one year following the end of the emergency period, but wildfire impacts can last longer. To the extent that emergency declarations in counties impacted by wildfires continue, utilization of BH services could increase past the first year after enactment. Since there may be a time lag between when a wildfire event occurs and people's need for BH services, utilization may extend past one year. Additionally, severity of conditions may change over time. As need continues, and to the extent that plans and policies are required to provide coverage under this bill, utilization could increase marginally. Should utilization of BH visits increase, premiums and enrollee cost sharing would increase proportionately.

There could be longer-term public health impacts of BH services utilization as provided under this bill. For instance, since trauma-induced anxiety and depression tend to persist longer past a disaster event, increased access to and use of care may lead to improved outcomes in the long term. Outcomes for PTSD may also improve in the long term to the extent that affected populations receive timely and consistent treatment. In addition, it may take weeks or months for the health benefits of psychotherapy and pharmacotherapy to be fully realized.

c) **Mental Health Parity.** Federal Mental Health Parity laws require if a health plan includes services for mental health and substance use disorders as part of their benefits that those services must be covered under the same terms and conditions as other medical services. The ACA also specifies coverage of the 10 EHBs, including mental health and substance use disorder treatment services. The ACA went beyond existing federal law by mandating coverage instead of requiring parity only if coverage is provided.

SB 855 (Wiener), Chapter 151, Statutes of 2020, requires commercial health plans and insurers in California to provide full coverage for the treatment of all mental health conditions and substance use disorders. SB 855 also establishes specific standards for what constitutes medically necessary treatment and criteria for the use of clinical guidelines. SB 855 applies to all state-regulated health plans and insurers that provide hospital, medical, or surgical coverage, and to any entity acting on the plan or insurer's behalf. A health plan cannot limit benefits or coverage for mental health or substance use disorder treatments or services when medically necessary.

d) Timely access laws. SB 221 (Wiener) Chapter 724, Statutes of 2021, codified DMHC regulations requiring health plans to meet a set of standards, including specific time frames under which enrollees must be able to access care. These requirements provide health plan members the right to behavioral health appointments within the following time frames:

i) Urgent care without prior authorization: **within 48 hours**;

ii) Urgent care with prior authorization: **within 96 hours**;

iii) Non-urgent psychiatrist appointments **within 15 business days**, and non-physician mental health or substance use disorder providers **within 10 business days**; and,

iv) Non-urgent follow-up appointments with a non-physician mental health care or substance use disorder provider **within 10 business days** of the prior appointment for those undergoing a course of treatment for an ongoing mental health or substance use disorder condition.

e) EHBs. The ACA requires health plans sold in the individual and small group markets to offer a comprehensive package of items and services, EHBs, with no dollar limits. Under the ACA, the federal government gave each state the authority to choose its "benchmark" EHB plan. EHBs require plans to cover ten categories of services: (1) ambulatory patient services (outpatient care); (2) emergency services; (3) hospitalization; (4) maternity and newborn care; (5) mental health and substance use disorder services, including behavioral health treatment; (6) prescription drugs; (7) rehabilitative and habilitative services and devices; (8) laboratory services; (9) preventive and wellness services and chronic disease management; and, (10) pediatric services, including dental and vision care. Under the ACA, if states require plans to cover services beyond those defined as EHBs in law, states must pay the costs of those benefits, either by paying the enrollee directly or by paying the qualified health plan (offered through Covered California). The federal department of Health and Human Services (HHS) issued rules in 2018, 2019, and 2024 that provided states with new flexibilities to augment their EHBs. California is currently undergoing the process of updating the state's benchmark EHB plan. After a series of public meetings and a Legislative hearing, DMHC announced California's intent to submit a proposal to the federal government to add three new benefits to the state's EHB benchmark plan: hearing aids, durable medical equipment, and infertility treatment. Notification from DMHC to HHS must take place by May 7, 2025 for the new benchmark to take effect by the January 1, 2027 plan year. If the proposed EHB benchmark is approved, legislation to codify the new benchmark plan will be necessary. AB 224 (Bonta) and SB 62 (Menjivar) have been introduced this session to codify any benchmark changes that may come out of this process.

f) Office of Health Care Affordability (OHCA) cost targets. OHCA was established in 2022 in response to widespread cost-related access challenges across California. According to the California Health Care Foundation, over half of Californians say they skip or delay health care due to costs. OHCA collects, analyzes, and publicly reports data on total health care expenditures and enforces spending targets. OHCA's spending targets are intended to reduce excess spending and slow health care spending growth. In April of 2024, OHCA approved a statewide cost growth target of 3.5% starting in 2025 and phasing down to 3% by 2029. Health care entities,

including health plans, are subject to the statewide spending target and are subject to progressive enforcement if the entity's costs exceed the target. Some entities have raised concerns that new legislative benefit mandates will make it difficult for them to meet the established cost growth target.

Current law does not explicitly require OHCA to adjust the cost growth targets based on changes to state policy, such as mandates, that may increase spending. However, it does require OHCA to consider state benefit mandates in its development and enforcement of cost growth targets. Specifically, when establishing cost growth target methodology, OHCA is required to review relevant state policy changes impacting covered benefits, provider reimbursement, and costs, among other factors. In addition, in enforcing cost growth targets, OHCA is required to consider factors that contribute to spending in excess of the applicable target, and the extent to which each entity has control over the applicable components of its cost target.

3) **SUPPORT.** The California Behavioral Health Association (CBHA) supports this bill, stating that although Californians are entitled to a set amount of annual visits to their BH provider, it is most important to account for additional visits during times of crisis. CBHA continues that this bill would ensure critical access to BH services and promote recovery and resilience for residents who have experienced traumatic impacts. CBHA cites data from the California Parent & Youth Helpline which showed a dramatic surge in activity, with 62% of all calls related to mental and BH needs coming from Southern California during this year's wildfires. This spike in demand was accompanied by sharp increases across all communication channels, including a 366% jump in overnight calls, a 68% rise in live chat usage, a 45% increase in text messages, and a 22% overall boost in call volume. CBHA argues that these statistics call for an immediate resolution that provides additional volumes of support services and behavioral health resources to those in need.

4) **OPPOSITION.** The California Association of Health Plans (CAHP) and Association of California Life and Health Insurance Companies (ACLHIC) oppose this bill, stating that current California and federal law require health plans and insurers to provide MH and SUD services at parity with physical health service and this bill seems to undermine those existing protections by imposing an arbitrary limit on services when they are related to a specific event. CAHP and ACLHIC further argue that this bill creates inequities as it would selectively offer additional BH benefits only to individuals residing in counties affected by wildfires. CAHP and ACLHIC continue that this approach is inherently inequitable as it treats those impacted by wildfires differently than individuals affected by other natural disasters, such as floods, earthquakes, or mudslides, many of which have similarly devastating physical and psychological impacts. CAHP and ACLHIC also cite operational and compliance challenges, stating that defining eligibility by county is overly broad, as California counties can be large and not uniformly affected by wildfires. CAHP and ACLHIC continue that this bill would create significant operational challenges for health plans/insurers, requiring them to verify member residency in declared wildfire emergency areas, track overlapping declarations, and administer a specialized benefit structure.

5) **PREVIOUS LEGISLATION.**

   a) SB 221 (Wiener), Chapter 724, Statutes of 2021, codifies existing timely access to care standards for health plans and insurers, applies these requirements to Medi-Cal Managed

Care plans, and adds a standard for non-urgent follow-up appointments for nonphysician MH care or SUD providers that is within 10 business days of the prior appointment.

b) SB 855 (Wiener), Chapter 151, Statutes of 2020, revises and recasts California's MH Parity provisions, and requires a health plan contract or disability insurance policy issued, amended, or renewed on or after January 1, 2021, to provide coverage for medically necessary treatment of MH and SUD, as defined, under the same terms and conditions applied to other medical conditions and prohibits a health plan or disability insurer from limiting benefits or coverage for MH and SUD to short-term or acute treatment. Specifies that if services for the medically necessary treatment of a MH and SUD are not available in network within the geographic and timely access standards in existing law, the health plan or insurer is required to arrange coverage to ensure the delivery of medically necessary out of network services and any medically necessary follow up services, as specified.

6) AUTHORS AMENDMENTS: The authors of this bill have submitted amendments for consideration by the committee that do the following:

a) Exclude individual market health plans and insurers from the provisions of this bill;

b) Prohibit utilization management for the benefits provided under this bill;

c) Require the benefits provided under this bill to apply even if the licensed BH provider is not a contracting provider;

d) Require health plans or insurers to assure continuity of medically necessary care, consistent with existing law;

e) Prohibit enrollees or insureds from paying more than the same cost sharing they would pay for the same covered services received from a contracting BH professional;

f) Require non-contracting providers be paid consistent with the requirements of existing law;

g) Require health plans and health insurers, upon implementation of this bill or within 30 days of when a local or state emergency due to wildfires has been declared, to provide notice to all affected enrollees of the provisions of this bill, as well as their rights under existing law, to receive out-of-network care if in-network care is not available within the time or geographic standards set by law or regulation and the obligation of the plan to arrange such services;

h) Requires the notice in f) to specify that an enrollee or insured's rights and benefits under this section are separate from and distinct from those in existing law, and enrollees can access the services under this bill from any licensed BH provider; and,

i) Make clarifying and technical changes.

REGISTERED SUPPORT / OPPOSITION:

Support

California Behavioral Health Association
California Pan - Ethnic Health Network
California Retired Teachers Association
Mental Health America of California
National Association of Social Workers—California Chapter
National Alliance on Mental Illness (NAMI-CA)

Opposition

Association of California Life & Health Insurance Companies
California Association of Health Plans

Analysis Prepared by: Riana King / HEALTH / (916) 319-2097

Date of Hearing: April 29, 2025

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 1084 (Zbur) – As Introduced February 20, 2025

SUBJECT: Change of name and gender and sex identifier.

SUMMARY: Streamlines the process for legally changing one's name, including a change of name to match a person's gender identity. Contains an urgency clause to ensure that the provisions of this bill go into immediate effect upon enactment. Specifically, **this bill**:

1) Deletes existing law's procedures whereby a person may object to an adult's petition for a change of name for a period of six weeks after the petition is filed with the court.

2) Requires the court to enter an order approving of an adult's petition for a change of name within two weeks of receiving the petition.

3) Requires a court to enter an order approving of a minor's petition for a change of name within two weeks of receiving the petition if all of the minor's living parents have signed the petition.

4) Requires, if a minor's petition for a change of name is not signed by all living parents, the court to direct all persons interested in the matter to make known any objection to the change of name by filing a written objection, which includes any reasons for the objection, within six weeks.

5) Requires an order issued pursuant to 4) above to be served on all living parents who did not sign the petition for a change of name.

6) Provides that a court may only deny a minor's petition for a change of name in the presence of good cause, which cannot be based solely on concerns that the proposed change is not the petitioner's actual gender identity or gender assigned at birth.

7) Exempts all proceedings for a change of name to conform the petitioner's name to the petitioner's gender identity from any requirement for publication.

8) Eliminates the 30-day deadline for filing orders granting a name change with the Secretary of State, State Registrar, and county clerk.

9) Requires the State Registrar, or county clerk, as applicable to issue a new birth certificate or marriage license and certificate within two weeks of receiving an application to update the documents, as specified.

EXISTING LAW:

1) Requires all applications for changes of names to be made in the superior court of the county where the person whose name is to be changed resides by either of the following methods:

   a) By petition signed by the person or, if the person is under 18 years of age, by one of the person's parents, by any guardian of the person; or

b) If both parents are deceased and there is no guardian of the person, then by some near relative or friend of the person, as specified. [Code of Civil Procedure (CCP) § 1276 (a)]

2) Requires, upon the application described in 4) below, the court to make an order reciting the filing of the petition, the name of the person by whom it is filed, and the name proposed, and order all persons interested in the matter to appear before the court at a time and place specified, which is not to be less than 6 weeks nor more than 12 weeks from the time of making the order, unless the court orders a different time, to show cause why the application for change of name should not be granted. [CCP § 1277 (a)(1)]

3) Requires the court to direct all persons interested in the matter described in 4) below to make known any objection that they may have to the granting of the petition for change of name by filing a written objection, which includes the reasons for the objection, with the court at least two court days before the matter is scheduled to be heard and by appearing in court at the hearing to show cause why the petition for change of name should not be granted. [*Ibid*.]

4) Requires the State Registrar to issue a new birth certificate reflecting a change of gender and sex identifier to female, male, or nonbinary without a court order for any person who has a birth certificate issued by this state who submits directly to the State Registrar an application to change the gender and sex identifier on the birth certificate and an affidavit attesting under penalty of perjury that the request for a change of gender and sex identifier to female, male, or nonbinary is to conform the person's legal gender and sex identifier to the person's gender identity and is not made for any fraudulent purpose, as provided. [HSC § 103426]

5) Requires the State Registar, upon receipt of the documentation and a fee, as specified, to establish a new birth certificate reflecting the gender and sex identifier stated in the application and any change in name, if accompanied by a certified copy of the court order for a change of name. [*Ibid*.]

6) Requires the State Registrar to issue a new birth certificate for the minor child or children who have a birth certificate issued by this state without a court order when a parent submits directly to the Registrar specified information, as provided. [*Ibid*.]

7) Requires the State Registrar to issue a new birth certificate for an adult child who has a birth certificate issued by this state without a court order when the parent submits directly to the State Registrar specified information, as provided. [*Ibid*.]

8) Requires the county clerk to issue a new confidential marriage license and certificate for a person who has a confidential marriage license and certificate that was issued from their county without a court order when the person submits specified information, as provided. [*Ibid*.]

9) Provides that a petition for a court order to recognize a change in the petitioner's gender and sex identifier as female, male, or nonbinary and to direct the issuance of new administrative documents to reflect those changes must be accompanied by an affidavit from the petitioner and a certified copy of the court order changing the petitioner's name, if applicable. The petitioner's affidavit must be accepted as conclusive proof of gender change if it contains substantially the following language: "I, (petitioner's full name), hereby attest under penalty of perjury that the request for a change in gender to (female, male, or nonbinary) is to

conform my legal gender to my gender identity and is not for any fraudulent purpose." [Health and Safety Code (HSC) § 103430 (a)]

10) Requires if the person whose gender is to be changed in accordance with 4) is under 18 years of age, the petition must be signed by either of the following:

    a) By at least one of the minor's parents, any guardian of the minor, or a specified person; or

    b) If both parents are deceased and there is no guardian of the minor, by either a near relative or friend of the minor. [HSC §103430 (b)(1)]

11) Requires, if the person whose gender is to be changed in accordance with 4), requests in their petition the issuance of a new marriage license and certificate or confidential marriage license and certificate to be signed by the spouse who shares the marriage license and certificate or confidential marriage license and certificate that would be changed by granting the petition if the spouse is living and capable of signing the petition or, if not signed by a living and capable spouse, notice to be given to the nonsigning spouse. [HSC § 103430 (b)(2)]

12) Provides that if a petition to recognize a change of gender of a minor does not include the signature of all living parents, then upon receipt of the petition, the court must make an order directing the parent or parents who did not sign the petition to show cause as to why the petition for a court order to recognize a change in the minor's gender and sex identifier to female, male, or nonbinary should not be granted by filing a written objection, which includes any reasons for the objection, within six weeks of the making of the order, and state that if no objection showing good cause to oppose the gender recognition is timely filed, the court must, without hearing, enter the order that the gender and sex identifier recognition is granted. [HSC § 103430 (e)(1)]

13) Provides that if a petition to recognize a change of gender of a minor is filed, and all parents are deceased or cannot be located, then upon receipt of the petition, the court must make an order directing the living grandparents to show cause why the petition for a court order to recognize a change in the minor's gender and sex identifier to female, male, or nonbinary should not be granted by filing a written objection, which includes any reasons for the objection, within six weeks of the making of the order, and state that if no objection showing good cause to oppose the gender recognition is timely filed, the court must, without hearing, enter the order that the gender and sex identifier recognition is granted. [HSC § 103430 (e)(2)]

14) Requires, if the person whose gender is to be changed requests in their petition the issuance of a new birth certificate for their adult child the petition must be signed by the child whose birth certificate would be changed by granting the petition if the child is 18 years of age or older. [HSC § 103430 (b)(3)]

15) Requires that if the petition and the order to show cause is made in accordance with 7) or 8) it must be served on the required person or persons who did not sign the petition, as specified, within four weeks from the date on which the order is made by the court, and that if service cannot reasonably be accomplished, the court may order that service be accomplished in a manner that the court determines is reasonably calculated to give actual notice to the person who did not sign the petition. [HSC § 103430 (f)]

16) Provides that, in lieu of separate proceedings, a single petition may be filed with the superior court to change the petitioner's name and recognize the change to the petitioner's gender and sex identifier and, if requested, to order the issuance of a new birth certificate, marriage license and certificate, confidential marriage license and certificate, or birth certificate of the petitioner's child. [HSC § 103435 (a)]

17) Specifies the procedure for alerting various state agencies of a petitioner's successfully approved new name, gender and sex identifier. [HSC § 103435 (b)]

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

COMMENTS:

1) **PURPOSE OF THIS BILL.** According to the author, transgender and nonbinary people across the country are facing relentless attacks that are part of a coordinated effort to both make it more difficult for them to live safely and openly as their authentic selves and to erase transgender people from public life entirely. The author concludes that this bill will help to ensure that transgender and nonbinary people do not experience unnecessary delays in obtaining accurate identification documents in California so that they can better protect themselves from growing legal threats to their safety and wellbeing and reduce their vulnerability to discrimination and harassment.

2) **BACKGROUND.**

   a) **Background.** According to the California Department of Justice, hate crimes motivated by anti-transgender bias increased by 10.2% between 2022 and 2023. According to the University of California, Los Angeles School of Law's *The Williams Institute* report titled, "*Gender Identity Disparities in Criminal Victimization: National Crime Victimization Survey, 2017-18,*" transgender people were over four times more likely to experience violent victimization, including rape, assault, and aggravated or simple assault than their cisgender peers. According to a report titled, "*Early Insights: A Report of the 2022 U.S. Transgender Survey,"* 48% of respondents who had at least one form of identity document (such a birth certificate, passport, or driver's license), said that none of their IDs listed the name they wanted. Twenty percent had the name they wanted on some of their IDs, and 33% had the name they wanted on all their IDs. The report additionally noted that 59% of respondents who had at least one ID said that none of their IDs listed the gender they wanted, 23% said some of their IDs listed the gender they wanted, and 19% said that all their IDs listed the gender they wanted. Further the report noted that 22% of all respondents reported being verbally harassed, assaulted, asked to leave a location, or denied services when they have shown someone an ID with a name or gender that did not match their presentation.

   b) **How does this bill change the judicial process with regard to name changes?** This bill eliminates the ability for a person to object to an adult seeking a legal name change through the courts with the intent of removing unnecessary impediments to legally changing one's name. Additionally, this bill removes the hearing requirement for minors seeking a name change so long as all living parents of the minor sign the petition seeking the change of name. Further, this bill also clarifies and streamlines the requirements for filing the court order granting the name change with the State Registrar, Secretary of State, and county recorder. These provisions were analyzed by the Assembly Committee

on Judiciary (AJUD). According to AJUD's analysis, this bill will reduce the time required to legally process and change of name and gender by at least a month, thus permitting transgender individuals access to new legal documentation in a more timely manner. AJUD's analysis further noted that in light of the recent actions by the federal government to limit transgender person's rights to government documents reflecting their true identity, for example only permitting male or female designations on passports, the need to ensure that transgender individuals can access state documents in an efficient and timely manner outweighs the risk of fraudulent name changes.

c) **Background on California Vital Records.** The California Department of Public Health – Vital Records (CDPH-VR) maintains birth, death, fetal death/still birth, marriage, and divorce records for California. Services provided by CDPH-VR include issuing certified copies of California vital records and registering and amending vital records as authorized by law. AB 218 (Ward), Chapter 577, Statutes of 2021 allows a person to obtain an amendment to the following vital records, to reflect the person's change of gender and sex identifier to female, male, or nonbinary: marriage license and certificate, confidential marriage license and certificate, birth certificate for their minor or adult child. This process does not require a court order if the person submits specific supporting documentation. According to DPH's website, once the amendment is registered, the original record will be sealed and replaced with a new record that reflects the amendment. It should be noted that confidential marriage records must be amended through the county clerk in the county where the license was issued CDPH-VR is funded by fees for certificates outlined in statute. Existing law does not stipulate a required timeline. This bill requires the State Registrar (or county clerk, in the case of a confidential marriage record) to issue updated birth certificates and marriage licenses within two weeks of receiving the required documentation indicating a person has been granted a change of name. This bill also requires the State Registrar to issue a new birth certificate for an adult child who has a birth certificate issued by this state without a court order when the parent submits directly to the State Registrar specified required information. According to DPH's website, DPH's average time to process an amendment request of a vital record is 12 to 14 weeks.

3) **SUPPORT.** Equality California (EC) is the sponsor of the bill and writes, under existing law, an individual seeking a court order recognizing their gender change and changing their legal name must wait a minimum of six weeks for anyone who has an objection to file a written objection with the court. EC continues that the six-week waiting period is burdensome and unnecessary as name and gender change petitions for minors are confidential, and for adults and minors who have consent from both of their parents, there is no notification or publication requirement. EC notes that additionally, birth certificates are a critical identification document used in many settings to verify an individual's identity, and they are often requested for purposes related to education, employment, and family law. EC states that unfortunately, it currently can take anywhere from two to nine months to receive an amended birth or marriage certificate. EC contends that these long wait times put transgender and nonbinary people in extremely vulnerable situations with identification documents that do not accurately reflect their identity. EC continues that this bill will address these challenges by shortening the court processing time for uncontested name and gender change petitions from a minimum of six weeks to a maximum of two weeks. EC further notes that this bill will also require DPH or the county clerk, as applicable, to issue an amended birth or marriage certificate within two weeks if it includes a request to change gender. EC notes that

this bill will eliminate the requirement for a petitioner to file a judgment ordering a new birth or marriage certificate within 30 days from the date of the judgment to allow greater flexibility for petitioners to file their paperwork when it is most feasible based on the circumstances. EC concludes that this bill, The Transgender Records Act, is crucial and timely legislation to ensure that transgender and nonbinary Californians can swiftly obtain accurate state-issued identification documents to protect themselves from growing legal threats and reduce their vulnerability to discrimination and harassment.

4) **OPPOSITION.** Protection of the Educational Rights of Kids-Advocacy (PERK) opposes this bill, stating it could result in name change decisions for minors being made more hastily, without full consideration of the social and legal consequences. PERK continues that minors, especially younger ones, may not fully understand the implications of a name change. PERK notes that it is crucial to ensure that they are emotionally and mentally prepared for such a significant step. PERK states that rushing this decision might lead to confusion, regret, or identity challenges later on, particularly if the child hasn't had time to fully explore their gender identity or personal sense of self. PERK contends that adolescents are still in the process of forming their personal and social identities. PERK argues that a rushed name change could conflict with this ongoing process, especially if the decision is made under pressure or without enough reflection. PERK states that while it's important to support a minor's right to express their identity, a rushed name change can have lasting emotional, legal, and social consequences. PERK concludes that it is critical to ensure that the decision is made thoughtfully, with time for reflection, and with the necessary support in place.

5) **RELATED LEGISLATION.**

   a) AB 1487 (Addis) renames the Transgender, Gender Nonconforming and Intersex Wellness Fund as the Two-Spirit, Transgender, Gender Nonconforming, and Intersex (2TGI) Wellness and Equity Fund. Expands the availability of grant funds to 2TGI-serving organizations for purposes of providing workforce development training for 2TGI individuals, resettlement and social integration programs for 2TGI asylees and immigrants, and diversion programs for, and outreach to, transitional-age 2TGI youth. Revises the definition of "health care" to include mental health services and defines "Two-Spirit" for purposes of these provisions. AB 1487 was heard in Assembly Health Committee on April 22, 2025 and passed with a vote of 12-3.

   b) SB 59 (Wiener) expands the protections of AB 223 (Ward) to persons over 18. The changes apply retroactively to make confidential all records relating to previous name, gender, and/or sex change held by the courts. SB 59 was heard in Senate Judiciary Committee and April 22, 2025 passed with a vote of 11-2.

6) **PREVIOUS LEGISLATION.**

   a) SB 179 (Atkins), Chapter 853, Statutes of 2017 provides for a third gender option on the state driver's license, identification card, and birth certificate; restructures the process for individuals to change their name to conform with their gender identity; and creates a new procedure for an individual to secure a court-ordered change of gender.

   b) AB 223 (Ward), Chapter 221, Statutes of 2023 expands privacy protections for transgender youth by requiring court records pertaining to name and gender marker changes for minors to be made confidential.

c) AB 218 (Ward) creates a process for a petitioner seeking a change of gender to also request that their marriage license and certificate and their children's birth certificates be reissued with updated information about the petitioner.

7) **SUGGESTED AMENDMENT.** This bill requires the State Registrar, or county clerk, as applicable to issue a new birth certificate or marriage license and certificate within two weeks of receiving an application to update the documents, as specified. Given the current 12 to 14 week processing timeline for amendments to vital records, the Committee may wish to extend the proposed timeline to six weeks. Moving forward, the author may also wish to consider working with DPH to determine the most feasible timeline given departmental resources.

8) **DOUBLE REFERRAL.** This bill is double referred, it passed the Assembly Committee on Judiciary with a 9-1 vote on March 25, 2025.

REGISTERED SUPPORT / OPPOSITION:

Support

Alice B. Toklas LGBTQ Democratic Club
Alliance for TransYouth Liberation
API Equality-LA
APLA Health
Asian Americans Advancing Justice-southern California
California Academy of Child and Adolescent Psychiatry
California Latinas for Reproductive Justice
California Legislative LGBTQ Caucus
California LGBTQ Health and Human Services Network
CalPride
CFT, a Union of Educators & Classified Professionals, AFT, AFL-CIO
Courage California
El/La Para Translatinas
Equality California
Flux
Grace Institute - End Child Poverty in CA
LGBTQ + Inclusivity, Visibility, and Empowerment (LIVE)
Los Angeles LGBTQ Center
Oasis Legal Services
Our Family Coalition
PFLAG Los Angeles
PFLAG Newport Beach
PFLAG Oakland-east Bay
PFLAG Sacramento
Sacramento LGBTQ Community Center
San Francisco Aids Foundation
The Source LGBTQ + Center
The Transgender District
Transfamily Support Services
Unique Woman's Coalition

West Hollywood
Two individuals

Opposition

Perk Advocacy
One individual

Analysis Prepared by: Eliza Brooks / HEALTH / (916) 319-2097

Date of Hearing: April 29, 2025

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 1103 (Ward) – As Amended April 10, 2025

SUBJECT: Controlled substances: research.

SUMMARY: Requires the Research Advisory Panel (RAPC) to review research projects that administer Schedule I and Schedule II controlled substances to human research subjects and requires RAPC to prioritize and expedite the review of projects that have sought or received certain federal approvals and have proof of independent peer review of the study, which would include authority of the chairperson to assign two or more panel members to review the research project and to approve it, without a vote by the entire panel. Specifically, **this bill**:

1) Requires RAPC to review research projects conducted in this state that require the administration of Schedule I and Schedule II controlled substances to human or animal research subjects.

2) Requires RAPC to prioritize and expedite the review of project applications containing all of the following:

    a) For all research projects:

        i) Proof of independent peer review of the study by the National Institutes of Health, the United States Department of Defense, the Heffter Research Institute, the United States National Science Foundation, or a comparable group; and,

        ii) A Schedule I research registration issued by the United States Drug Enforcement Administration (DEA), an approval from the DEA for a research registration that is conditional on the approval of RAPC, or a copy of the application for a research registration submitted to the DEA.

    b) For projects with human subjects:

        i) If approval by the United States Food and Drug Administration (FDA) of an investigational new drug (IND) application is otherwise required by law, the application must include a letter from the FDA approving the application for an IND, a letter from the FDA indicating that the study may proceed, documentation that the 30-day statutory period for the FDA to respond to a project's submission of an application for approval of an IND has expired, or a signed copy of FDA IND application; and,

        ii) An approval letter from a federally chartered institutional review board (IRB) of all study documents demonstrating that the board has considered relevant federal and state laws regarding the use of human subjects.

    c) For projects with animal subjects: An approval letter from an institutional animal care and use committee (IACUC) established pursuant to federal law of all study documents demonstrating that the IACUC has considered relevant federal and state laws regarding

for the use of live, vertebrate animals in the research project, and their humane treatment in compliance with all applicable state and federal regulations.

3) Requires applications for research projects that do not satisfy the expedited review criteria in 2) above to be reviewed pursuant to the standard review process and approved by a vote of the full panel. Requires the posting of the RAPC expedited review criteria and process on the RAPC website.

4) Requires the Attorney General (AG) to continue to employ an executive officer of RAPC.

5) Authorizes the RAPC chairperson, in consultation with the RAPC executive officer, to assign two or more RAPC members to conduct an expedited review of eligible research applications and approve them on behalf of the panel without the need for a full panel vote at a regularly scheduled bimonthly meeting.

6) Authorizes RAPC members to communicate and consult asynchronously with RAPC members with complementary core competencies outside of RAPC meetings in order to conduct their individual reviews and approvals.

7) Limits RAPC's current authority to withdraw approval of a research project to only circumstances in which RAPC has substantial concerns about the safety and well-being of human research subjects or substantial concerns that controlled substance research samples are being diverted. Requires RAPC to communicate written concerns in a notice of pending withdrawal to the head of a research project including a course of action to address the concerns and a reasonable period in which to cure, not less than 10 days prior to the effective date of the withdrawal. Requires approval to be reinstated if the concerns are addressed.

8) Extends the current authorization of RAPC to hold closed sessions for the purpose of discussing, reviewing, and approving research projects that contain sensitive and confidential information, including trade secrets, intellectual property, or proprietary information in its possession, the public disclosure of which is prohibited by law, from January 1, 2027 to January 1, 2029. Makes Legislative findings about the need to limit public access to the meetings of RAPC.

EXISTING LAW:

1) Establishes RAPC as an independent panel to encourage further research into the nature and effects of cannabis and hallucinogenic drugs and to coordinate research efforts on such subjects. Permits RAPC to hold hearings and approve research projects, which have been registered by the AG, concerning cannabis or hallucinogenic drugs, or the treatment of abuse of controlled substances in the state. Permits RAPC to withdraw approval of a research project at any time. [Health & Safety Code (HSC) § 11480 and § 11481]

2) Requires RAPC to annually, and in the manner determined by RAPC, report to the Legislature and the Governor those research projects approved by RAPC, the nature of each research project, and where available, the conclusions of the research project. [HSC § 11480]

3) Permits people who are entitled to use controlled substances for the purpose of research, instruction, or analysis, to lawfully obtain and use those substances upon approval by RAPC in bona fide research, instruction, or analysis. [HSC § 11213]

4) Permits the AG, with the approval of RAPC, to authorize persons engaged in research on the use and effects of controlled substances to withhold the names and other identifying characteristics of individuals who are the subjects of the research, and prohibits them from being compelled in any civil, criminal, administrative, legislative, or other proceedings to identify the individuals who are the subjects of research for which the authorization was obtained. [HSC § 11603]

5) Permits the AG, with the approval of RAPC, to authorize the possession and distribution of controlled substances by persons engaged in research and exempts those persons from state prosecution for possession and distribution of controlled substances to the extent of the authorization. [HSC § 11604]

6) Establishes the experimental subjects bill of rights. [HSC § 24172]

7) Requires that experimental subjects provide their informed consent, voluntarily and freely given, prior to any medical experiment being undertaken. Defines informed consent to include, but not be limited to, being provided both verbally and in the written consent form, in nontechnical terms and in a language the subject is fluent in, a number of enumerated facts regarding the proposed experiment, which might influence the decision to undergo the experiment. [HSC § 24173]

8) Exempts from state informed consent requirements any person who is conducting a medical experiment as an investigator within an institution that holds an assurance with the United States Department of Health and Human Services pursuant to Part 46 of Title 45 of the Code of Federal Regulations and who obtains informed consent in the method and manner required by those regulations. [HSC § 24178]

9) Establishes the Bagley-Keene Open Meeting Act (Bagley-Keene), which requires state bodies to conduct their business in open public meetings, except as provided by Bagley-Keene, and establishes requirements and procedures for such meetings. [Government Code (GOV) § 11120, *et seq.*]

10) Prohibits Bagley-Keene from being construed to prevent various state bodies from holding closed sessions for specified purposes. [GOV § 11126]

11) Defines a "state body" as each of the following:

    a) Every state board, or commission, or similar multimember body of the state that is created by statute or required by law to conduct official meetings and every commission created by executive order;

    b) A board, commission, committee, or similar multimember body that exercises any authority of a state body delegated to it by that state body;

    c) An advisory board, advisory commission, advisory committee, advisory subcommittee, or similar multimember advisory body of a state body, if created by formal action of the state body or of any member of the state body, and if the advisory body so created consists of three or more persons; or,

d) A board, commission, committee, or similar multimember body on which a member of a body that is a state body pursuant to this section serves in his or her official capacity as a representative of that state body and that is supported, in whole or in part, by funds provided by the state body, whether the multimember body is organized and operated by the state body or by a private corporation. [GOV § 11121]

12) Defines Schedule I-V drugs for the purposes of state law. [HSC § 11053, *et seq.*]

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

COMMENTS:

1) **PURPOSE OF THIS BILL.** According to the author, this bill would expedite the AG's mandatory review and required approval of substance use disorder research and other clinical research projects to be conducted at California institutions, including clinical trials administering Schedule I and II psychedelics (as well as other hallucinogens and cannabis) to treat opioid use disorders, traumatic brain injury, post-traumatic stress disorder, and other mental health conditions fueling the disproportionate incidence of suicide among California veterans. The author states that eliminating any and all unnecessary delays in commencing such clinical research in California will save lives.

2) **BACKGROUND.**

   a) **RAPC.** Research entities seeking to conduct research projects concerning cannabis or hallucinogenic drugs in California must submit their research proposals to the RAPC prior to receiving a DEA license to use controlled substances in a research project. These researchers are affiliated with public and private research universities, as well as private pharmaceutical companies and drug manufacturers. RAPC evaluates the scientific validity of each proposed project, and may reject proposals where the research is poorly conceived, would produce conclusions of little scientific value, or would not justify the exposure of human subjects in California to the risk of the proposed controlled substance exposure. Members of the panel are experts in their fields, and are appointed by the Governor, the Department of Public Health, the State Board of Pharmacy, the University of California, a statewide professional medical society, a private medical university, and the AG. The California Department of Justice (DOJ) provides administrative and legal support to the RAPC. RAPC's work complements a regulatory approval process that includes IRBs, the FDA, and DEA review of controlled substance research studies using Schedule I and II controlled substances, or that involve new treatments for misuse of substances, such as fentanyl and other opioids. While the FDA and DEA are government institutions, IRBs are institutional entities registered with the FDA and charged with providing ethical oversight of research involving human subjects.

   b) **Bagley-Keene**. Bagley-Keene applies to all state boards and commissions, and requires these entities to publicly notice their meetings, prepare agendas, accept public testimony, and conduct their meetings in public, unless authorized to meet in closed session. Bagley-Keene covers multimember bodies and advisory bodies. Examples of entities covered by the act are: state boards; commissions; committees; panels; councils; advisory bodies created by the Legislature; and, advisory bodies having three or more members that are created by formal action of another body. The only gatherings of members of a body that are exempt from Bagley-Keene are social gatherings and conferences. Entities are

required to provide notice of a meeting to any person who requests notice in writing, and are required to make the notice available on the Internet at least ten days in advance of the meeting. Notices are required to include the name, address, and telephone number of any person who can provide further information prior to the meeting and an agenda, including a brief description of the items of business to be transacted or discussed in either open or closed session, as specified. Upon request, entities are required to provide a person notice for all meetings of a state body or for a specific meeting or meetings. Notices are required to be made available in appropriate alternative formats that comply with the Americans with Disabilities Act of 1990 and the relevant related federal rules and regulations, as specified.

c) **RAPC meetings halt because of interpretation of Bagley-Keene**. A January 2024 article in the *San Francisco Chronicle* noted that a group of more than 70 leading addiction researchers and advocates sent a letter to Governor Newsom, California AG Rob Bonta, and state lawmakers requesting a dissolution of RAPC, which they called a nonviable obstruction to essential research and public health activities in California. The letter argued the cost of the RAPC delays is immense, entirely unique to California, and limiting the state's capacity to respond to health crises tightly intertwined with homelessness. The *San Francisco Chronicle* story states this extra regulatory step delays trials by five to 10 months, costing taxpayers hundreds of thousands of dollars and leading some study funders to abandon California entirely. RAPC traditionally meets bimonthly, but it had not held a meeting from August 2023 to July 2024. A story in the *Los Angeles Times* in May 2024 stated that RAPC had long met behind closed doors to make its decisions, but concerns arose last year that it was supposed to fall under Bagley-Keene. The story states that holding those meetings in public raised alarm about exposing trade secrets and other sensitive information, so RAPC stopped meeting at all. The result was a ballooning backlog which, according to the author's office, has been completely addressed after AB 2841 (Waldron), Chapter 156, Statutes of 2024, gave RAPC an exemption to Bagley-Keene in order to address one barrier to them meeting.

d) **Scientific review of research proposals.** Research proposals are reviewed by several entities before they are ultimately approved. The steps in this approval process can vary based on the subject of the research. Human subjects, animal subjects, and In-Vitro studies dealing with Schedule I and II controlled substances in California are all approved their funder, the DEA, and RAPC at a minimum. Research on human subjects must also be approved by an IRB. In practice, all of these approvals and reviews happen before the proposal is reviewed by RAPC. Following RAPC approval, the study is then subject to continuous monitoring by the IRB, DEA, FDA, and RAPC.

    i) **FDA.** For clinical drug trials, the FDA requires an IND application, which is a request for authorization from the FDA to administer an investigational drug or biological product to humans. The FDA defines a clinical investigation as any experiment in which a drug is administered or dispensed to, or used involving, one or more human subjects. An experiment is any use of a drug except for the use of a marketed drug in the course of medical practice. The sponsor is any person who takes responsibility for and initiates a clinical investigation. The sponsor may be an individual of a pharmaceutical company, government agency, academic institution, private organization, or other organization.

The FDA is responsible for reviewing the pre-clinical pharmacology and toxicology, chemistry and manufacturing, and previous human data (if available) under an IND application. The FDA has two primary objectives in reviewing an IND: 1) To assure the safety and rights of subjects in all phases of an investigation, and 2) to help assure that the quality of the scientific evaluation of the drug is adequate to permit an evaluation of the drug's effectiveness and safety in phases two and three studies.

ii) **DEA.** For pharmaceutical controlled substances, the DEA's responsibility is twofold: to prevent diversion and abuse of these substances while ensuring an adequate and uninterrupted supply is available to meet the country's legitimate medical, scientific, and research needs. The DEA works closely with state and local authorities and other federal agencies to carry out this responsibility. According to the DEA, there are two separate categories for researcher registration which are based on controlled substance schedules: a schedule I researcher and a schedule II-V researcher. If a researcher wishes to conduct research in schedules I and schedules II-V, they must obtain two separate registrations. The DEA may require a state license to conduct research and/or a state controlled substance registration, if applicable, to be obtained before issuing a federal registration.

A schedule I research protocol must include the name, address, and DEA registration number of the investigator, as well as their institution or company and their qualifications. The protocol must also include the purpose of the research project, the controlled substances involved, including the amount needed (with justification) and the source, a detailed description of the research procedures, the dosages to be administered, the method of administration, the location of the study, a statement of security provisions for handling the substances, and a manufacturing or import statement.

iii) **IRB.** According to the University of California (UC), IRBs are administrative committees designated to provide ethical and regulatory oversight of research that involves human subjects. IRBs exist to protect the rights, safety, and welfare of human subjects involved in research projects, consistent with ethical principles and federal, state, and local regulations. IRBs are enacted under federal regulation (45 CFR 46) and are regulated by the Office for Human Research Protections within the U.S. Department of Health & Human Services.

iv) **IACUC.** An IACUC is required by federal regulations for most institutions that use animals in research, teaching, and testing. The IACUC has a key oversight role, including the review and approval of animal use activities, and inspection of animal facilities. The principal investigator or instructor, and their staff, are responsible for understanding and following the regulations, as well as institutional policies, governing animal care and use. Members of each IACUC are appointed by the chief executive of the research facility, and must include at least one Doctor of Veterinary Medicine, with training or experience in laboratory animal science and medicine, who has direct or delegated program responsibility for activities involving animals at the research facility, and at least one member not affiliated in any way with the facility other than as a member of the IACUC, to provide representation for general community interests in the proper care and treatment of animals.

3) **SUPPORT.** Veterans Exploring Treatment Solutions (VETS) is sponsoring this bill and states in support that it will maintain the proper safety and oversight function of RAPC while eliminating statutory burdens that slow the ability of the panel to approve research. VETS applauds the commitment of individual RAPC panel members to facilitate life-saving research, but recognizes existing statutory requirements that slow the work of RAPC, slow the approval of research, and ultimately slow the development of life-saving treatments for veterans experiencing suicidality and other mental health conditions. VETS argues that we desperately need to accelerate the development of more effective treatments for service-related injuries and mental health conditions fueling the disproportionate incidence of suicide among veterans.

   Smart Justice also supports this bill arguing it comes at a critical time when the Trump Administration is making cuts to Medicaid and other federal programs that will impact treatment programs in California for mental health and substance use disorder. California must treat addiction and mental health treatment as a public health emergency. Smart Justice argues that removing burdensome administrative barriers from the ability to commence clinical research in California will expedite new and more effective FDA-approved treatments that will save lives that might otherwise be lost due to effective treatments arriving too late.

4) **PREVIOUS LEGISLATION.** AB 2841 (Waldron), Chapter 156, Statutes of 2024, authorizes RAPC, until January 1, 2027, to meet in closed session for the purpose of discussing, reviewing, and approving research projects that require the sharing of trade secrets, potential intellectual property, or proprietary information in its possession, the public disclosure of which is prohibited by law.

5) **POLICY COMMENT.** Last year the Legislature granted a temporary exemption from Bagley-Keene to allow RAPC to resume meetings and address a backlog of research applications. Since resuming meetings, RAPC has tested an expedited review, similar to the process proposed in this bill, for amended research applications. This bill seeks to codify an expedited process for review and approval of new research applications as well. While this process may streamline and improve the operations of RAPC, it may not address the broader concern raised by researchers in 2023 about the continued utility of RAPC. However, without RAPC as an additional layer of approval, research approved in the state may disproportionately reflect federal priorities and policy goals, rather than those of California. Should this bill move forward, the author should continue discussions with research institutions regarding the practical implementation of the expedited review from the researcher perspective.

6) **AMENDMENTS.** The committee may wish to amend this bill to shorten the proposed Bagley-Keene exemption extension by one year to 2028 and repeal the expedited review process on the same date to allow the Legislature to reassess RAPC in two years. The committee may also wish to clarify that RAPC can continue to withdraw approval of an application for reasonable cause, but the panel must provide researchers with notice of their concerns and an opportunity to address them, and to clarify that RAPC may reinstate approval upon these concerns being addressed, but is not required to reinstate approval. Finally, the committee may wish to make a corresponding change to HSC § 11480.5 to extend the sunset date to January 1, 2028 to match the Bagely-Keene exemption extension.

REGISTERED SUPPORT / OPPOSITION:

Support

Veterans Exploring Treatment Solutions (Sponsor)
Biocom California
Navy Seal Foundation
Smart Justice California, a Project of Tides Advocacy
The American Legion

Opposition

None on file

Analysis Prepared by: Logan Hess / HEALTH / (916) 319-2097

Date of Hearing: April 29, 2025

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 1113 (Mark González) – As Amended April 10, 2025

SUBJECT: Federally qualified health centers.

SUMMARY: Requires each federally qualified health center (FQHC) to have an annual "mission spend ratio," as defined, of no less than 90% and would provide a methodology for calculation of that ratio, as specified, until the Department of Public Health (DPH) has adopted a methodology for this purpose. Requires DPH to adopt that methodology, as specified, sufficient for implementation by January 1, 2027. By June 30, 2026, and annually thereafter by June 30, requires each FQHC or its parent corporation to report to DPH total revenues collected in a form to be determined by DPH. Exempts an FQHC participating in a bona fide labor-management cooperation committee (LMCC) from the requirements of this bill. Specifically, **this bill**:

1) Requires each FQHC to have an annual "mission spend ratio" of no less than 90%.

2) Specifies that, until DPH has adopted a methodology for this purposes of calculating the mission spend ratio, pursuant to 4) below, an FQHC's total revenue from all payer sources means the FQHC's total revenue for the calendar year, calculated consistent with Line 12 of Part I of Internal Revenue Service (IRS) Form 990, as set out in the form and instructions applicable to the 2024 taxable year. *(Line 12 of part I of IRS Form 990 is used to provide information on grants and other assistance made by the filing organization during the tax year to domestic organizations, domestic governments, and domestic individuals. The form helps nonprofits keep their tax-exempt status and demonstrate transparency to donors and the IRS.)*

3) Requires, until DPH has adopted a methodology for this purpose pursuant to 4) below, for the calculation of the mission spend ratio of each FQHC in the 2026 calendar year, "mission-directed expenses" to be the total program service expenses reported under Line 25 of Column B of Part IX of IRS Form 990, as set out in the form and instructions applicable to the 2024 taxable year.

4) Requires for the calculation of the mission spend ratio of each FQHC in the 2027 calendar year and all subsequent years, DPH to adopt a methodology to determine the expenses associated with activities that further an FQHC's patient services mission, consistent with this section. Requires, if the department has not adopted a methodology for implementation by January 1, 2027, then the specified methodology to continue to be used until the department has adopted a methodology.

5) Requires, by June 30, 2026, and annually thereafter by June 30, each FQHC or its parent corporation to report total revenues collected from all revenue sources, along with the portion of revenues that are expended on all mission-directed expenses, to DPH in a form to be determined by DPH. Requires each report to include, at a minimum:

    a) The FQHC or parent corporation's filed IRS Form 990, 990-PF, 990-EZ, or 1120, from the most recent taxable year, with all attachments and schedules as applicable, in the

same form as filed with the IRS, along with a list identifying which FQHC's activities are included in the information on the IRS form.

b) A copy of the annual report filed for each FQHC with the Department of Health Care Access and Information (HCAI) pursuant to existing state law;

c) A certification signed by a duly authorized official of the FQHC or its parent corporation that certifies that, to the best of the official's knowledge and information, each statement and amount in the accompanying report is believed to be true and correct; and,

d) For any FQHC that is required to prepare an annual financial statement, as specified, certification from an independent certified public accountant that the report submitted has been audited in conformity with generally accepted auditing standards.

6) Requires each FQHC to submit an annual registration fee in an amount to be determined by DPH and adjusted as necessary to fund the activities set forth in this bill.

7) Requires DPH, no later than 90 days after the deadline for receipt of each FQHC's submission of the report described in 5) above, to calculate the mission spend ratio for each FQHC and prepare a report of the mission spend ratios of every FQHC. Requires DPH to transmit the report to the subunit of the Department of Health Care Services (DHCS) responsible for conducting Change in Scope-of-Service Request (CSOSR) audits.

8) Requires DPH to publish the report of the mission spend ratios of every FQHC on its internet website.

9) Requires DPH to conduct an audit of the financial information reported by FQHCs pursuant to this bill every three years, in a manner and form prescribed by DPH, to ensure the accuracy of the information reported and compliance with the requirements of this section. Authorizes these audits to also include any audits of contractors or related party entities.

10) Prohibits, notwithstanding any other provision to the contrary, the requirements of this bill from applying to any FQHC participating in a bona fide LMCC.

11) Defines the following for purposes of this bill:

a) "Bona fide labor-management cooperation committee" or "bona fide LMCC" to mean a statewide, multiemployer joint labor-management committee that is established pursuant to the federal Labor Management Cooperation Act of 1978 and meets the following criteria:

i) The bona fide LMCC is not involved in the governance of an FQHC but exists to promote worker training, workforce expansion, and support for workers during training;

ii) The bona fide LMCC has the following composition:

(1) Fifty percent of the committee consists of representatives of organized labor unions that represent health center workers in the state;

(2) Fifty percent of the committee consists of representatives of FQHCs located in the state; and,

(3) The membership of the bona fide LMCC includes one or more labor organizations that are certified or recognized as the exclusive bargaining representative of applicable workers at FQHCs in the state.

b) "FQHC" to mean any community or public federally qualified health center as that term is defined in federal law, including FQHC look-alikes;

c) "FQHC look-alike" to mean an organization that does not receive an FQHC award, but is designated by the federal Health Resources and Services Administration (HRSA) as meeting FQHC program requirements, as set forth in federal law. Clarifies that for purposes of this bill, an FQHC look-alike is considered an FQHC and all references to FQHCs apply with equal force to FQHC look-alikes;

d) "Mission-directed expenses" to mean expenses associated with activities that further an FQHC's patient services mission and for which the FQHC was created to conduct, and that "mission-directed expenses" include all of the following:

i) The total compensation for all staff employed by the FQHC, including salaries, wages, and employee benefits, but excluding all compensation for executive and administrative officers and employees. Specifies that employee benefits include payroll benefits, paid time off, health insurance, life insurance, pension and retirement, and workers' compensation insurance;

ii) The cost of consumable supplies that are used to provide patient care;

iii) Outside patient care services, which includes expenses associated with patient care services purchased under contract from any entity, including a hospital, laboratory, or physician group;

iv) Professional liability insurance;

v) Continuing education, which includes the total cost of providing continuing education classes for health care professionals; and,

vi) Capital expenditures that directly relate to patient care services, including rent, mortgage interest, depreciation, property taxes, property insurance, utilities, and other capital expenditures determined by DPH.

e) Specifies that "Mission-directed expenses" do not include any of the following:

i) Administrative costs, including compensation paid to management and executive officers and employees, all costs to management companies, administrative service companies, home office expenses for parent companies and holding companies, legal expenses, trade association fees and dues, insurance costs, licensing fees, and all administrative costs and profits paid to contractors or related party entities for staffing services, ancillary services, support services, or other services;

ii) Capital expenditures that relate to administrative, overall operations or management purposes, including rent, mortgage interest, depreciation, property taxes, property insurance, utilities, and other capital expenditures determined by DPH; and,

iii) Profits, including net income and any profit paid to related parties on leases and property, and any profits paid to management companies.

f) "Mission spend ratio" to mean the percent of an FQHC's total revenue from all payer sources in a calendar year expended on mission-directed expenses; and,

g) "Related party" to means an organization related to the FQHC or that is under common ownership or control, as those terms are defined in Section 413.17(b) of Title 42 of the Code of Federal Regulations. includes in the related party definition, a management organization, owners of real estate, entities that provide staffing, any parent companies, holding companies, sister organizations, and others.

12) Continues in the Special Deposit Fund, the Mission Spend Ratio Penalty Account, subject to appropriation by the Legislature. Requires the account to contain all moneys deposited pursuant to 13) and 14), below.

13) Requires DPH to impose sanctions for the failure to comply with the reporting provisions of this bill, in the form of an administrative fine of five thousand dollars ($5,000) for a first violation and ten thousand dollars ($10,000) for each subsequent month that an FQHC fails to submit annual reports as required.

14) Requires, if DPH determines that an FQHC has not met the required mission spend ratio for any reporting year, DPH to assess an administrative penalty equal to the difference between the amount of the FQHC spent on mission-directed expenses and 90% of the FQHC's total revenue that year.

15) Prohibits any penalties paid pursuant to this bill from being considered mission-directed expenses for the calculation of the FQHC's mission spend ratio in the year the penalty was incurred.

16) Requires, if the FQHC does not dispute the determination or assessment, the penalties to be paid in full to DPH within 30 days of receipt of a notice of penalty and deposited into the Mission Spend Ratio Penalty Account. Requires if the FQHC disputes the determination or assessment made pursuant to this subdivision, the FQHC to, within 30 days of the FQHC's receipt of the determination or assessment, simultaneously submit a request for appeal to both DPH and DHCS. Requires the request to include a detailed statement describing the reason for appeal and include all supporting documents the FQHC will present at the hearing.

17) Requires DPH, within 30 days of receipt of the request for appeal, to submit, to both the FQHC and DHCS, its responsive arguments and all supporting documents that DPH will present at the hearing. Requires DHCS to timely hear an appeal and issue a decision as follows:

a) The hearing to commence within 60 days from the date of receipt by DHCS of the FQHC's timely request for appeal;

b) DHCS to issue a decision within 120 days from the date of receipt by DHCS of the FQHC's timely request for appeal; and,

c) The decision of the DHCS' hearing officer, when issued, to be the final decision of DPH.

18) Makes the appeals process described in 17) above exempt from the administrative adjudication provision of the Administrative Procedure Act.

19) Authorizes an FQHC to apply to DPH for a waiver providing a temporary pause of the mission spend requirements or for an alternative mission spend ratio requirement, on the basis of unexpected or exceptional circumstances or the FQHC's economic condition. Makes the issuance and terms of the waiver pursuant to be solely and exclusively within the authority of DPH. Requires a waiver issued pursuant to this provision to be for a term of one year from the date of issuance.

20) Requires, in order to obtain a waiver based on unexpected or exceptional circumstances, an FQHC to detail the following circumstances experienced by the FQHC:

a) When the FQHC first learned of the unexpected or exceptional circumstances;

b) Why the FQHC could not have anticipated those circumstances arising;

c) Actions the FQHC took to address those circumstances;

d) Expenses incurred as a result of addressing those circumstances;

e) When the FQHC expects those circumstances to be resolved; and,

f) Preventive steps the FQHC is taking to ensure that those circumstances do not unexpectedly arise in the future.

21) Requires, in order to obtain a waiver based on economic condition, an FQHC to demonstrate that compliance with the mission spend requirements would raise doubts about the FQHC's ability to continue as a going concern under generally accepted accounting principles. Requires the evidence to include documentation of the FQHC's financial condition, the financial condition of any parent or affiliated entity, and evidence of the actual or potential direct financial impact of compliance with the mission spend ratio.

22) Requires consideration of an FQHC's ability to continue as a going concern to include the following factors regarding the FQHC or any affiliated entity:

a) Actual or likely closure of the FQHC or any affiliated entity;

b) Actual or likely closure of patient services or programs;

c) Actual or likely loss of jobs;

d) Whether the FQHC is small, rural, frontier, or serves a rural catchment area;

e) Whether closure of the FQHC would significantly impact access to services in the region or service area; and,

f) Whether the FQHC is in financial distress that results or is likely to result in the closure of the FQHC or any affiliated entity, closure of patient services or programs, or loss of jobs. Specifies that factors to consider in determining financial distress include, but are not limited to, the FQHC's prior and projected performance on financial metrics, including the amount of cash on hand, and whether the FQHC has, or is projected to experience, negative operating margins.

23) Requires requests for a waiver based on economic conditions to be submitted in writing to DPH.

24) Requires DPH to notify the FQHC of the decision on the waiver request in writing. Authorizes an FQHC to apply to renew a waiver issued pursuant to 21) above at any time no fewer than 180 days before the expiration of the existing waiver.

25) Exempts any FQHC participating in a bona fide LMCC, as defined, from the provisions described above.

26) Requires DPH to adopt all regulations necessary to implement this bill. Authorizes DPH to implement, interpret, or make specific the bill's provisions, in whole or in part, by means of information notices, all-county letters, or other similar instructions without taking regulatory action.

27) Makes the provisions of this bill severable. States that if any provision of this act or its application is held invalid, that invalidity does not affect other provisions or applications that can be given effect without the invalid provision or application.

EXISTING LAW:

1) Establishes the Medi-Cal Program, administered by DHCS, to provide comprehensive health benefits to low-income individuals who meet specified eligibility criteria. [Welfare and Institutions Code (WIC) § 14000 *et seq*.]

2) Requires FQHC services to be covered benefits under the Medi-Cal program and requires these services to be reimbursed on a per-visit basis, as defined. [WIC § 14132.100]

3) Establishes the HCAI in the California Health and Human Services Agency to expand equitable access to quality, affordable health care for all Californians through resilient facilities, actionable information, and the health workforce each community needs. [Health and Safety Code (HSC) § 127000, *et seq*.]

4) Requires every clinic holding a license to, on or before the 15th day of February each year, file with HCAI, upon forms to be furnished by HCAI, a verified report showing the following information relating to the previous calendar year:

   a) Number of patients served and descriptive information, including, but not limited to, age, gender, race, and ethnic background of patients;

   b) Number of patient visits by type of service, including all of the following:

      i) Child health and disability prevention screens, treatment, and follow-up services;

ii) Medical services;

iii) Dental services;

iv) Other health services;

v) Total clinic operating expenses;

vi) Gross patient charges by payer category, including Medicare, Medi-Cal, the Child Health Disability Prevention Program, county indigent programs, other county programs, private insurance, self-paying patients, nonpaying patients, and other payers;

vii) Deductions from revenue by payer category, bad debts, and charity care charges; and,

viii) Additional information as may be required by HCAI or DPH. [HSC § 1216]

5) Requires, commencing January 1, 2027, every clinic holding a license and, every intermittent clinic operated by a licensed clinic and exempt from licensure to file with HCAI a verified report showing the following information relating to the previous calendar year:

a) Number of patients served and descriptive information, including, but not limited to, age, sex, race, ethnicity, preferred language spoken, disability status, sexual orientation, gender identity, and payor category. Prohibits a clinic from being subject to any adverse action for not providing sexual orientation and gender identity information if the patient refused to provide that information;

b) Number of patient visits by type of service, including all of the following:

i) Child health and disability prevention screens, treatment, and follow up services;

ii) Medical services;

iii) Dental services; and,

iv) Other health services.

c) Requires primary care clinics participating in the Medi-Cal program or county indigent programs to include the following:

i) Number of assigned members per Medi-Cal managed care plan and county indigent program;

ii) Number of assigned members per Medi-Cal managed care plan and county indigent program that had one or more clinic visits;

iii) Total clinic operating expenses;

iv) Gross patient charges by payer category, including Medicare, Medi-Cal, the Child Health Disability Prevention Program, county indigent programs, other county

programs, private insurance, self-paying patients, nonpaying patients, and other payers;

v) Deductions from revenue by payer category, bad debts, and charity care charges;

vi) Average weekly number of clinic operating hours and whether or not the clinic is licensed or intermittent; and,

vii) Additional information as may be required by the department or the State Department of Public Health. [HSC § 128905]

6) Authorizes, under federal labor law, the Federal Mediation and Conciliation Service (Service) to provide assistance in the establishment and operation of plant, area and industrywide labor management committees which:

a) Have been organized jointly by employers and labor organizations representing employees in that plant, area, or industry; and,

b) Are established for the purpose of improving labor management relationships, job security, organizational effectiveness, enhancing economic development or involving workers in decisions affecting their jobs including improving communication with respect to subjects of mutual interest and concern. [Title 29, United States Code § 175a]

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

COMMENTS:

1) **PURPOSE OF THIS BILL.** According to the author, this bill is a key component of a broader legislative effort to put the health of our communities' front and center. The author states that when our health is supported, our students can thrive, working families can succeed, and our seniors can age with dignity. The author continues that at a time when many Californians face growing challenges, we must ensure that the institutions responsible for community health are transparent and accountable. The author argues that this bill affirms the importance of directing resources where they're needed most—toward patient care and the dedicated workforce that makes it possible. The author concludes that this bill promotes a standard of stewardship that ensures community clinic funding is aligned with the mission of serving those most in need.

2) **BACKGROUND.**

a) FQHCs. FQHCs are federally designated clinics that provide primary care services to serve medically underserved populations. Pursuant to federal requirements, health centers must meet specified requirements, including being located in or serving a medically underserved area or population, provide comprehensive primary care services furnished regardless of ability to pay, and governance by a community-based board that meets certain composition requirements (including a board composed of a majority of individuals who are served by the health center) that exercises specified authorities.

Medi-Cal reimbursement to FQHCs is governed by state and federal law. FQHCs are reimbursed by Medi-Cal on a per-visit rate (prospective payment systems) which is

known as the PPS rate for services provided by specific providers listed in statute. Each FQHC has a specific Medi-Cal PPS rate for each face-to-face encounter, irrespective of the reason for the visit. For Medi-Cal managed care (MCMC) plan patients, DHCS reimburses FQHCs for the difference between its per-visit PPS rate and the payment made by the plan. This payment is known as a "wrap around" payment. The MCMC wrap-around rate was established to reimburse providers for the difference between their PPS rate and their MCMC reimbursement rate. The rationale for the enhanced reimbursement is to ensure that FQHCs do not use federal grant funds intended for the uninsured and special needs populations to back-fill for potentially below-cost Medicare or Medi-Cal rates.

The mean and median PPS rate for FQHC services, as calculated based on DHCS's December 2024 Rates Sheet for clinic rates, is approximately $291 and $262, respectively. According to the DHCS' November 2024 Medi-Cal Local Assistance Estimate, clinics receive an annual rate adjustment based on the percentage increase in the Medicare Economic Index and is effective October 1st of each year. In addition, an FQHC can apply for an adjustment to its per-visit rate based on a change in the scope of services provided by the FQHC.

b) **Medical Loss Ratios (MLR).** The Patient Protection and Affordable Care Act (ACA) requires health insurance issuers to submit data on the proportion of premium revenues spent on clinical services and quality improvement, also known as the Medical Loss Ratio (MLR). It also requires them to issue rebates to enrollees if this percentage does not meet minimum standards. The ACA requires insurance companies to spend at least 80% or 85% of premium dollars on medical care. If an issuer fails to meet the applicable MLR standard in any given year, as of 2012, the issuer is required to provide a rebate to its customers. The 90% "mission spend ratio" in this bill appears to be based on MLR requirements.

c) **Nonprofit Health Center Spending Rules.** Federal and state law requires community health centers and clinics to focus on their healthcare mission. By definition, community health centers and clinics must be nonprofit or public entities. Under IRS 501(c)(3) rules, an organization must operate exclusively for charitable (health) purposes, and cannot distribute profits to private individuals. Surplus funds are reinvested in expanding services or improving care.

d) **Current Clinic Reporting Requirements.** Health centers and clinics are regulated by both the federal and state government and have extensive reporting requirements including audits that detail how resources are spent on patient care. The federal HRSA provides oversight of grants and ensures administrative costs are reasonable. One of HRSA's monitoring roles includes reviewing that a community health center or clinic's budget and spending align with project goals, and that administrative expenses are proportional. Medicare cost principles also allow CMS to impose a cap or adjustment if "the level of administrative and general expenses" is excessive.

Community health centers and clinic federal grantees also report data to HRSA annually as part of Uniform Data System (UDS) reporting, including total revenues (by source) and total expenditures (by category). HRSA uses this data to assess each health center's performance and financial soundness. Community health centers and clinics must also

submit their independent audit results to HRSA each year. These audits contain financial statements and a schedule of federal program expenditures. This bill also requires DPH to conduct independent audits every three years.

This bill requires clinics to file their IRS Form 990 or equivalent to the state every year, a document they already file with the federal government annually, which are public documents available via IRS or charity databases. The Form 990 discloses executive compensation, program vs. administration expense breakdown, and related-party transactions – all information this bill is asking to be submitted to the state.

California also has oversight of clinic finances through HCAI. Licensed community clinics must file annual utilization and financial reports with HCAI. HCAI collects data on clinic revenues, expenses, and services. Additionally, in 2023, the Legislature passed, and Governor Newsom signed SB 779 (Stern) Chapter 505, Statutes of 2023 which requires community health centers and clinics to provide additional data reporting to the state, commencing on January 1, 2027.

e) **The Federal Mediation and Conciliation Service (FMCS).** FMCS is a small, independent federal agency that plays a role in sustaining the economy by preventing, minimizing, and resolving work stoppages and labor disputes. These efforts help avoid disruptions in production, services, and supply chains, ensuring economic stability and growth. FMCS accomplishes this mission by offering mediation, training, and facilitation services to employers and unions nationwide, fostering collaborative labor-management relationships.

f) **LMCCs.** An LMCC is a forum where employers and union workers work together to solve problems. They generally include a relatively equal number of employer and union members and can include a neutral chairperson or facilitator who all meet periodically to identify, discuss, and resolve issues or problems that are not typically covered under their collective bargaining agreement.

g) **Tribal Clinics.** All Tribal health clinics (THPs and TFQHCs) operate their healthcare programs under the federal authority of the Indian Self-Determination and Education Assistance Act (ISDEAA), enacted in 1975. This law explicitly provides flexibility in how funds are allocated and spent by Tribes, allowing them to prioritize and respond to the unique needs of Tribal communities. ISDEAA marked a significant shift away from paternalistic federal policies and empowered Tribes by recognizing their inherent autonomy and control over their own programs and services, particularly in areas like healthcare and education. This bill does not provide an exemption from the mission spend requirement for tribal clinics.

3) **SUPPORT.** SEIU California is the sponsor of this bill and states that nonprofit community clinics receive hundreds of millions of taxpayer dollars each year to fulfill their mission of reducing disparities in access to care. SEIU notes that when clinic funding is not being directed toward adequate staffing, high-quality care, and accessible services, the consequences are felt most acutely by those already facing barriers to healthcare. In many communities—particularly for communities of color, rural populations, and immigrant families—clinic revenue mismanagement can manifest as long wait times, insufficient staffing, or even a lack of access altogether. SEIU contends that even as Congress threatens cuts to Medicaid funding, certain clinic CEOs and executives are irresponsibly spending

precious clinic resources on unrelated expenditures. In some cases, serious concerns have been raised regarding the mismanagement of resources. Certain community clinics have been mired in multiple scandals over allegations of false reporting and fraudulent claims, and across the state, many clinic workers report chronic understaffing, high workloads and staffing turnover, and long wait times for patients.

SEIU argues that by requiring FQHCs to spend a predetermined percentage of their revenue on core program services, a mission spend ratio (MSR) threshold will improve financial accountability, ensure equitable and efficient use of federal resources, and align spending with the core mission of providing high-quality, accessible care to vulnerable populations. This is similar to the ACA requirement that large group healthcare insurance companies spend most of their premium dollars they receive on healthcare services and activities to improve healthcare quality. More specifically, the ACA's Medical Loss Ratio (MLR) requires health insurers in the large group market to spend at least 85% of premium revenues on medical care and quality improvement rather than administrative costs and profits.

SEIU continues that while each part of the healthcare system is unique, these policies all aim to ensure that patient care is prioritized over excessive overhead and profit-taking, improving healthcare value and access for consumers. SEIU concludes that with increased transparency and accountability of public dollars, community clinics will be better situated to improve health outcomes for patients, expand access to care, and invest in improving the working conditions of clinic workers who provide care and support for California's most vulnerable residents.

4) **OPPOSITION.** The California Primary Care Association (CPCA) Advocates is opposed to this bill and states that it will create harmfully broad restrictions with an unworkable spending mandate on how community health centers and clinics can use resources for patient care. CPCA notes that this bill also creates a duplicative and conflicting regulatory burden on clinics already overseen by numerous federal and state government agencies and will ultimately divert millions from patient care into bureaucracy with uncapped state fees, recurring audits and steep and unnecessary penalties. And most importantly, it will harm patients by cutting funding for providers, healthcare services, and infrastructure, disproportionately hurting low-income, rural, and medically underserved patients.

   CPCA notes that this bill will impose an arbitrary spending requirement which mandates community health centers and clinics to spend at least 90% of their total revenue from all payer sources on an extremely narrow list of services that ignores real operational needs. This does not include community outreach and education, medical devices and technology, state licensing fees, health insurance enrollment assistance, and patient case management, among many other essential services and functions which directly improve patient outcomes. The bill also requires DPH to determine every year, for every individual community health center and clinic in California if capital expenditures like rent, property taxes, mortgage interest, fire and earthquake insurance, and utilities relate to patient care and can or cannot be included in the minimum spend. This would create huge volatility and uncertainty for community health centers and clinics and the vulnerable patients they serve, at a time when Medicaid is already on the chopping block.

   Additionally, community health centers and clinics receive a set reimbursement rate from DHCS under the PPS, which comes from both state and federal Medicaid dollars. The PPS

rate is set by the Audit and Investigation Unit based on a multiple year deep cost evaluation of each individual health center's patient population and operations. Many of the vital services excluded from this bill like community outreach and education, are services the federal HRSA, the Centers for Medicare & Medicaid Services (CMS) and DHCS require community health centers to provide. This makes this bill in direct conflict with state and federal law.

CPCA also notes that the entirely new regulatory structure created under this would be funded by three different fines and fees foisted on community health centers and clinics. The largest of which is an ongoing annual registration fee of uncapped size which the bill explicitly states can be adjusted as high as necessary to fund implementing this immensely complex legislation. This bill would force health centers and clinics to waste millions of limited dollars and staff resources on bureaucracy and red tape that should be directed toward patient care. This includes the time and effort to meet all the reporting requirements of the bill, the cost of DPH's administration of the program, and large fees for missing reporting deadlines or not meeting the spending requirements in this bill, in addition to the uncapped ongoing annual fee to fund administering the program. This just further siphons away precious resources that should be invested in broadening patients' access to critical services.

CPCA points to the fact that this bill exempts community health centers and clinics who are in a union-sponsored statewide multi-employer labor management committee (LMCC) from the 90% spending requirement. Approximately 30% of workers in California health centers and clinics are represented by several different labor unions. But only one of those unions runs a health center LMCC as defined in the bill. CPCA contends that this reveals the bill's true intent is not to improve patient care but to penalize community health centers and clinics that happen to not participate in one union's LMCC. While labor-management collaboration is important, exempting some FQHCs from all the law's requirements undermines fairness and suggests a dual standard not based on quality or accountability, but organizational structure. All workers of course have a right to join a union. And there is an established process for workers at individual health centers to decide whether to unionize. But LMCC's aren't subject to any government approval, oversight, or public accountability. And the LMCC members themselves create their own rules regarding who to accept. The exemption of community health centers and clinics who are in LMCCs from this bill is deeply problematic for patients because it creates an unequal system. CPCA concludes patients in our communities have no control over their proximity to a union affiliated or non-union health center and changing health standards based on that will create an unequal system of care.

5) PREVIOUS LEGISLATION.

a) SB 525 (Durazo) Chapter 890, Statutes of 2023 enacts a phased-in multi-tiered statewide minimum wage schedule for health care workers employed by covered healthcare facilities, as defined; requires, following the phased-in wage increases, the minimum wage for health care workers employed by covered healthcare facilities to be adjusted, as specified; provides a temporary waiver of wage increases under specified circumstances; and establishes a 10-year moratorium on wage ordinances, regulations, or administrative actions for covered health care facility employees, as specified.

b) SB 779 (Stern) Chapter 505, Statutes of 2023 requires, beginning January 1, 2027, an organization that operates or maintains a primary care clinic or an intermittent clinic, to file an annual report with HCAI containing specified information for the previous calendar year. Creates new reporting requirements for all PCCs, including intermittent clinics, to report various types of data to HCAI, including a labor report, workforce demographic information, and a detailed workforce development report. Revises and recasts current reporting requirements for specialty clinics.

c) AB 2079 (Wood) of 2022 would have established, no later than July 1, 2023, a requirement that skilled nursing facilities (SNFs) report revenues and expenses to the DHCS, and based on these reports, requires 85% of a SNF's total non-Medicare health revenues from all payer sources in each fiscal year to be expended on the direct patient-related services of residents. Would have required a SNF that does not meet the minimum spending requirements on direct patient services to issue a pro rata dividend or credit to the state and anyone that made non-Medicare payments to the SNF for resident services, in an amount to bring the total spending up to 85%. AB 2079 was vetoed.

d) SB 1014 (Hertzberg) of 2022, would have required DHCS to authorize a new and voluntary supplemental payment program known as the Enhanced Clinically Integrated Program (ECIP) for FQHCs, or, pursuant to DHCS' discretion, another type of payment program that DHCS determines will best meet the clinical and financial goals of ECIP and is permissible under federal law. Would have required ECIP to improve quality and access to care by allocating funds to FQHCs that commit to ensuring that all health center workers are paid a minimum wage equivalent to $25 per hour, as specified, and that commit to participate in a bona fide LMCC. Would have required 80% of ECIP funds to be allocated to FQHCs for the purpose of improving patient access primarily by strengthening the workforce, through improved wages, benefits, and salaries, addressing specialist physician reimbursement, and investing in clinic infrastructure and capacity, as specified, and 20% for purposes of training workers and financially supporting workers as they train through a bona fide LMCC. SB 1014 died on the Assembly inactive file.

6) AMENDMENTS.

a) In order to address concerns raised by the Association of California Health Care Districts, among others, the author is proposing to amend his bill as follows: ***This article does not apply to any FQHC or FQHC look-alike that is owned or operated by a county, a city and county, a healthcare district organized pursuant to Health and Safety Code 32000 et seq., the University of California, a special health authority described in Part 4 of Division 101 of the Health and Safety Code, or any other political subdivision of the state.***

b) As noted above, Tribal health clinics operate their healthcare programs under the federal authority of the Indian Self-Determination and Education Assistance Act (ISDEAA), enacted in 1975. Imposing a state-mandated mission-spend requirement on these entities conflicts with the flexibility afforded under ISDEAA and raises concerns regarding Tribal sovereignty and federal preemption. While some Tribal Health Programs may be exempt from IRS Form 990 filing due to their governmental status, others do file and would be directly subject to the bill's requirements. Those that do not file may still be indirectly affected through Medi-Cal implementation, audit processes, or related

reporting mechanisms. The Committee may wish to amend this bill as follows: ***"This article shall not apply to any Federally Qualified Health Center operated by a Tribe or Tribal organization receiving funding under the Indian Self-Determination and Education Assistance Act (25 U.S.C. § 5301 et seq.)."***

REGISTERED SUPPORT / OPPOSITION:

Support

SEIU California (sponsor)
Alliance for a Better Community
California Alliance for Retired Americans
California Black Health Network
California Federation of Labor Unions, AFL-CIO
Kate Daniels, District 5, Monterey County Board of Supervisors
Felipe Hernandez, District 4, Santa Cruz County Board of Supervisors
Monterey Bay Central Labor Council, AFL-CIO
The Translatin@ Coalition
Working Partnerships USA

Opposition

Achievable Health
Alexander Valley Healthcare
AltaMed Health Services Corporation
Altura Centers for Health
Anderson Valley Health Center
APLA Health
Aria Community Health Center
Arroyo Vista Family Health Center
Asian Pacific Health Care Venture, INC.
Bartz-Altadonna Community Health Centers
Benevolence Health Centers
Calexico Wellness Center
California Consortium for Urban Indian Health
California Human Development
Camino Health Center
Celebrating Life Community Health Center
Central Valley Opportunity Center (CVOC)
Clinica Sierra Vista
Coalition of Orange County Community Health Centers
Communicare+ole
Community Clinic Association of Los Angeles County (CCALAC)
Community Health Association of Inland Southern Region
Community Health Partnership
Community Medical Wellness Centers, USA
Comprehensive Community Health Centers
CPCA Advocates, Subsidiary of the California Primary Care Association
Eisner Health

El Centro Del Pueblo
El Dorado Community Health Centers
El Proyecto Del Barrio, INC.
Elica Health Centers
Family Health Centers of San Diego
First Day Foundation
Fresno American Indian Health Project
Friends of Family Health Center
Golden Valley Health Centers
Harbor Community Health Centers
Health Alliance of Northern California
Health and Life Organization, Inc./ Dba Sacramento Community Clinics
Health Care LA, IPA
Health Center Partners of Southern California
Hill Country Community Clinic
Hurtt Family Health Clinic
Indian Health Center of Santa Clara Valley
Inland Family Community Health Center
InnerCare
JWCH Institute, INC.
LA Clinica De LA Raza, INC.
LA Cooperativa Campesina De California
Laguna Beach Community Clinic
Los Amigos De LA Comunidad, INC.
Los Angeles LGBT Center
Marin Community Clinics
Mendocino Coast Clinics, INC.
Mountain Valleys Health Centers
North Coast Clinics Network
North East Medical Services (NEMS)
Northeast Valley Health Corporation
Omni Family Health
One Community Health
Parktree Community Health Centers
Petaluma Health Center, INC.
Proteus, INC.
Saban Community Clinic
Salud Para LA Gente
Samuel Dixon Family Health Center, INC.
San Fernando Community Health Center
San Francisco Community Clinic Consortium
San Ysidro Health
Santa Cruz Community Health
Santa Rosa Community Health
Share Our Selves
Shasta Cascade Health Centers
Shasta Community Health Center
Shingletown Medical Center
Southside Coalition of Community Health Centers

St. Jude Neighborhood Health Center
Tarzana Treatment Centers, INC.
Truecare
Umma Community Clinic
Universal Community Health Center
Valley Community Healthcare
Venice Family Clinic
Via Care Community Health Center
Watts Healthcare Corporation
Wesley Health Centers
Westside Family Health Center
White Memorial Community Health Center
Wilmington Community Clinic

Analysis Prepared by: Lara Flynn / HEALTH / (916) 319-2097

Date of Hearing: April 29, 2025

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 1129 (Celeste Rodriguez) – As Amended April 22, 2025

SUBJECT: Birth defects monitoring.

SUMMARY: Authorizes a local health officer (LHO) to maintain a system for the collection of information related to birth defects and other birth conditions. Authorize an LHO to require laboratories, as specified, in addition to the facilities listed above, to either make available or to transmit to the local health department birth defects and other birth conditions information, as specified. Authorizes an LHO to enter into contracts for implementation of programs to collect and monitor birth conditions in their jurisdiction. Exempts umbilical cord and pregnancy blood samples collected under the supervision of an LHO in a local health jurisdiction for the purpose of monitoring birth defects or other birth conditions or for other purposes from the provisions described above. Specifically, **this bill**:

1) Includes "birth conditions" as defined in 25) below within the scope of the existing legislative authority held by the State Department of Public Health (DPH) to operate the statewide birth defects monitoring program.

2) Affirms the authority of LHOs to monitor the prevalence and incidence of birth defects and conditions in their local health jurisdictions in order to supplement state efforts or in the absence of state efforts in their jurisdiction.

3) Authorizes an LHO to maintain a system for the collection of information necessary to accomplish the purposes of this bill, subject to adequate funding.

4) Authorizes information about birth defects and conditions to be reported using either of the following systems at the discretion of the director or the LHO:

    a) A system that requires reporting institutions to make their records available for review and information collection by designated staff of the local program to monitor birth defects and conditions; and,

    b) A system that requires reporting institutions, including, but not limited to, providers and laboratories, to transmit specified data manually or electronically to the LHO.

5) Authorizes an LHO to require reporting institutions to make their records available to authorized local program staff pursuant to 4) a) above, require reporting of selected information about birth defects and conditions to the local public health program pursuant to 4) b) above, or implement a hybrid of the two systems.

6) Prohibits an LHO from impeding or contradicting activities of the state birth defects monitoring program (CBDMP) in their jurisdiction, but authorizes an LHO to supplement the activities for local uses and purposes.

7) Provides that birth defects and conditions are to be reported in a local health jurisdiction at the direction of and at the discretion of the LHO, subject to adequate funding.

8) Specifies legislative intent that the adequacy of program resources to support the state birth defects monitoring program is to be assessed annually to determine where and in which jurisdictions the state will offer its program.

9) Authorizes an LHO to require reporting institution participation in reporting of birth defects and conditions, as needed, to assess and address the needs of the local health jurisdiction, to supplement the state birth defects monitoring program in jurisdictions where it is conducted, if needed, or for reporting of birth defects and conditions in a local health jurisdiction where there are no state birth defect monitoring activities.

10) Authorizes the director of DPH to use information collected pursuant to 4) above to conduct studies to investigate the causes of birth defects and conditions.

11) Authorizes an LHO to require reporting of birth defects and conditions in their jurisdiction and may use that information for similar purposes described in 10) above.

12) Prohibits the LHO's investigation of poor reproductive outcomes shall not be limited to geographic, temporal, or occupational associations, but may include investigation of past exposures.

13) Authorizes an LHO to use resources, subject to their availability, from their local health program or jurisdiction representing the epidemiology, hospital administration, biostatistics, maternal and child health, and public health and others as necessary, to formulate sound policy and health orders for information collected regarding birth defects and condition.

14) Requires the LHO, as appropriate, to maintain an accurate record of all persons who are given access to confidential information.

15) Requires all research proposed to be conducted by persons other than program staff, using confidential information in the system to be reviewed by the institutional review board in the local health jurisdiction if the research is conducted at the direction of the LHO.

16) Requires, before confidential information is disclosed, the requesting entity to demonstrate to the LHO as appropriate that the entity has established the procedures and ability to maintain the confidentiality of this section.

17) Prohibits the furnishing of confidential information to the LHO or their authorized representative to not expose any person, agency, or entity furnishing the information to liability and from being considered a waiver of any privilege or a violation of the confidential relationship.

18) Specifies that this bill does not prohibit the publishing by a local jurisdiction of reports and statistical compilations relating to birth defects, still birth, or miscarriage that do not in any way identify individual cases.

19) Specifies any person who, in violation of a written agreement to maintain confidentiality, discloses any information provided pursuant to this section, or who uses information provided pursuant to this section in a manner other than as approved pursuant to this section may be denied further access to any confidential information maintained the LHO.

20) Specifies that person is required to be subject to a civil penalty of $500.

21) Prohibits the penalty described in 20) above from being construed as restricting any remedy, provisional or otherwise, provided by law for the benefit of DPH, a local jurisdiction, or any person.

22) Authorizes an LHO to enter into contracts for implementation of programs to collect and monitor birth conditions and to collect information regarding those defects or conditions in their jurisdiction.

23) Prohibits funds from the Genetic Disease Testing Fund from being used to support birth defects and other birth conditions information collection or research activities in a local health jurisdiction initiated by the jurisdiction's health office.

24) Exempts umbilical cord and pregnancy blood samples collected under the supervision of an LHO in a local health jurisdiction from the requirements with regard to the statewide Birth Defects Monitoring Program.

Definitions

25) Defines "Conditions" to mean conditions or disorders affecting an individual that occur during the 12-month period after an individual's birth or are later diagnosed to have occurred during the 12-month period after the individual's birth, in conformity with one or more of the following:

    a) The list of Birth Defects Descriptions for National Birth Defects Prevention Network (NBDPN) Core, Recommended, and Extended Conditions issued by the federal Centers for Disease Control and Prevention (CDC);

    b) Medical eligibility for the California Children's Services Program or its High-Risk Infant Follow-Up (HRIF) program; and,

    c) As dictated by the needs of, and response to, a public health or environmental emergency.

26) "Birth defect" to mean any medical problem of organ structure, function, or chemistry of possible genetic or prenatal origin.

27) "Reporting institutions" to mean health facilities, as that term is defined in existing law 3) below, providers, and laboratories that regularly provide services for the diagnosis or treatment of birth defects or conditions, genetic counseling, or prenatal or general diagnostic services.

EXISTING LAW:

1) Requires the State Public Health Officer (SPHO) to maintain a system for the collection of information related to birth defects, as specified. [Health and Safety Code (HSC) § 103830]

2) Requires the SPHO to require health facilities to make available to the State Department of Public Health (DPH) the medical records of children suspected or diagnosed as having birth defects, as specified. [*Ibid.]*

3) Defines a "health facility" to mean general acute care hospitals, and physician-owned or operated clinics, as specified, that regularly provide services for the diagnosis or treatment of birth defects, genetic counseling, or prenatal diagnostic services. [*Ibid.]*

4) Requires the Director of DPH to use the information collected pursuant to 1) above and information available from other reporting systems and health providers to conduct studies to investigate the causes of birth defects, stillbirths, and miscarriages and to determine and evaluate measures designed to prevent their occurrence. Prohibits DPH's investigation of poor reproductive outcomes from being limited to geographic, temporal, or occupational associations, but may include investigation of past exposures. [HSC § 103835]

5) Requires the California Birth Defects Monitoring Program (CBDMP) to operate statewide. States legislative intent that the adequacy of program resources to be assessed annually, and requires that the annual assessment to include a consideration of at least all the following factors:

   a) The numbers of births in the state;

   b) The scope of program activities; and,

   c) Any urgent situation requiring extraordinary commitment of present or planned program staff or resources. [HSC § 103835]

6) All information collected pursuant to this chapter shall be confidential and shall be used solely for the purposes provided in this chapter. [HSC § 103850]

7) Authorizes DPH to enter into a contract for the establishment and implementation of the birth defects monitoring program. [HSC § 103850]

8) Requires DPH to collect and store any umbilical cord blood samples it receives from hospitals for storage and research and states the intent of the Legislature that pregnancy blood samples be stored and made available to any researcher who is approved by DPH for specified purposes. [HSC § 124991]

9) Prohibits, except as provided by statute hereafter enacted by a two-thirds vote of the membership in each house of the Legislature, relevant evidence from being excluded in any criminal proceeding, including pretrial and post-conviction motions and hearings, or in any trial or hearing of a juvenile for a criminal offense, whether heard in juvenile or adult court. Prohibits this prevision from affecting any existing statutory rule of evidence relating to privilege or hearsay, or Evidence Code § 352, 782 or 1103. Prohibits this section from affecting any existing statutory or constitutional right of the press. [California Constitution, Article I, § 28, subdivision (f)(2)]

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

COMMENTS:

1) **PURPOSE OF THIS BILL.** According to the author, achieving healthy communities is a multifaceted approach. The author continues that public health professionals and medical professionals play a vital role in making sure our communities are healthy, protected, and

have access to care. The author contends that whenever possible, we must expand resources to support their roles in achieving healthy communities. The author states that making improvements to healthcare needs and ensuring our communities are safe from environmental hazards entails evaluating the health data we collect and making sure we identify needs or gaps. The author continues that one way DPH is doing so is by monitoring birth defects in the state through CBDMP. The author notes that this program is restricted to just ten counties. The author states that this bill expands on this program. The author continues that specifically, this bill gives local health jurisdictions the ability to implement a local birth conditions reporting program should they choose to do so. The author states that this allows local health jurisdiction to collect their own data and improve services for families facing healthcare challenges. The author concludes that this bill builds upon the work that DPH is doing and allows all counties to have the option to do monitoring.

2) BACKGROUND.

a) Background on birth defects and conditions. According to the Eunice Kennedy Shriver National Institute of Child Health and Human Development, congenital conditions, also known as birth defects, are structural (how the body is built) or functional (how the body works) conditions present at birth that can cause physical disability, intellectual and developmental disorders, and other health problems. According to the Centers for Disease Control, birth defects can vary from mild to severe. Health outcomes and life expectancy depend on which body part is involved and how it is affected. Birth defects can occur during any stage of pregnancy. Most birth defects occur in the first 3 months of pregnancy, when the organs of the baby are forming. However, some birth defects do occur later in pregnancy as tissues and organs continue to develop. Birth defects are common, affecting 1 in every 33 babies born in the United States each year. They are also the leading cause of infant deaths, accounting for 20%, or 1 in 5, of all infant deaths. According to an article titled "*The Association Between Race/Ethnicity and Major Birth Defects in the United States, 1999-1997*," the American Indiana/Alaska Native (AIAN) population had significantly higher prevalence of seven birth defects compared to non-Hispanic white population studied.

b) Importance of early detection. According to a study titled, "*Inpatient Hospitalizations Costs Associated with Birth Defects Among Persons Aged less than 65 Years, United States, 2019"*, the estimated cost of these birth defect-associated hospitalizations in the United States was $22.2 billion. Birth defect-associated hospitalizations bore disproportionately high costs, constituting 4.1% of all hospitalizations among persons aged less than 65 years and 7.7% of related inpatient medical costs.

c) Background on CBDMP. According to DPH, CBDMP is a population-based registry. It has been an active ascertainment registry since 1982 when the California State Legislature authorized it to collect data on birth defects, stillbirths, and miscarriages. CBDMP currently monitors over 150,000 births in 10 counties—approximately 30% of the births in California. The geographic coverage of the CBDMP includes: Fresno; Kern; Kings; Madera; Merced; Orange; San Diego; San Joaquin; Stanislaus; and, Tulare.

According to DPH, these births are representative of the state's population. The CBDMP registry data are used for ongoing tracking (also called surveillance) to monitor rates and

trends of select birth defects. The data are also used to provide pregnancy outcome data for the pregnancy blood samples included in the California Biobank Program, which makes specimens and data available to researchers for the following approved purposes: to identify risk factors for children's and women's diseases; to develop and evaluate screening tests; to develop and evaluate screening strategies; and, to develop and evaluate treatments.

The program objectives of CBDMP are to: increase the quality and quantity of California-based birth defect data available for purposes of public health monitoring and investigator-led research; Increase communication of birth defects information; and, monitor public health and safety concerns relating to birth defects.

CBDMP provides ongoing surveillance on rates and trends of select birth defects and periodically publishes non-identifiable data from these surveillance efforts as a public health practice.

d) What does this bill do? Currently, local health jurisdictions are able to implement disease reporting programs for infectious and communicable diseases or food or vector borne conditions. This bill authorizes local health jurisdictions to implement birth defect and birth conditions reporting in their respective jurisdictions, subject to adequate funding.

The bill establishes a definition in state law for birth conditions as conditions or disorders affecting an individual that occur during the 12-month period after an individual's birth or are later diagnosed to have occurred during the 12-month period after the individual's birth. The definition of conditions requires conformity with one the three as follows: the list of Birth Defects Descriptions for National Birth Defects Prevention Network (NBDPN) Core, Recommended, and Extended Conditions issued by the federal Centers for Disease Control and Prevention (CDC); Medical eligibility for the California Children's Services Program or its High-Risk Infant Follow-Up (HRIF) program; and, as dictated by the needs of, and response to, a public health or environmental emergency.

According to information provided by the Los Angeles Department of Public Health (LADPH), the sponsor of this bill, there are over 80 conditions on the NBDPN list and within the scope of the medically eligible conditions for the California Children's Services Program. The third definition could capture multiple consequences of public health and/or environmental disasters, following are some examples from events where a health jurisdiction may want to monitor birth conditions temporarily or long-term:

i) In the aftermath of the LA wildfires, perhaps respiratory conditions that are emerging in newborns in wildfire areas;

ii) Possible unknown health consequences in infants from landfill, trash removal or debris collection activities;

iii) Newborn exposure to environmental smoke, pollutions, adverse weather conditions;

iv) Potential early stage physical or developmental delays or impairments from toxic leakage, spills or groundwater contamination; and,

v) Immediate after-effects of beach or coastal water erosion or contamination, or water pollution and release of particulates and contaminants.

Additionally, the bill authorizes an LHO to require providers and laboratories, as specified, in addition to the facilities listed above, to either make available or to transmit to the local health department information related to birth defects and other birth anomalies information, conditions, as specified. The bill would authorize an LHO to enter into contracts for implementation of programs to collect and monitor birth anomalies information regarding, and to monitor, birth defects and conditions in their jurisdiction. Further, this bill authorizes an LHO to use the information birth defects and conditions information gathered by LHOs to conduct studies to investigate the causes of birth defects and conditions.

According to information provided by LADPH, surveillance of birth defects and other birth conditions is vitally important to healthcare decision-making because it can help to:

i) Identify and assess impact of environmental and communicable disease exposures leading to birth anomalies;

ii) Signal unsafe products, liabilities and/or manufacturing processes that impact local populations;

iii) Discern if there are challenges contributing to low-quality care in neighborhoods, geographies or institutions;

iv) Ascertain potential disparities in health care quality and access that may be adversely affecting the maternal and child health (MCH) populations;

v) Provide case finding and intervention support for programs like the California Children's Services Program, a state program which provides health care and services to children with certain diseases or health problems up to 21 years old, and Enhanced Care Management (ECM), a statewide Medi-Cal managed care plan benefit which addresses the clinical and non-clinical needs through the coordination of services and comprehensive care management;

vi) Guide how science and practice need to focus their efforts to reduce chronic disease and disability; and,

vii) Direct where public health may need to invest resources, programmatic problem-solving and birth anomalies prevention strategies.

The author notes that this bill could create an opportunity for earlier intervention, along with revealing possible adverse health trends that the LHO would want to address more directly.

According to the Assembly Committee on Public Safety (ACOPS), this bill amends HSC § 103850 related to the confidentiality of birth defect information to allow an LHO access to birth defect information for demographic, epidemiological or other similar studies related to health, as specified.

In 1982, California voters approved Proposition 8, which included a provision known as the "Right to Truth-in-Evidence." The Right to Truth-In-Evidence is codified in the California Constitution, and stands for the principle that no relevant evidence may be excluded from a criminal proceeding, with specific exceptions that were already in place at the time Proposition 8 was adopted.

Consistent with that provision, this bill has been marked as a 2/3 vote because it could potentially exclude relevant evidence from being presented in a criminal proceeding.

ACOPS notes that it is difficult to imagine what sort of criminal prosecution would rely on information related to birth defects. For instance, existing law prohibits evidence of birth defects as a basis to charge child abuse based on mother's use of a controlled substance. Generally, only the defendant may seek to admit evidence of a birth or genetic defect in a criminal proceeding or otherwise put their genetic defect at issue in a criminal proceeding. (*Sharp v. Superior Court (People)* (2012) 54 Cal.4th 168, 172.)

ACOPS notes that while Proposition 8 requires admission of relevant evidence, federal constitutional protections still require exclusion of evidence if required. (*In re Tyrell J.* (1994), 8 Cal. 4th 68; *People v. Ewoldt* (1994) 7 Cal.4th 380 ["Even if adoption of 'Truth in Evidence' provision abrogated evidentiary statute which prohibits use of character evidence to prove conduct on specific occasion, the Legislature reenacted [relevant portions of the Evidence Code] in 1986 by more than two-thirds vote"].) Therefore, while this may require 2/3 vote, it likely will have no impact on criminal proceedings.

3) **SUPPORT.** The County of Los Angeles Board of Supervisors (LACBOS) is the sponsor of this bill and states, current law authorizes the DPH Birth Defects Monitoring Program (CBDMP) to monitor fourteen conditions, but only in 10 counties: Fresno, Kern, Kings, Madera, Merced, Orange, San Diego, San Joaquin, Stanislaus, and Tulare. LACBOS continues that LA County seeks to include birth conditions reporting as part of their public health measures. LACBOS continues that current statute limits birth defects reporting to CBDMP activities or to birth disorders caused by communicable diseases or foodborne illnesses. LACBOS continues that this bill seeks to address this gap for local health programs by allowing LHJs to develop their own birth conditions monitoring systems, without interfering with or duplicating the work of the CBDMP. LACBOS continues that monitoring birth conditions can be an indispensable tool for local health programs to: identify newborns and infants with select health conditions and connect them with necessary care; determine the best prevention strategies and allocate resources more effectively; highlight areas for further research, address care gaps or quality issues, and evaluate underperforming practices or products; and, respond to environmental or public health emergencies that may pose risks. LACBOS concludes with multiple examples of how they propose to use the authority granted under this bill, including monitoring the effects of the recent Los Angeles fires on births in the coming years to identify possible impacts of exposure to after-fire toxicity in air, water, or soil.

4) **OPPOSE UNLESS AMENDED.** The American College of Obstetricians and Gynecologists (ACOG) opposes the bill unless amended on the grounds that ACOG believes more clarity and improvement is needed, including with the new definition of postnatal "conditions" and its required conformity to birth defects. ACOG notes that ensuring clarity around medical terminology is essential when designing public health surveillance systems with significant implications for both patients and provider.

5) **PREVIOUS LEGISLATION.** SB 1099 (Nguyen), Chapter 598, Statutes of 2024 requires DPH, commencing July 1, 2026, and each July 1 thereafter, to provide a report to the Legislature that includes specified information regarding the collection of residual screening specimens stored at the California Biobank. Requires DPH to make the report available on its website.

6) **POLICY COMMENT.** As this bill moves forward, the author and sponsors may wish to work with stakeholders to further clarify how birth conditions are defined within the bill.

REGISTERED SUPPORT / OPPOSITION:

Support

County of Los Angeles Board of Supervisors (sponsor)
Children Now
Health Officers Association of California
March of Dimes

Opposition

None on file

Analysis Prepared by: Eliza Brooks / HEALTH / (916) 319-2097

Date of Hearing: April 29, 2025

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 1161 (Harabedian) – As Amended April 21, 2025

SUBJECT: Public social services: state of emergency or health emergency.

SUMMARY: Provides for continuous eligibility for at least 90 calendar days or the conclusion of the proclamation, to a Medi-Cal beneficiary that was displaced by or affected by a proclaimed a state of emergency by the Governor or a health emergency declared by the State Public Health Officer. Provides similar protections for a recipient of California Work Opportunity and Responsibility to Kids (CalWORKs), CalFresh, California Food Assistance Program (CFAP), In-home Supportive Services (IHSS), and/or the Cash Assistance Program for Immigrants (CAPI) with respect to a recipient affected by a state of emergency. Specifically, **this bill**:

1) Requires the Department of Health Care Services (DHCS) and the California Department of Social Services (CDSS) to provide continuous eligibility to programs, as specified, for a recipient that was displaced or affected by an event proclaimed a state of emergency by the Governor for Medi-Cal, CalWORKs, CalFresh, CFAP, IHSS, and/or CAPI. Requires, for purposes of Medi-Cal, continuous eligibility based on a health emergency declared by the State Public Health Officer.

2) Requires, for the purposes of 1) above, continuous eligibility to maintain a recipient's current scope of benefits under the applicable program for at least 90 calendar days starting from the proclamation or declaration, whichever one is later, and continues eligibility through at least the conclusion of the proclamation or declaration.

3) Requires DHCS and CDSS to implement 2) above, or each recipient described in 1) above, through automated programming of eligibility systems to pause all discontinuances and all negative actions, without requiring manual eligibility worker action, and establishes requirements for notifications to beneficiaries, as specified.

4) Requires a county to immediately restore eligibility for the applicable program for any recipient whose eligibility was discontinued and who informs the county that they have been impacted by emergencies described in 1) above, as specified.

5) Establishes other rules specific to various social services programs to protect beneficiaries impacted by an emergency described in 1) above.

6) Clarifies that this bill is not to be construed as limiting the Governor's authority under the California Emergency Services Act or the authority of the State Public Health Officer.

7) Specifies that this bill will only be implemented to extent not in conflict with federal law.

8) Permits the DHCS and CDSS directors to implement this bill by issuing county directives in the form of all-county letters or eligibility division letters, exempt from the Administrative Procedures Act, during the first three years following the proclamation of a state of emergency or the declaration of a health emergency, or until the state of emergency or the health emergency is terminated, whichever occurs first.

EXISTING LAW:

1) Establishes the California Emergency Services Act, which defines emergencies and the emergency powers of the Governor. [Government Code (GOV) § 8550, *et seq.*]

2) Defines "state of emergency" as the duly proclaimed existence of conditions of disaster or of extreme peril to the safety of persons and property within the state caused by conditions such as air pollution, fire, flood, storm, epidemic, riot, drought, cyberterrorism, sudden and severe energy shortage, plant or animal infestation or disease, the Governor's warning of an earthquake or volcanic prediction, or an earthquake, or other conditions, other than conditions resulting from a labor controversy or conditions causing a "state of war emergency," which, by reason of their magnitude, are or are likely to be beyond the control of the services, personnel, equipment, and facilities of any single county, city and county, or city and require the combined forces of a mutual aid region or regions to combat, or with respect to regulated energy utilities, a sudden and severe energy shortage requires extraordinary measures beyond the authority vested in the California Public Utilities Commission. [GOV § 8558]

3) Empowers the Governor to proclaim a state of emergency in an area affected or likely to be affected when:

   a) He (*sic*) finds that circumstances described in 2) above exist; and either,

   b) He is requested to do so by local authorities; or,

   c) He finds that local authority is inadequate to cope with the emergency. [GOV § 8625]

4) Grants the Governor the authority, during a state of emergency, to the extent he deems necessary, have complete authority over all agencies of the state government and the right to exercise within the area designated all police power vested in the state by the Constitution and laws of the State of California to address the emergency. Requires the Governor to promulgate, issue, and enforce such orders and regulations as he deem necessary. [GOV § 8627]

5) Authorizes the Governor to make, amend, and rescind orders and regulations necessary to carry out provisions related to emergency declarations and gives such orders and regulations the force and effect of law. [GOV § 8567]

6) Allows the Governor, during a state of emergency, to suspend any regulatory statute, or statute prescribing the procedure for conduct of state business, or the orders, rules, or regulations of any state agency, where the Governor determines and declares that strict compliance with any statute, order, rule, or regulation would in any way prevent, hinder, or delay the mitigation of the effects of the emergency. [GOV § 8571]

7) Allows the Governor, during a state of emergency, to direct all agencies of the state government to utilize and employ state personnel, equipment, and facilities for the performance of any and all activities designed to prevent or alleviate actual and threatened damage due to the emergency, as well as direct such agencies to provide supplemental services and equipment to political subdivisions to restore any services which must be

restored in order to provide for the health and safety of the citizens of the affected area. [GOV § 8628]

8) Requires the Governor to proclaim the termination of a state of emergency at the earliest possible date that conditions warrant, and terminates all emergency powers when the state of emergency has been terminated by proclamation of the Governor or by concurrent resolution of the Legislature declaring it at an end. [GOV § 8629]

9) Authorizes the State Public Health Officer or local health officers to declare a local health emergency due to hazardous waste, medical waste, infectious disease, or chemical, biologic, toxic, or radioactive agents and establishes powers of the state or local health officers to address such a health threat. [Health and Safety Code (HSC) § 101075 *et seq.* and HSC § 101080]

10) Establishes the Medi-Cal Program, administered by DHCS, to provide comprehensive health benefits to low-income individuals who meet specified eligibility criteria. [Welfare and Institutions Code (WIC) § 14000 et seq.]

11) Makes Medi-Cal eligibility and enrollment functions a county function and responsibility, subject to the direction, authority, and regulations of DHCS. [WIC § 14001.11]

12) Establishes a processes for the determination and redetermination of an individual's eligibility for Medi-Cal. [WIC § 14005, *et seq.*]

13) Requires a county to perform redeterminations of eligibility for beneficiaries every 12 months and promptly redetermine eligibility whenever the county receives information about changes in a beneficiary's circumstance that may affect eligibility. [WIC § 14005.37]

14) Requires a loss of contact, as evidenced by the return of mail marked in such a way as to indicate it could not be delivered or that there was no forwarding address, to prompt a redetermination of eligibility. [*Ibid*.]

15) Requires eligibility to continue during the redetermination process and prohibits eligibility from being terminated until the county makes a specific determination based on facts clearly demonstrating the beneficiary is no longer eligible, and due process rights have been met. [*Ibid*.]

16) Specifies procedures whereby an individual can request to receive retroactive eligibility for the three months preceding an eligibility determination. [*Ibid*.]

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

COMMENTS: This analysis only discusses policy issues germane to the jurisdiction of the Assembly Committee on Health.

1) PURPOSE OF THIS BILL. According to the author, when disaster strikes, no one should be left without food, medical care, or the basic support they need to survive. The author indicates that public benefits programs are designed to provide stability, yet without guaranteed protections during disasters, recipients are left vulnerable to abrupt terminations due to administrative barriers, lost documents, or mail disruptions—through no fault of their

own. The author argues the absence of clear, permanent safeguards means that each disaster brings uncertainty, forcing people already facing immense hardship to fight for the assistance they should never have to fear losing. The author concludes is bill is intended to ensure individuals and families do not lose their benefits simply because they have been displaced or are struggling to recover from a disaster.

2) BACKGROUND.

a) Medi-Cal Eligibility, Redetermination, and Termination. Individuals who have been found eligible and are enrolled in Medi-Cal must have their eligibility redetermined every 12 months in order to retain coverage for the next year. If, during the 12-month period, new information that affects eligibility becomes available to the county, either reported by the individual or accessed through other electronic data sources, a beneficiary or enrollee will automatically have their eligibility redetermined based on the new information. Beneficiaries must also report to the county any change in their circumstances that may affect their Medi-Cal eligibility within ten calendar days of the change.

State law establishes specific process requirements and due process safeguards for redeterminations of eligibility. Many individuals are redetermined eligible automatically. However, if additional information is needed to establish eligibility, a beneficiary generally has 30 days to respond to a request for information. If the beneficiary does not provide the necessary information to the county within the 30-day period, the county may send the beneficiary a ten-day Notice of Action of terminating their eligibility. If terminated, the beneficiary still has 90 days from termination to "cure" or provide the information requested. Beneficiaries also have the right to appeal an adverse determination, and can also receive a period of retroactive eligibility.

This bill is intended to make exceptions to the normal Medi-Cal redetermination process for beneficiaries affected by disasters.

b) State and Federal Disasters and Emergencies. At the federal level, the President can declare a major disaster for any natural disaster event, or, regardless of cause, if the President determines has caused damage of such severity that it is beyond the combined capabilities of state and local governments to respond. A major disaster declaration provides a wide range of federal assistance programs for individuals and public infrastructure, including funds for both emergency and permanent work. In addition, the President can declare an emergency for any occasion or instance when the President determines federal assistance is needed—for instance, to protect lives, property, public health, and safety, or to lessen or avert the threat of a catastrophe.

Similarly, California law authorizes the California Governor to declare a state of emergency based on a range of natural disasters, as well as cyberterrorism, sudden and severe energy shortage, plant or animal infestation or disease, the Governor's warning of an earthquake or volcanic prediction, or other conditions. States of emergency may be requested by a local entity or declared by the Governor when the Governor deems the conditions are beyond the control of local entities to manage. The significant flexibility offered in the law to suspend laws and regulations, as well as to issue orders, allows the Governor to respond to the unique and unpredictable circumstances created by disasters.

c) **Recent Disaster Experience: COVID-19 Public Health Emergency (PHE) and Los Angeles (LA) County Fires.** The author, sponsor, and supporters of this bill point to continuous coverage during the COVID-19 PHE and the actions taken in response to recent fires as examples of beneficiary protections that the state should normalize in response to disasters.

i) **Eaton and Palisades Fires**. On January 7th, 2025, wildfires spread quickly into urban parts of northeastern and western Los Angeles County. The Eaton and Palisades fires burned over 37,000 acres, destroying over 16,000 structures and killing 30 civilians and 10 firefighters. In response to these disasters, DHCS took a number of actions to ensure continuity of eligibility and health care for Medi-Cal beneficiaries, including:

(1) DHCS issued guidance to counties, providing reminders on processing applications, delaying disenrollments, and reinstating coverage for individuals affected by the wildfires;

(2) Medi-Cal members in LA County, who reside in areas affected by the wildfires, with eligibility renewals in February, March, and April 2025 will have their renewals extended for six months;

(3) Medi-Cal members who were disenrolled in January 2025 for being unable to return their Medi-Cal eligibility renewal packet will be reinstated immediately with no gap in their Medi-Cal coverage/benefits;

(4) Families in affected areas can quickly enroll or renew Medi-Cal coverage, with streamlined processes to minimize delays in accessing care;

(5) Applicants impacted by the disaster can self-attest to residency and income when documentation is unavailable;

(6) Counties are required to extend benefits for affected populations throughout the emergency;

(7) Applicants impacted by the disaster are provided additional time to submit verifications; and,

(8) When documentation is unavailable, applicants may self-attest to California residency and income through signed affidavits under penalty of perjury.

Additionally, DHCS reports that Medi-Cal managed care plans that operate in the areas subject to the emergency have activated their emergency response protocols, which include deploying care management teams to conduct member outreach, waiving prior authorization requirements, providing transportation to care, and ensuring members do not face out-of-pocket costs for receiving care from out-of-network providers, as needed.

ii) **Continuous Coverage During the COVID-19 PHE**. The Medicaid continuous coverage requirement initiated by the federal government during the federally declared COVID-19 PHE also offers another recent example of pausing and restarting Medi-Cal eligibility determinations based on a declared emergency. The federal

Families First Coronavirus Response Act (FFCRA) authorized enhanced federal funding for Medicaid (Medi-Cal in California) programs, conditioned upon Maintenance of Eligibility requirements that prohibited disenrolling Medicaid beneficiaries in most circumstances for the length of the PHE. Under these temporary rules and a variety of federal flexibilities offered to states, California paused regular eligibility redeterminations statewide from March 2020 to March 31, 2023, allowing millions of Californians to maintain coverage through a volatile period in the state's history. Counties began processing Medi-Cal eligibility redeterminations in June 2023, which required a significant statewide administrative, training, and communications effort.

d) Considerations for Basing Program Eligibility on Emergency Declarations.

i) Types of Emergencies and their Effect on Medi-Cal Beneficiaries. This bill limits continuous eligibility to beneficiaries "affected by" a proclaimed a state of emergency or a health emergency. States of emergency can be declared for a number of different types of disasters. Many disasters, like the examples discussed directly above, could significantly affect Medi-Cal beneficiaries' access to health care or ability to renew their Medi-Cal eligibility, while others may have a limited effect. Disasters have been declared in the last few years, for instance, for numerous fires of varying severity, winter storms and wind storms, a 2022 earthquake in Humboldt County, bird flu, and impacts to utility services.

ii) Length of Emergencies. This bill continues Medi-Cal eligibility through at least the conclusion of the proclamation or declaration or an emergency. Current law requires the Governor to proclaim the termination of a state of emergency at the earliest possible date that conditions warrant. However, it is unclear whether emergency declarations are always terminated at the earliest possible date that conditions warrant, and there may be administrative or fiscal reasons that emergencies remain active for months or even years after the immediate damage is contained. For example, a July 1, 2024, proclamation by Governor Newsom terminated 22 emergency declarations that had been declared over a number of years, the oldest of which was declared in March of 2017. Because of how emergency declarations are practically used, and because some emergency periods last for multiple years, in many cases the length of a continuous Medi-Cal eligibility period that may be meaningful in the wake of a disaster is shorter than the length of declared emergency.

3) SUPPORT. This bill is supported by a number of consumer, senior, children's, and health advocacy organizations as well as health care provider organizations, who point to the need to ensure we have processes and systems in place to protect our most vulnerable Californians when disaster strikes. According to Western Center on Law and Poverty (WCLP), the bill's sponsor, California's public benefits programs are set up to automatically terminate eligibility if people do not submit required documentation within certain timeframes, typically 30 days. During ordinary times, WCLP notes, people can check their mail and return information needed to keep their benefits active; however, during and after disasters, these rules penalize survivors at the most vulnerable time of their lives. WCLP notes the emergency protections require manual workarounds and emergency systems programming, which has highlighted the need for both information technology systems and processes to be

in place to allow for continued eligibility of all public benefit programs during the next disasters.

4) PREVIOUS LEGISLATION.

a) AB 2956 (Boerner) of 2024 would have extended numerous temporary federally allowable processes (federal flexibilities) related to the redetermination of Medi-Cal eligibility, following the COVID-19 PHE, and established 12-month continuous Medi-Cal eligibility for adults. AB 2956 was held on the Suspense File of the Assembly Appropriations Committee.

b) SB 979 (Dodd), Chapter 421, Statutes of 2022, expands provisions of law permitting the Department of Managed Health Care and the Department of Insurance to take actions to protect enrollee access to health care during a state of emergency proclaimed by the Governor by extending this ability to health emergencies declared by the State Public Health Officer, and by extending this authority to when the emergency affects health care providers or the enrollee's health, rather than just when the emergency displaces enrollees.

c) AB 1494 (Aguiar-Curry), Chapter 829, Statutes of 2019, prohibits face-to-face contact or a patient's physical presence on the premises of an enrolled community clinic, as specified, to be required for services provided to a Medi-Cal beneficiary during or immediately following a state of emergency. Requires Medi-Cal reimbursement for telephonic services and a broader availability for telehealth services when provided by an enrolled community clinic during and up to 90 calendar days of the conclusion of a state of emergency. Requires federally qualified health centers (FQHCs) and rural health centers (RHCs) services provided outside the four walls of the FQHC or RHC to be Medi-Cal reimbursable, if within the boundaries of the state of proclamation declaring the state of emergency. Permits DHCS to allow other enrolled fee-for-service Medi-Cal providers, clinics or facilities to provide receive Medi-Cal reimbursement for the telephone and extended telehealth services. Permits DHCS to grant an extension beyond 90 calendar days after the conclusion of the emergency if necessary for the health and safety of the public. Implements the requirements above only to the extent DHCS obtains any necessary federal approvals and DHCS obtains federal matching funds to the extent permitted by federal law. Requires DHCS to issue guidance to facilitate reimbursement.

d) AB 690 (Aguiar-Curry), Chapter 679, Statutes of 2019, allows for a pharmacy license to be transferred in a declared state of emergency.

e) AB 607 (Gloria), Chapter 501, Statutes of 2017, establishes the Community Resiliency and Disaster Preparedness Act of 2017 to provide for expanded and improved disaster readiness and response in the CalWORKs and CalFresh programs, as specified.

5) AMENDMENTS. To ensure the bill is specific to disasters that affect a beneficiary's ability to complete the redetermination process, to correct drafting errors, and to ensure the bill is implemented, like the vast majority of the Medi-Cal provisions, pursuant to federal approval and the availability of federal financial participation, the author and Committee have agreed to the amendments listed below. In addition, per the discussion of the significant length of some emergency declarations, the author is encouraged to engage with DHCS and other

stakeholders to further refine the length of the period of continuous eligibility to ensure it is terminated at a time appropriate to circumstances on the ground.

Amendments are reflected below in bold underlined italics as follows:

(a) ***(1)*** The department shall provide continuous Medi-Cal eligibility to a beneficiary who, ~~has been displaced by, or who has otherwise been affected by,~~ ***due to*** a state of emergency, as proclaimed by the Governor pursuant to Section 8625 of the Government Code, or a health emergency, as declared by the State Public Health Officer pursuant to Section 101080 of the Health and Safety Code, ***has been affected by any of the following circumstances:***

(A) County social service office(s) operating at reduced capacity, including but not limited to staffing, office closures or operating at reduced hours.
(B) Being displaced or otherwise experiencing limited freedom of movement, including but not limited to relocating to shelter or emergency housing, stay-at-home orders, and evacuation orders or warnings.
(C) A disruption in providers, infrastructure, or other services necessary to maintain daily life and health, including but not limited to disruption in utilities, school, childcare, medical services or providers, access to food, transportation, or mail services.

(2) The department may implement paragraph (1) by providing continuous eligibility to all beneficiaries within a geographic region where the department finds, after consulting with counties, consumer stakeholders, and the Governor's Office of Emergency Services, that multiple beneficiaries within the geographic region have experienced any of the circumstances described in subparagraph (A) through (C), inclusive, of paragraph (1), due to a state of emergency or health emergency.

(b) The continuous Medi-Cal eligibility described in subdivision (a) shall maintain a beneficiary's current scope of Medi-Cal coverage for at least 90 calendar days starting from the ***date of the*** proclamation or declaration described in subdivision (a), ~~whichever one is later, and shall continue~~ ***or*** through ~~at least~~ the ***date*** ~~conclusion of~~ the proclamation or declaration described in subdivision (a) ***is terminated,*** whichever one is later.

Add: ***This section shall be implemented only to the extent that any necessary federal approvals are obtained, and federal financial participation is available and not otherwise jeopardized.***

REGISTERED SUPPORT / OPPOSITION:

Support

Asian Americans Advancing Justice-southern California
California Association of Food Banks
California Coalition for Youth
California Community Foundation
California Hospital Association
California Senior Legislature
CANHR
Children Now
Disability Rights Education and Defense Fund
Health Access California

Justice in Aging
LeadingAge California
National Health Law Program
Second Harvest Food Bank of Orange County
The Arc and United Cerebral Palsy California Collaboration
The Children's Partnership
Western Center on Law & Poverty

Opposition

None on file

Analysis Prepared by: Lisa Murawski / HEALTH / (916) 319-2097

Date of Hearing: April 29, 2025

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 1196 (Gallagher) – As Amended March 17, 2025

SUBJECT: Health facilities: cardiac surgery.

SUMMARY: Requires, when a general acute care hospital (GACH) is performing cardiac surgery, that the surgical team for all cardiovascular operative procedures that require extracorporeal bypass (use of a heart-lung machine) consist of a minimum of one surgeon and two additional individuals, each of whom is either a physician's assistant (PA) or a registered nurse (RN) that meet specific requirements. Requires the State Department of Public Health (DPH) on or before January 1, 2027, to amend its regulations to be consistent with the provisions of this bill.

EXISTING LAW:

1) Licenses and regulates health facilities, including GACHs, by DPH. Defines GACH to mean a health facility having a duly constituted governing body with overall administrative and professional responsibility and an organized medical staff that provides 24-hour inpatient care, including the following basic services: medical, nursing, surgical, anesthesia, laboratory, radiology, pharmacy, and dietary services. Permits GACHs, in addition to the basic services all hospitals are required to offer, to be approved by DPH to offer special services, including cardiac surgery. [Health and Safety Code (HSC) § 1250 and § 1255 *et seq*.]

2) Establishes, through regulation, requirements for cardiovascular surgery services. Requires a physician to have overall responsibility and requires a minimum of three surgeons to constitute a surgical team for the performance of all cardiovascular operations which require extracorporeal bypass. [Title 22, California Code of Regulations (CCR), § 70435]

3) Requires regulations adopted by DPH that set standards for adequacy, safety, and sanitation of licensed health facilities, staffing of these facilities, and the services provided by the facilities, to permit program flexibility by the use of alternate concepts, methods, procedures, techniques, equipment, personnel qualifications, bulk purchasing of pharmaceuticals, or conducting of pilot projects as long as statutory requirements are met and the use has the prior written approval of DPH. This is known as "program flexibility." [HSC § 1276]

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

COMMENTS:

1) **PURPOSE OF THIS BILL.** According to the author, patients should not be denied vital care because of outdated regulations. Title 22 is an important set of regulations but progress in the healthcare sector leaves some of its standards in need of an update. The author concludes that many understaffed, underfunded hospitals are struggling to meet these unnecessary standards, and this bill helps them provide important surgery to patients without delay.

2) BACKGROUND.

a) Coronary artery bypass grafting (CABG), also called heart bypass surgery, is a medical procedure to improve blood flow to the heart. It may be needed when the arteries supplying blood to the heart, called coronary arteries, are narrowed or blocked. A doctor may recommend the surgery to lower the risk of a heart attack if a patient has coronary heart disease, or in an emergency to treat a severe heart attack.
CABG uses healthy blood vessels from another part of the body and connects them to blood vessels above and below the blocked artery. This creates a new route for blood to flow that bypasses the narrowed or blocked coronary arteries. The blood vessels are usually arteries from the arm or chest, or veins from the legs. In traditional "open heart" CABG, the heart is stopped, and a heart-lung bypass machine takes over the job of pumping blood throughout the body.

According to a 2023 article in Dialogues in Cardiovascular Medicine*, "Minimally Invasive CABG: Current Trends and Future Perspectives,"* CABG has been the gold standard of surgical revascularization for patients with complex coronary artery disease since its inception in the 1960s. While the traditional open technique, requiring a median sternotomy (open heart surgery), has been highly effective, it is associated with significant morbidity, prolonged recovery times, and increased risk of complications. In response to these challenges, there has been a growing interest in minimally invasive CABG techniques, which aim to reduce surgical trauma while maintaining the clinical benefits of traditional CABG. Minimally invasive CABG can be performed using several approaches to limit the invasiveness of the procedure while preserving the efficacy of revascularization. One of the most commonly used techniques is the minimally invasive direct coronary artery bypass (MIDCAB), which involves performing a left anterior thoracotomy to access the left internal mammary artery for anastomosis to the left anterior descending (LAD) artery. MIDCAB avoids the need for cardiopulmonary bypass and is particularly advantageous for single-vessel disease affecting the LAD. Robotic-assisted CABG represents another significant advancement in minimally invasive surgery. This technique utilizes robotic systems to enhance precision, often through smaller incisions. The da Vinci robotic system has been the most widely adopted platform for robotic-assisted CABG, allowing for three-dimensional visualization and highly accurate movements. Early studies have demonstrated favorable outcomes, with reduced pain, shorter hospital stays, and faster recovery times compared to traditional CABG.

b) CAGB in California. According to the Department of Health Care Access and Information, CABG utilization in California decreased from 2009 to 2022. There were 62.2 CABG surgeries per 100,000 adult population in 2009 compared to 49.8 CABG surgeries per 100,000 adult population in 2022. Utilization rates are as follows:

i) Males had higher CABG utilization rates than females, but the rate of decline over time was much greater for females (34.0 %) than males (15.4%).

ii) CABG utilization rates decreased in all race/ethnicity subgroups. Whites had the highest CABG utilization rate and the highest rate of decline (26.9%) compared to Blacks (17.6%), and Hispanics (1.3%).

iii) CABG utilization rate increased for American Indian / Alaskan Native adults (25.3%) and Asian / Pacific Islander adults (15.5%) subgroups over the 13-year period.

iv) Adults 85 years of age and older had the highest in-hospital mortality rate (8.8 percent in 2022), followed by those 65 to 84 years of age (3.1%), 18 to 44 years of age (2.0%) and 45 to 64 years of age (1.6%).

v) In-hospital mortality rates for Blacks (3.2% in 2022) are often higher than rates for other race/ethnic subgroups, but do vary by year; this variation is likely due to low volume of procedures when compared to other racial/ethnic groups.

c) Title 22 Regulations regarding cardiovascular operative service. As noted in existing law, above, current regulations require a minimum of three surgeons to constitute a surgical team for the performance of all cardiovascular operative procedures which require extracorporeal bypass. Anesthesia for cardiovascular procedures must be administered by a physician who is certified or eligible for certification by the American Board of Anesthesiology. The regulations also state that a physician who is certified or eligible for certification in cardiology by the American Board of Internal Medicine should be a member of the surgical team and should assist in monitoring the patient. The regulations additionally require two persons (registered nurses or cardiovascular technicians) to assist during the performance of all cardiac catheterization procedures. These personnel must be trained in the use of all instruments and equipment and be supervised by a physician.

d) Current Regulatory Timelines. This bill requires DPH, on or before January 1, 2027, to amend its regulations to be consistent with the provisions of this bill. According to DPH a regulation package takes three to five years to complete depending on the complexity of the package. There are currently 39 packages pending at DPH in total: 23 are active packages (two of which are emergency packages) and 16 are inactive. This number has the potential to increase with each legislative session as new bills are signed into law. The average cost to promulgate a regulation package is $448,071.

DPH has submitted a Budget Change Proposal (BCP) this year requesting $1,138,000 (ongoing) for a new team that will consist of six regulation writers and one manager to oversee them.

e) Program Flexibility. Division 5 of Title 22 contains the regulations that govern the different types of health facilities, home health agencies and clinics. However, there a number of places in the Health and Safety Code which permit DPH to grant "program flexibility" to comply with the law in an alternate manner. For example, in the statutes governing primary and specialty clinics, the statutes permit applications for program flexibility for the use of "alternate concepts, methods, procedures, techniques, equipment, personnel qualifications, bulk purchasing of pharmaceuticals, or conducting of pilot projects as long as statutory requirements are met and the use has the prior written approval" of DPH. With regard to hospitals, there is similar explicit authority permitting DPH to grant program flexibility with regard to hospital building code requirements, among other provisions of law. DPH has a Program Flexibility page on its website for facilities to request program flexibility.

Forty-eight hospitals have program flexibility for the cardiovascular operative service regulations [Title 22, CCR, Section 70435 (b)(2)]. DPH has previously allowed a surgical team doing cardiac surgery with bypass to be two surgeons and either a PA or RN first assistant. The hospitals with current waivers are noted in the chart below:

Hospitals with program flexibility for 22 CCR 70435 (b)(2).
Adventist Health And Rideout
Adventist Health Bakersfield
Arrowhead Regional Medical Center
Children's Hospital of Orange County
Clovis Community Medical Center
Community Memorial Hospital - Ventura
Community Regional Medical Center
Dameron Hospital
Desert Regional Medical Center
Doctors Medical Center
Emanate Health Inter-Community Hospital
Enloe Health
French Hospital Medical Center
Fresno Heart and Surgical Hospital
Hoag Hospital Irvine
Hoag Memorial Hospital Presbyterian
John Muir Medical Center-Concord Campus
John Muir Medical Center-Walnut Creek Campus
Kaiser Foundation Hospital Fontana
Kaiser Foundation Hospital-Santa Clara
Keck Hospital Of USC
Loma Linda University Children's Hospital
Loma Linda University Medical Center
Loma Linda University Medical Center - Murrieta
Los Robles Hospital & Medical Center
Memorialcare Orange Coast Medical Center
Memorialcare Saddleback Medical Center
Mercy General Hospital
Mercy Medical Center Redding
Mercy San Juan Medical Center
Northbay Medical Center
PIH Health Downey Hospital
PIH Health Good Samaritan Hospital
PIH Health Whittier Hospital
Pomona Valley Hospital Medical Center
Providence Mission Hospital
Providence Santa Rosa Memorial Hospital
Riverside Community Hospital

Saint Agnes Medical Center
Santa Monica - UCLA Medical Center and Orthopaedic
St. John's Regional Medical Center
Stanford Health Care
Stanford Health Care Tri-Valley
Sutter Medical Center, Sacramento
Sutter Santa Rosa Regional Hospital
Temecula Valley Hospital
Torrance Memorial Medical Center
University Of California Davis Medical Center

DPH does not anticipate any adverse events related to program flexibilities for Title 22, CCR, Section 70435 (b)(2) because those program flex approvals typically require two surgeons and a PA or RN first assistant. DPH did not find any program flex approvals for one surgeon only.

3) **SUPPORT.** The California Hospital Association (CHA) supports this bill and states that by recognizing the critical role of PAs and qualified RNs as part of cardiovascular surgical teams, this bill provides greater flexibility to these teams while maintaining the highest standards of patient care.

   Specifically, the current three-surgeon requirement for procedures involving extracorporeal cardiac bypass surgery does not reflect modern clinical practices or the capabilities of highly trained advanced practice providers. CHA states that this bill strikes the right balance between ensuring patient safety and supporting a more efficient, team-based approach to care delivery. This is especially needed in underserved and rural areas where recruiting multiple surgeons can be challenging. CHA concludes that cardiac surgery saves lives, improves long-term heart health, and gives people a second chance at life.

4) **OPPOSE UNLESS AMENDED.** The California Chapter of the American College of Cardiology (California ACC) has an oppose unless amended position on this bill. California ACC emphasizes the critical need for two cardiac surgeons to be present during CABG procedures. California ACC states that this collaborative approach is essential for ensuring patient safety, optimizing outcomes, and addressing the inherent complexity of these life-saving surgeries. California ACC highlights many reasons for the need for two surgeons as follows:

   a) **Management of Complex Cases**: CABG often involves multi-vessel grafting and intricate surgical techniques. Having multiple surgeons allows for task distribution—for example, while one surgeon prepares the heart, others may harvest grafts from the patient's body—reducing operative time and improving precision. This is especially crucial in cases requiring triple or quadruple bypasses.

   b) **Enhanced Team Coordination**: Cardiac surgeries demand seamless communication and coordination among surgical teams. A group of experienced surgeons working together ensures better decision-making and procedural efficiency, particularly when complications arise during surgery.

c) **Emergency Preparedness**: CABG procedures carry risks such as arrhythmias, bleeding, or difficulty accessing blocked arteries. The presence of two surgeons ensures that unforeseen complications can be addressed promptly without compromising patient safety or outcomes.

d) **Reduced Surgeon Fatigue**: These surgeries are lengthy and physically demanding, often lasting several hours. Rotating tasks among two surgeons reduces fatigue and maintains focus throughout the procedure, minimizing errors caused by exhaustion.

e) **Training and Mentorship**: In teaching hospitals, having multiple surgeons fosters mentorship opportunities between senior and junior practitioners, ensuring continuity in expertise while maintaining high standards of care for patients.

California ACC also states that the risks of relying on a single surgeon are significant including:

a) **Increased Fatigue**: A single surgeon performing an extended procedure may experience physical and mental exhaustion, which can lead to reduced precision and increased likelihood of errors during critical moments of the operation.

b) **Limited Expertise in Emergencies:** CABG can involve unpredictable complications such as excessive bleeding or arrhythmias. A lone surgeon may struggle to manage these challenges effectively without additional support from other skilled professionals.

c) **Higher Risk of Technical Errors:** Some complications during CABG—such as mediastinitis or reoperation for bleeding—are often linked to technical factors rather than patient-related risks. Having multiple surgeons reduces the likelihood of such errors through shared oversight and expertise; and,

d) **Reduced Efficiency:** Task distribution is impossible with only one surgeon, leading to longer operative times and potentially higher risks for patients undergoing prolonged cardiopulmonary bypass.

California ACC concludes that the presence of two cardiac surgeons during bypass surgery is not merely a matter of convenience but a necessity for delivering safe, efficient, and high-quality care. Conversely, relying on a single surgeon increases risks related to fatigue, technical errors, and emergency management, all of which can compromise patient outcomes in this critical procedure.

5) **PREVIOUS LEGISLATION.** AB 1422 (Gabriel) Chapter 716, Statutes of 2021 requires DPH, on or before July 1, 2022, to create a standardized form for any nurse-to-patient-ratio program flexibility request. Requires a health facility that submits a staffing ratio program flexibility request to conspicuously post a copy of the request in a location accessible to patients and employees. Requires DPH to post all approved requests by a health facility for program flexibility on its internet website and include specified information.

6) **AMENDMENTS.** As currently drafted this bill changes the requirements for hospitals to have three physicians present at extracorporeal bypass surgeries, to instead only require one, and requires DPH to update its regulations to reflect this change. The committee may wish to

amend this bill to require DPH to update its regulations based on current professional standards of care related to extracorporeal bypass surgery by January 1, 2029.

REGISTERED SUPPORT / OPPOSITION:

Support

California Hospital Association

Opposition

None on file

Analysis Prepared by: Lara Flynn / HEALTH / (916) 319-2097

Date of Hearing: April 29, 2025

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 1199 (Patterson) – As Amended March 17, 2025

SUBJECT: Hospitals: employee identification.

SUMMARY: Requires a hospital, as defined, to develop and implement a policy that requires all employees who have patient contact to wear an identification tag while on duty, with specified information, that may or may not include the employees first and last name. Specifically, **this bill**:

1) Requires a hospital to develop and implement a policy that requires all employees who have patient contact to wear an identification tag while on duty.

2) Defines, for purposes of this bill, "hospital" to mean a general acute care hospital (GACH), as defined, and an acute psychiatric hospital (APH), as defined.

3) Requires the name badge to include, in 18-point type or larger, the employee's vocational classification or California license status, and one of the following:

    a) The employee's first and last name;

    b) The employee's first name and last initial;

    c) The employee's first initial and last name; or,

    d) The employee's first name or last name only.

4) Authorizes the hospital to make an exception from the identification tag requirement for purposes of employee safety.

5) Makes findings and declarations as follows:

    a) Existing professional licensing law requires health care practitioners to disclose their name and California license status on a name tag, with specified exceptions. One such exception applies to practitioners working in psychiatric settings, where safety concerns may warrant the absence of a name tag to protect staff from potential harm;

    b) Existing hospital licensing regulations require hospitals to implement a policy that requires all employees having patient contact to wear an identification tag while on duty. There are no exceptions to this requirement. The regulation does not specify whether the employee's full first and last name must be printed on the name tag;

    c) To maintain the safety and privacy of hospital employees while maintaining workplace security and professional identification standards, the Legislature finds it necessary to align hospital licensing regulations with health care practitioner licensing statutes by allowing hospitals to implement policies that protect employee identity through clarified identification tag requirements; and,

d) It is the intent of the Legislature to align hospital licensing regulations with health care practitioner licensing statutes by allowing hospitals to implement policies that protect employee identity through clarified identification tag requirements.

EXISTING LAW:

1) Licenses and regulates hospitals, including GACHs and APHs, by the Department of Public Health (DPH). Permits GACHs, in addition to the basic services all hospitals are required to offer, to be approved by DPH to offer special services, including, among other services, psychiatric services. [Health and Safety Code (HSC) § 1250 (a) and (b)]

2) Requires, except as otherwise provided, a health care practitioner to disclose, while working, his or her name and practitioner's license status, on a name tag in at least 18-point type. Authorizes a health care practitioner in a practice or an office, whose license is prominently displayed, to opt to not wear a name tag. [Business and Professions Code (BPC) § 680 *et seq.*]

3) Grants an employer, if a health care practitioner or a licensed clinical social worker is working in a psychiatric setting or in a setting that is not licensed by the state, to have the discretion to make an exception from the name tag requirement for individual safety or therapeutic concerns. Makes it unlawful, in the interest of public safety and consumer awareness, for any person to use the title "nurse" in reference to himself or herself and in any capacity, except for an individual who is a registered nurse or a licensed vocational nurse. [*Ibid.*]

4) Defines for purposes of the provisions of existing law above, "health care practitioner" to mean any person who engages in acts that are the subject of licensure or regulation under specified BPC. [*Ibid.*]

5) Requires hospitals to conduct a security and safety assessment (annually reviewed and updated) and, using the assessment, develop a security plan with measures to protect personnel, patients, and visitors from aggressive or violent behavior. The plan must include specified security considerations. The plan may include security considerations relating to efforts to cooperate with local law enforcement regarding violent acts in the facility and requires the hospital to consult with affected employees, including the recognized collective bargaining agent or agents, if any, and members of the medical staff. [HSC § 1257.7]

6) Establishes the Division of Occupational Safety and Health (Cal/OSHA) within the Department of Industrial Relations (DIR) to, among other things, propose, administer, and enforce occupational safety and health standards. [Labor Code (LAB) § 6300 *et seq.*]

7) Establishes the Occupational Safety and Health Standards Board (Cal/OSHA Standards Board), within DIR, to promote, adopt, and maintain reasonable and enforceable standards that will ensure a safe and healthful workplace for workers. [LAB § 140 *et seq.*]

8) Requires employers to establish, implement and maintain an Injury and Illness Prevention Program that must include, among other things, a system for identifying and evaluating workplace hazards, including a workplace violence prevention plan. [LAB § 6401.7]

9) Requires every employer to file a complete report with Cal/OSHA of every occupational injury or occupational illness to each employee which results in lost time beyond the date of the injury or illness, or which requires medical treatment beyond first aid. A report must be filed within five days after the employer obtains knowledge of the injury or illness. In addition to this report, in every case involving a serious injury or illness, or death, the employer is required to make an immediate report to Cal/OSHA by telephone or email. Failure to file this report as required deems an employer guilty of a misdemeanor punishable by up to six months in a county jail and/or a $5,000 fine. [LAB § 6409.1]

10) Requires the Cal/OSHA Standards Board to adopt standards that require a licensed GACH, APH, or special hospital to adopt a workplace violence prevention plan to protect health care workers and other facility personnel from aggressive and violent behavior. Requires these workplace violence plans to include, among other requirements, a system to assess and improve upon factors that may contribute to, or help prevent workplace violence, including sufficiency of security systems, including alarms, emergency response, and security personnel availability. [LAB § 6401.8]

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

COMMENTS:

1) **PURPOSE OF THIS BILL.** According to the author, by limiting the information on hospital name tags at acute care GACHs and APHs, we protect the safety and privacy of hospital employees, ensuring a secure environment where care is the focus, not personal exposure.

2) **BACKGROUND.**

   a) **Workplace Violence in Hospitals.** According to an umbrella review of meta-analyses published in Frontiers in Public Health in 2022, healthcare workers are at high risk for workplace violence exposure, with studies reporting that 50% to 88% of health care workers have been exposed to workplace violence. The rates can be higher depending on the type and setting of the health care environment, with up to 90% of emergency medicine health care workers reporting some degree of workplace violence. According to the Bureau of Labor Statistics, health care workers accounted for 73% of all nonfatal workplace injuries and illnesses due to violence in 2018. A study that looked at the effect of the COVID-19 pandemic on workplace violence in California's hospitals, comparing the number of violent incidents in the period before the pandemic to the period following California's shutdown, found that despite major reductions in patient volume, workplace violence incidents remained essentially unchanged. Workplace violence is constantly on the rise in the health care industry due to workloads, demanding work pressures, excessive work stress, deteriorating interpersonal relationships, social uncertainty, and economic restraints. Most violent cases are committed by patients' family members or friends, followed by patients themselves. The most vulnerable health care workers victimized are staff at emergency departments, especially nurses and paramedics, and staff directly involved with inpatient care.

   b) **Cal/OSHA.** Cal/OSHA developed a regulation for certain hospitals to adopt a workplace violence prevention plan following passage of Senate Bill 1299 (Padilla) Chapter 842, Statutes of 2014 addressing workplace violence in health care. Cal/OSHA's Violence

Prevention in Heath Care standard (Title 8, California Code of Regulations, Section 3342) became effective on April 1, 2017. Current law also requires that Cal/OSHA post a report on its website each year containing information on violent incidents at hospitals, based on reports submitted by the hospitals. Cal/OSHA's report must include which hospitals submitted reports, the total number of incidents reported, the outcome of any related inspection or investigation, citations levied against a hospital based on a violent incident, and recommendations for the prevention of violent incidents in hospitals. Hospitals must submit reports to Cal/OSHA regarding any incident involving either of the following: (A) The use of physical force against an employee by a patient or a person accompanying a patient that results in, or has a high likelihood of resulting in, injury, psychological trauma, or stress, regardless of whether the employee sustains an injury; and, (B) An incident involving the use of a firearm or other dangerous weapon, regardless of whether the employee sustains an injury. For reporting purposes, the definition of "injury" is any injury that results in loss of consciousness, medical treatment beyond first aid, days away from work, restricted work or transfer to another job, significant injury or illness diagnosed by a physician or other licensed health care professional, or death.

The March 22, 2024 report contains data from October 1, 2021 through September 30, 2022. Cal/OSHA received 10,280 violent incident reports from 301 hospital facilities during the reporting period. This number does not include reports that were duplicative, erroneous, or replaced by a corrected report. Five Department of State Hospitals (DSH) facilities reported incidents using an alternative reporting method, while 296 facilities reported incidents using the Cal/OSHA online reporting system. Starting October 1, 2022, DSH began using the same online reporting system as all other hospitals and their incidents will be included in next year's report. Each violent incident report contains the following information:

(1) Name and address of the hospital where the incident occurred;

(2) Date, time, and location of the incident;

(3) Brief description of the incident;

(4) Number of employees injured (if any) and the types of injuries;

(5) Whether security or law enforcement was contacted;

(6) Whether there is a continuing threat, and if so, what measures are being taken to protect employees; and,

(7) Whether the incident was reported to the nearest Cal/OSHA district office as required.

According to the California Hospital Association, the sponsor of this bill, while this data doesn't tie to I.D. badges (so it is hard to say how many could have been prevented by being able to remove or hide an I.D. badge), if the ability to do so reduces workplace violence by just 5%, then this would mean over 500 fewer violent episodes against employees in hospitals annually.

3) **SUPPORT.** The California Hospital Association (CHA) supports this bill and states that hospital employees are facing increasing threats, harassment, and even violence from patients and visitors. CHA notes that although hospital employees are generally required to wear name tags while on duty, current law acknowledges this requirement's potential risks by allowing an exception in psychiatric settings. Unfortunately, threatening behavior is not limited solely to those units — aggressive individuals can also be encountered in emergency rooms, general medical wards, and outpatient settings. CHA contends that, while it is important for patients to know who is caring for them, it is equally critical to protect the well-being and security of California's health care workforce. CHA argues that this bill would ensure that patient care is not compromised while giving hospitals the flexibility to protect employees when necessary, thus providing an important and necessary step toward ensuring the safety of hospital employees.

4) **OPPOSITION.** The Union of American Physicians and Dentists (UAPD) is opposed to this bill and states that treating patients in the Department of State Hospitals is dangerous work. UAPD Psychiatrists face harassment, assault and worse daily in the course of their professional career. Their personal identifying information (PII) must be closely guarded at all times to protect their safety. UAPD contends that if this bill is passed it will expose UAPD member PII and subject UAPD physicians to undue dangers both in the scope of their professional life and may also expose them and their families outside of the institution to unnecessary risk.

5) **PREVIOUS LEGISLATION.** AB 2975 (Gipson) Chapter 749, Statutes of 2024 requires the Cal/OSHA Board, by March 1, 2027, to amend the workplace violence prevention in health care standards to require certain licensed hospitals to implement a weapons detection screening policy that requires the use of weapons detection devices that automatically screen a person's body at specified entrances, and adopt related policies, staffing and signage, as specified.

6) **AMENDMENTS.** As currently drafted this bill provides a broad exemption, solely at the discretion of the hospital, to allow to make an exception from the identification tag requirement for purposes of employee safety. The Committee may wish to amend this bill to remove that exemption to ensure identification requirements are more consistently applied.

7) **POLICY COMMENT.** In order to better assess the danger to health care workers that directly results from wearing a name tag, the author may wish to consider amending this bill to require Cal/OSHA to collect data specific to injuries related to name tags.

REGISTERED SUPPORT / OPPOSITION:

Support

California Hospital Association

Opposition

Union of American Physicians and Dentists

Analysis Prepared by: Lara Flynn / HEALTH / (916) 319-2097

Date of Hearing: April 29, 2025

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 1312 (Schiavo) – As Introduced February 21, 2025

SUBJECT: Hospital pricing.

SUMMARY: Requires a hospital to prescreen a patient for presumptive eligibility for participation under the hospital's charity care policy and discount payment policy, if the patient meets specific criteria, including, among others, that the patient is enrolled in CalFresh or CalWORKs. Specifically, **this bill**:

1) Requires a hospital to prescreen a patient for presumptive eligibility for participation under the hospital's charity care policy and discount payment policy if the patient is any of the following:

    a) Uninsured;

    b) Enrolled in Medi-Cal or eligible for Medi-Cal under the Hospital Presumptive Eligibility (HPE) program;

    c) Enrolled in a Covered California plan and has a household income at or below 400% of the federal poverty level;

    d) Enrolled in CalFresh, CalWORKs, or Tribal Temporary Assistance for Needy Families (TANF), Women, Infants, and Children (WIC), California Alternate Rates for Energy (CARE), the Low-Income Home Energy Assistance Program, Housing Choice Voucher program, and any other programs as determined by the Department of Health Care Access and Information (HCAI) and any additional programs determined by each hospital that would reasonably reflect the approximate patient household income;

    e) Experiencing homelessness; or,

    f) Will owe the hospital five hundred dollars ($500) or more after all adjustments from insurance or third-party payers, if applicable, have been made.

2) Authorizes a hospital to prescreen a patient who does not meet any of the criteria listed in 1) above at the hospital's discretion or as established in the hospital's charity care policy and discount payment policy.

3) Specifies, when prescreening a patient for presumptive eligibility, the provision described in 2) above do not preclude a rural hospital's ability to establish eligibility levels for charity care and discounted payment at less than 400% of the federal poverty level, as appropriate to maintain their financial and operational integrity.

4) Requires, effective July 1, 2026, each hospital to establish a written process for prescreening patients within its charity care policy and discount payment policy that is accessible to the public and is provided to HCAI. Requires written policy process documentation to disclose the name of the software products and all other third-party services used to evaluate a patient for presumptive eligibility.

5) Prohibits the prescreening process and presumptive eligibility determination from:

   a) Being considered a request or application for charity care or a discounted payment;

   b) Disqualifying a patient, or patient's legal representative from requesting charity care or discounted payment; and,

   c) Disqualifying a patient, or patient's legal representative from submitting an application or documentation of income for the purposes of determining eligibility for charity care or discounted payment.

6) Requires a hospital to complete prescreening for presumptive eligibility prior to patient discharge and make any resulting adjustments to hospital charges imposed on the patient prior to sending the patient a billing statement.

7) Requires a hospital, prior to taking any other prescreening actions, to determine if, during the previous 12-month period, the patient has requested charity care, discounted payment, or other assistance and the hospital has determined that the patient is eligible for assistance based on documentation provided by the patient. Requires, if the hospital has determined that the patient qualified for assistance, the patient to receive an adjustment to charges prior to receiving a billing statement.

8) Authorizes a hospital to provide the patient an opportunity to verify information and involve the patient in the prescreening process, but prohibits a hospital from denying a patient charity care or discounted payment, or refusing to consider any information on the basis that it was not verified by the patient. Authorizes a hospital to accept voluntary submission of information or documentation that would assist the hospital in the prescreening process as long as the hospital does not compel the patient to provide the information as a condition of prescreening.

9) Authorizes a hospital to use existing patient data in the prescreening process, including, but not limited to, all of the following:

   a) Existing patient records;

   b) Information routinely collected during patient registration or admission;

   c) Information voluntarily supplied by the patient; and,

   d) Previous eligibility determination for charity care or discounted payment.

10) Authorizes a hospital to use third-party presumptive eligibility software tools or services or contract with a third party, including a public agency, to conduct the prescreening, if all of the following conditions are met:

   a) The process does not cause any negative impact on a patient's credit score;

   b) Evaluations are based on eligibility criteria established in the hospital's written charity care policy and discount payment policy. Prohibits evaluations from considering any assessment, evaluation, or score that predicts the patient's propensity or ability to pay; and/or,

c) The third-party software tool or service is used in a way that is reasonably calculated to lead to an accurate result.

11) Requires, in the event a third-party service or software tool fails to return information about the patient, or specifies the patient's income is unknown, the hospital to make a good faith effort to evaluate the patient's presumptive eligibility status based on information available to the hospital.

12) Requires a hospital to document any methods it utilized to prescreen a patient.

13) Requires a hospital to notify a patient in writing of the results of the prescreening process, for all outcomes, including, but not limited to:

a) The patient is presumptively eligible for charity care;

b) The patient is presumptively eligible for discounted payment;

c) The patient is not presumptively eligible for charity care or discounted payment; or,

d) The hospital is unable to determine presumptive eligibility.

14) Requires a hospital, if the prescreening process determines that a patient is not eligible or the patient is only eligible for a discounted payment, or the hospital is unable to determine eligibility, to notify the patient within five business days of the results in writing that the patient may still apply for charity care, discounted payment, or additional assistance pursuant to each hospital's charity care policy and discount payment policy.

EXISTING LAW:

1) Establishes HCAI in the California Health and Human Services Agency to expand equitable access to quality, affordable health care for all Californians through resilient facilities, actionable information, and the health workforce each community needs. [Health and Safety Code (HSC) § 127000, *et seq*.]

2) Requires a hospital to provide a person without health coverage with a written estimate of the amount the hospital will require the person to pay for the health care services, procedures, and supplies that are reasonably expected to be provided to the person by the hospital, based upon an average length of stay and services provided for the person's diagnosis. Allows the hospital to provide this estimate during normal business office hours. Requires the hospital to provide information about its financial assistance and charity care policies and contact information for a hospital employee or office from which the person may obtain further information about these policies. Requires the hospital to also provide the person with an application form for financial assistance or charity care. Excludes emergency services from these requirements. [HSC § 1339.585]

3) Requires each hospital to maintain an understandable written policy regarding discount payments for financially qualified patients as well as an understandable written charity care policy. Makes uninsured patients or patients with high medical costs who are at or below 400% of the federal poverty level (FPL) level eligible to apply for participation under a hospital's charity care policy or discount payment policy. Requires the written policy

regarding discount payments to include a statement that an emergency physician who provides emergency medical services in a hospital that provides emergency care is also required to provide discounts to uninsured patients or patients with high medical costs who are at or below 400% of FPL. [HSC § 127405]

4) Prohibits a hospital from selling patient debt to a debt buyer unless all of the following apply:

   a) The hospital has found the patient ineligible for financial assistance or the patient has not responded to any attempts to bill or offer financial assistance for 180 days;

   b) The hospital includes contractual language in the sales agreement in which the debt buyer agrees to return, and the hospital agrees to accept, any account in which the balance has been determined to be incorrect due to the availability of a third-party payer, including a health plan or government health coverage program, or the patient is eligible for charity care or financial assistance;

   c) The debt buyer agrees to not resell or otherwise transfer the patient debt, except to the originating hospital or a tax-exempt organization, or if the debt buyer is sold or merged with another entity;

   d) The debt buyer agrees not to charge interest or fees on the patient debt; and,

   e) The debt buyer is licensed as a debt collector by the Department of Financial Protection and Innovation. [HSC § 127425]

5) Requires a hospital to provide a copy of its discount payment policy, charity care policy, eligibility procedures for those policies, review process, and the application for charity care or discounted payment programs, as well as a copy of its debt collection policy to HCAI. Requires the information to be provided at least biennially on January 1, or when a significant change is made. Requires HCAI to make this information available to the public on its internet website. Prohibits a patient from being denied financial assistance that would be available pursuant to the policy published on HCAI's internet website at the time of service. [HSC § 127435]

6) Establishes Covered California as California's health benefit exchange for individual and small business purchasers as authorized under the ACA. [Government Code (GOV) §§ 100500 - 100522]

7) Establishes the Medi-Cal Program, administered by DHCS, to provide comprehensive health benefits to low-income individuals who meet specified eligibility criteria. [Welfare and Institutions Code (WIC) § 14000 *et seq.*]

8) Prohibits a provider of health care services rendered to a Medi-Cal beneficiary, who obtains a label or copy from the Medi-Cal card or other proof of Medi-Cal eligibility, from seeking reimbursement or attempting to obtain payment for the cost of covered health care services from the eligible applicant or recipient, or a person other than DHCS or a third-party payor who provides a contractual or legal entitlement to health care services. [WIC § 14019.4]

9) Exempts from 8) above the Medi-Cal spend down of excess income owed by a Medi-Cal beneficiary, unless the beneficiary's spend down of excess income has been met for the

month in which services were rendered (allows billing of individuals who have not met their "share of cost" obligation, which allows the individual to establish eligibility for Medi-Cal in a given month). [*Ibid*.]

10) Subjects providers who do not comply with the requirements in 8) above to penalties, as specified. [*Ibid*.]

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

COMMENTS:

1) **PURPOSE OF THIS BILL.** According to the author, rising health care costs are threatening access to care and patients continue to face barriers to financial assistance. With as little as someone's full name and zip code, a hospital can quickly estimate a patient's eligibility for free or discounted care and immediately apply that financial assistance before a patient ever receives a bill. Under the Hospital Fair Pricing Act, hospitals are already required to provide free or discounted care to patients who are enrolled in Medi-Cal or CalWORKs. The author concludes that this bill will ensure that income-eligible patients actually receive the care they deserve without the heavy burden of medical debt.

2) **BACKGROUND.**

   a) **Fair pricing policies.** AB 774 (Chan), Chapter 755, Statutes of 2006, established Hospital Fair Pricing Policies effective January 1, 2007. AB 774 required each licensed general acute care hospital, psychiatric acute hospital, and special hospital to increase public awareness of the availability of charity care, payment discounts, government-sponsored health insurance, and to standardize its billing and collections procedures. AB 774 also required HCAI to collect and make available to the public a copy of each hospital's charity care and discount payment policies, eligibility procedures for those policies, review processes, and application forms.

   b) **Medical Debt.** According to the California Health Care Foundation 2024 Health Policy Survey (CHCF Survey), Californians, especially Californians with low incomes, continue to be burdened by high health care costs and medical debt. Reducing what people pay for health care is one of Californians' top health care priorities for state government. More than half of Californians overall (53%), and nearly three in four Californians with low incomes (74%), say they skipped or postponed care due to cost in the past year. More than a quarter of Californians (28%), and nearly half of Californians with low incomes (46%), report trouble paying medical bills. Close to four in 10 Californians (38%), and over half of Californians with low incomes (52%), report having medical debt, and 82% of Californians say it's "extremely" or "very" important to reduce what people pay for health care, making it a top health care priority for state government.

      The CHCF Survey also notes that medical debt is a significant driver of bankruptcy, poverty, and racial inequities. Over a third (38%) of Californians report having medical debt, which disproportionately impacts Black, Latino/x, and low-income people. According to a 2023 Urban Institute Issue Brief, "*Most Adults with Past-due Medical Debt Owe Money to Hospitals,*" hospital debt makes up over 70% of medical debt, and hospital bills are generally much larger than other types of medical bills.

c) **Decreasing charity care spending**. Nonprofit hospitals must offer charity care and other community services as a condition of their exemption from income, property, and sales taxes. The facilities provide charity care to eligible uninsured and insured patients, with no expectation of payment. According to a 2020 John Hopkins University study published in the *Journal of the American Medical Association*, the highest-earning nonprofit hospitals in the United States provided less charity care to patients than lower-earning hospitals did, relative to the facilities' respective profits. The study also found that in states where Medicaid was expanded under the Patient Protection and Affordable Care Act (such as California), hospitals gave less charity care than hospitals in other states did: $12 versus $37.8 for uninsured patients, and $8.7 versus $11 for insured patients, measured against every $100 of net income.

According to a 2023 Lown Institute report (the report), "Fair Share Spending," non-profit hospitals, in particular, are under-delivering on their community benefit and charity care obligations. The report found that, out of 1,773 nonprofit hospitals evaluated, 77% spent less on charity care and community investment than the estimated value of their tax breaks — what they call a "fair share" deficit. The total "fair share" deficit for these hospitals amounted to $14.2 billion in 2020, enough to erase the medical debts of 18 million Americans or rescue the finances of more than 600 rural hospitals at risk of closure. According to the report, in California 71 hospitals have a "fair share deficit" of $1.4 billion, an amount large enough to wipe out 581,510 medical debts (or 18% of medical debt in the state).

3) **SUPPORT.** Consumer, health, legal, and children's advocates, labor organizations, and advocates for LGBTQ health and a number of ethnic communities support this bill, arguing rising health care costs are threatening patients' access to care and that patients' access to care and livelihoods are further threatened by medical debt. According to Health Access California, a cosponsor of this bill, states that hospital bills are driving a medical debt crisis in California. According to Health Access California, some hospitals in California and nationwide have already implemented prescreening, which makes practical and economic sense. Health Access California argues we can quickly and easily provide eligible patients with charity care without extra hassles and red tape.

4) **OPPOSE UNLESS AMENDED.** The California Hospital Association (CHA) is opposed to this bill unless it is amended to address a number of concerns. CHA states that it recognizes the author's and sponsors' intent to ease the financial and emotional strain on patients who struggle or are unable to pay for medical services. However, this bill would require that hospitals pre-screen and automatically apply financial assistance before discharge to specific patient populations— including those who are uninsured, experiencing homelessness, qualify for programs and services that assist low-income families and individuals, or will owe the hospital $500 or more in out-of-pocket costs — and without the benefit of verifying charity care or discount payment eligibility. CHA argues that this bill creates a new pathway for financial assistance that bypasses hospitals' ability to verify income and offer the type of financial assistance that best suits the patient's needs and personal finances.

CHA points to the Hospital Fair Billing Program, under which hospitals provide a written notice at the time of service explaining the discount payment/charity care policies, including information about eligibility and how to apply. If a patient is unconscious at the time of service, a hospital will provide the information at discharge. If the patient is not admitted, the

written notice is given when the patient leaves the facility. If the patient leaves without receiving the information, a hospital mails it to the patient within 72 hours. In addition, notices about financial assistance are posted in clear and conspicuous locations throughout hospital facilities, including in the emergency department and outpatient settings. Each hospital website also includes information about financial assistance with a link to the hospitals' charity care and discount payment policies. CHA contends that hospitals offer many touch points informing patients about financial assistance —creating a program that presumes eligibility not only discounts those efforts, but also denies a patient's right to choose whether they want to inquire about and/or receive financial assistance.

CHA voices concerns that this bill also contemplates the use of income-verifying software tools, which are costly to purchase, expensive to maintain, and charge a fee on a per-patient basis. CHA concludes that California has been a national leader in adopting requirements to protect low-income, uninsured, and underinsured Californians from potentially devasting medical bills. Identifying ways to make it easier for eligible patients to receive financial assistance should not be to the detriment of accuracy or patient choice.

5) PREVIOUS LEGISLATION.

a) AB 2297 (Friedman), Chapter 511, Statutes of 2024, authorizes an emergency physician to grant eligibility for a discount payment policy to patients with incomes over 400% of the FPL. Prohibits a hospital from considering the monetary assets of the patient when determining eligibility for both charity care and discount payment policies. Prohibits a hospital or emergency physician from using liens on any real property as a means of collecting unpaid hospital or emergency physician bills, and prohibits a collection agency from conducting a sale of any real property owned by a patient, or placing a lien on any real property as a means of collecting unpaid hospital or emergency physician bills.

b) AB 1020 (Friedman), Chapter 473, Statutes of 2021, prohibits a hospital from selling patient debt to a debt buyer, unless specified conditions are met, including that the hospital has found the patient ineligible for financial assistance or the patient has not responded to attempts to bill or offer financial assistance for 180 days. Prohibits a debt collector from collecting consumer debt that originated with a hospital without first communicating with the debtor in writing, and including the name and address of the hospital and information on how to obtain an itemized hospital bill. Revises eligibility requirements for charity care or discount payments from a hospital, redefines "high medical costs" and requires a hospital to display a notice of the hospital's policy for financially qualified and self-pay patients on the hospital's internet website. Requires HCAI, commencing on January 1, 2024, to impose an administrative penalty against a hospital that improperly bills a patient, as specified, and to establish an appeals process by regulation.

6) SUGGESTED AMENDMENTS. In order to more clearly delineate screening and eligibility requirements for charity care and discounted payment policies under this bill, the author is proposing to amend this bill as follows:

a) To require a hospital to ***automatically determine***, rather than "prescreen" a patient, as eligible for participation in charity care and discount payment policies if the patient is currently enrolled in various public assistance programs or experiencing homelessness before the patient is discharged;

b) To require a hospital to ***automatically screen*** a patient for eligibility for charity care and discount payment policies if the patient is: uninsured, enrolled in Medi-Cal with cost-sharing or eligible for Medi-Cal under the existing Hospital Presumptive Eligibility program, is enrolled in a Covered California health plan, or, will owe the hospital $500 dollars or more after all adjustment from insurance or third-party payers are made, as applicable; and to require the hospital to collect necessary information for screening before the patient is discharged, but allow the hospital to make the determination before the bill is sent and require all applicable adjustments be applied to the bill; and,

c) To require a hospital to provide a written notice of determination of eligibility for patients eligible for charity care or discounted payment pursuant to this bill.

d) To require, if the patient is eligible for discounted payment policies, the hospital to also include a statement that additional assistance may be available under the hospital's charity care policy.

7) **POLICY COMMENT.** This bill requires hospitals to prescreen individuals enrolled in or presumptively eligible for Medi-Cal, for presumptive eligibility for participation in charity care and discount payment policies. However, state law prohibits a provider, including a hospital, from billing most Medi-Cal enrolled individuals for the cost of services covered by Medi-Cal, including inpatient services. If an individual is not being billed for services, it is unnecessary to assess them for eligibility for charity care or discount payments. The author is encouraged to clarify how a hospital should handle such cases, to ensure an efficient process and prevent unnecessary administrative work.

REGISTERED SUPPORT / OPPOSITION:

Support

California Pan-ethnic Health Network (cosponsor)
Health Access California (cosponsor)
The Leukemia & Lymphoma Society (cosponsor)
Rising Communities (formerly Community Health Councils) (cosponsor)
AARP
APLA Health
Asian Americans Advancing Justice-southern California
Buen Vecino
California LGBTQ Health and Human Services Network
California Physicians Alliance
California State Council of Service Employees International Union (SEIU California)
Communities Actively Living Independent & Free
Courage California
Dollar For
Friends Committee on Legislation of California
Having Our Say Coalition
Healthy Contra Costa
Latino Coalition for a Healthy California
Public Counsel
The Black Alliance for Just Immigration
The Children's Partnership

Vision Y Compromiso
Western Center on Law & Poverty
One individual

Opposition

None on file

Analysis Prepared by: Lara Flynn / HEALTH / (916) 319-2097

Date of Hearing: April 29, 2025

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 1320 (Patterson) – As Introduced February 21, 2025

SUBJECT: California Affordable Drug Manufacturing Act of 2020: opioid antagonists.

SUMMARY: Prohibits a state agency from awarding a contract pursuant to the California Affordable Drug Manufacturing Act of 2020 on a noncompetitive basis for the purchase of an opioid antagonist with any entity that has entered into a multistate settlement agreement for its role in contributing to the opioid epidemic and would void any contract entered into under the conditions prior to January 1, 2026. Specifically, **this bill**:

1) Prohibits a state agency from awarding a contract pursuant to the California Affordable Drug Manufacturing Act of 2020 on a noncompetitive basis for the purchase of an opioid antagonist with any entity that has entered into a multistate settlement agreement for its role in contributing to the opioid epidemic.

2) Deems a contract void and unenforceable if it violates this prohibition and applies the law retroactively to any contract entered into before January 1, 2026.

3) Defines opioid antagonist for the purposes of this bill to mean naloxone hydrochloride or another drug approved by the United States Food and Drug Administration that, when administered, negates or neutralizes in whole or in part the pharmacological effects of an opioid in the body, and has been approved for the treatment of an opioid overdose.

EXISTING LAW:

1) Establishes the California Affordable Drug Manufacturing Act of 2020. Requires the California Health and Human Services Agency (CHHSA) or its departments to enter into partnerships to increase competition, lower prices, and address shortages in the market for generic prescription drugs, to reduce the cost of prescription drugs for public and private purchasers, taxpayers, and consumers, and to increase patient access to affordable drugs. Permits CHHSA and its departments to enter into exclusive or nonexclusive contracts on a bid or negotiated basis. [Health and Safety Code (HSC) § 127690 *et seq.*]

2) Requires CHHSA to enter into partnerships resulting in the production, procurement, or distribution of generic prescription drugs, with the intent that these drugs be made widely available to public and private purchasers, providers and suppliers, and pharmacies. States that CHHSA will only enter into production partnerships at a price that results in savings, targets failures in the market for generic drugs, or improves patient access to affordable medications. Requires CHHSA to prioritize the selection of generic prescription drugs that have the greatest impact on lowering drug costs to patients, increasing competition and addressing shortages in the prescription drug market, improving public health, or reducing the cost of prescription drugs to public and private purchasers. [HSC § 127693]

3) Permits CHHSA and its departments, including the Department of Health Care Access and Information (HCAI), to enter into exclusive or nonexclusive contracts on a bid or negotiated basis in accomplishing 2) above. Exempts contracts entered into or amended pursuant to this

authority from 7) and 8) of existing law below, and exempts these contracts from the review or approval of any division of the Department of General Services (DGS). [HSC § 127692]

4) Requires, upon appropriation by the Legislature, CHHSA to submit a report to the Legislature, by December 31, 2023, that assesses the feasibility of directly manufacturing generic prescription drugs and selling generic prescription drugs at a fair price. Requires the report to include an analysis of governance structure options for manufacturing functions, including chartering a private organization, a public-private partnership, or a public board of directors. [HSC § 127694]

5) Permits CHHSA to enter into partnerships regarding over-the-counter naloxone products that may allow the development, manufacturing, or distribution of over-the-counter naloxone products by any entity that is authorized to do so under federal or state law. [HSC § 127697]

6) Establishes the Opioid Settlements Fund (OSF) in the State Treasury to receive funds allocated to the state for state opioid remediation from various opioid settlements. Requires, upon appropriation by the Legislature, OSF be used for opioid remediation in accordance with the terms of the judgment or settlement from which the funds were received. [Government (GOV) Code § 12534]

7) Establishes the State Contract Act to regulate contracting between state agencies and private contractors, and outlines requirements for bidding and awarding of contracts for projects. [Public Contract Code § 10100 *et seq.*]

8) Requires DGS to publish the California State Contracts Register, which includes contracting opportunities with the state. [GOV § 14825 *et seq.*]

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

COMMENTS:

1) **PURPOSE OF THIS BILL.** According to the author, days after settling a lawsuit for $272.5 million with a pharmaceutical company for allegedly "fueling the opioid epidemic," California knowingly entered into a contract with that same company to provide the antidote (naloxone) on a no-bid basis. The author argues that the company is being paid to solve a problem it may have helped create, without the benefit of an open and public bidding process. With 5,502 Californians dying due to an opioid overdose in 2020, and more dying every year since, the author does not believe the state should reward this reprehensible conduct with lucrative state contracts. The author states this bill takes a more measured approach by permitting companies settling opioid-related lawsuits to win naloxone contracts only if they go through a competitive and transparent bidding process. This bill will also void any existing contracts that were signed on a no-bid basis. The author concludes that this approach ensures that any state contract is a win for taxpayers, while also recognizing the magnitude of the opioid crisis and the impact it has had in every region of the state.

2) **BACKGROUND.**

   a) **Prevalence of Substance Use Disorders (SUD) in California.** A 2024 publication from Health Management Associates and the California Health Care Foundation titled, "*Substance Use Disorder in California — a Focused Landscape Analysis"* reported that

approximately 9% of Californians ages 12 years and older met the criteria for SUD in 2022. According to the report, the prevalence of SUD among individuals 12 years of age and older increased to 8.8% in 2022 from 8.1% in 2015. While the health care system is moving toward acknowledging SUD as a chronic illness, only 6% of Americans and 10% of Californians ages 12 and older with an SUD received treatment for their condition in 2021. More than 19,335 Californians ages 12 years and older died from the effects of alcohol from 2020 to 2021, and the total annual number of alcohol-related deaths increased by approximately 18% in the state from 2020 to 2021. Overdose deaths from both opioids and psychostimulants (such as amphetamines), are soaring. This issue, compounded by the increased availability of fentanyl, has resulted in a 10-fold increase in fentanyl related deaths between 2015 and 2019. According to the Department of Public Health (DPH) Overdose Prevention Initiative, 7,847 opioid-related overdose deaths occurred in California in 2023. In the first two quarters of 2024, 2,975 opioid-related overdose deaths were recorded in California.

b) **DPH statewide standing order for Naloxone.** According to the CDC naloxone is a medicine that can help people who are overdosing on an opioid, and can be given safely to people of all ages, from infants to older adults. This includes an adolescent or young adult who may have unintentionally taken an opioid. Opioids include prescription medications, heroin, and fentanyl. Naloxone will not harm someone if you give it to them and they are not overdosing on an opioid. During an overdose, a person's breathing can be dangerously slowed or stopped, causing brain damage or death. Sometimes other drugs, including cocaine and methamphetamine, are mixed with fentanyl, and the user may not be aware of this mixture or contamination.

   Unfortunately many organizations found it difficult to obtain the required standing order to obtain naloxone from health care providers. DPH issued a standing order in 2017 to address this need and support equitable naloxone access. The standing order:

   i) Allows community organizations and other entities in California that are not currently working with a physician, to distribute naloxone to a person at risk of an opioid-related overdose or to a family member, friend, or other person in a position to assist; and,

   ii) Allows for the administration of naloxone by a family member, friend, or other person to a person experiencing or reasonably suspected of experiencing an opioid overdose.

   Among the organizations and entities that can distribute naloxone under the order are colleges, first responders, veteran organizations, homelessness programs, libraries, religious entities, recovery facilities, harm reduction and syringe access programs, and more. An individual at risk of experiencing an opioid-related overdose or someone who can assist an individual at risk is allowed to do so. Under the statewide standing order, staff of community organizations and other entities distributing naloxone must be trained. They are also required to provide training to individuals who receive naloxone from them. Colleges and other organizations may apply to use the statewide standing order if they meet certain conditions. As of November 2023, DPH stated that a standing order is no longer needed for Narcan or other approved over-the-counter naloxone nasal sprays,

but all other formulations remain available by prescription only and require a standing order to distribute and administer.

c) **CalRx.** To help reduce the cost of prescription drugs in state programs and to consumers, the state recently created the CalRx program at HCAI. Established by SB 852 (Pan), Chapter 207, Statutes of 2020, the program aims to reduce the cost of drugs by expanding the availability of low-cost generics in the market. According to the Legislative Analyst's Office (LAO), CalRx accomplishes this objective by entering into partnerships with private entities to distribute or manufacture generic drugs. Before entering into these partnerships, HCAI must ensure they result in savings, address market failures, improve patient access, and are viable. The Legislature has directed HCAI to work on two key drug initiatives through CalRx, insulin and naloxone. The 2023-24 budget provided $30 million one-time from OSF for a partnership to produce a generic, over the counter naloxone nasal spray product. The 2024-25 budget later reduced this amount to $25 million.

   HCAI reports eight respondents to their request for applications in July 2023. HCAI evaluated several criteria, including: key expertise, development progress, manufacturing capability, speed to market, pricing, distribution strategies, expected market entry impact, scalability, delivery risk, non-profit status, and funding requests. Additionally, HCAI conducted follow-up interviews with all eight respondents to ensure a comprehensive evaluation and understanding of the written materials they submitted. HCAI states that it was aware of the pending settlement at the time the contract was negotiated and that two of the eight applicants were part of opioid litigation.

   The LAO recently provided an update on the naloxone initiative. The LAO reports that in February 2024, HCAI entered into a contract with a private company (Amneal Pharmaceuticals) for the naloxone initiative. Under the contract, which extends through the end of 2026 (with two additional one-year options to extend), the contractor is to sell the new over-the-counter naloxone nasal spray product at $24 for each twin pack. The product entered the market in May 2024. The Naloxone Distribution Project (NDP), which is administered by DHCS, provides free naloxone products by request to hospitals, schools, law enforcement, and other public and community-based organizations, is used as the distribution method for CalRx naloxone. The CalRx naloxone product is the primary supplier to this state program, reflecting a 40% lower rate than the previous supplier. As a result, HCAI estimates the new product has saved the state millions of dollars annually. In April 2025, HCAI announced that CalRx branded naloxone would be available for direct consumer, over the counter purchase.

   "*Increasing competition, improving access, and lowering the cost of naloxone in California*" published in *Health Affairs Scholar* (with disclosed funding from HCAI) reports that in its first six months, internal calculations suggest that the CalRx generic naloxone has saved the state over $2.6 million, which could be used to provide more than 108,000 additional units of naloxone free of charge to communities across California. The article notes that overall generic naloxone prices declined by 22% in a single quarter immediately following CalRx entry into the market. The article concludes that the CalRx experience has helped disrupt the naloxone market by increasing competition and reducing prices and demonstrates that leveraging states' substantial purchasing power to negotiate lower prescription drug prices can have immediate market impact.

d) Opioid Settlements. According to a DHCS FAQ on opioid settlements, state, local, and tribal governments have brought lawsuits against pharmaceutical and drug distribution companies that have fueled the opioid crisis. The lawsuits allege that these companies fueled the opioid crisis by marketing opioids in misleading ways, downplaying risks, exaggerating benefits, and engaging in reckless distribution practices. The lawsuits seek to recover costs associated with the opioid epidemic and remediation. To address and prevent further crises, California has joined several lawsuits against manufacturers, distributors, pharmacies, and other entities responsible for aiding the opioid epidemic. Participating subdivisions (participating cities and counties) in California are receiving funding from settlements to be used for future opioid remediation activities. California's participating subdivisions are expected to receive additional funds as more settlements are finalized. Funds from the California opioid settlements originate from multistate settlements with prescription opioid manufacturers, distributors, and pharmacies.

3) OPPOSITION. The Drug Policy Alliance, the California Syringe Exchange Program Coalition, End the Epidemics, and the National Harm Reduction Coalition oppose this bill stating it decreases competition between opioid antagonist distributors, thus jeopardizing the cost and availability of overdose reversal medication. They argue this bill could potentially exclude the distributors of naloxone who were sued as part of the settlements, which includes AmerisourceBergen, McKesson, and Cardinal — the main wholesale distributors of naloxone to states. This bill would aggravate procurement contracts in place with one of these wholesale distributors meaning harm reduction organizations, first responders, and treatment providers throughout the state could experience lengthy delays in naloxone access. Opponents state evidence suggests that out-of-pocket naloxone prices remain a substantial barrier to access, and this bill will spur the consolidation of the market and risks driving up the cost of opioid antagonists.

The Association for Accessible Medicines (AAM) also opposes this bill due to the significant restrictions on the sale and distribution of life-saving opioid antagonist drug products it imposes. AAM says it is the nation's leading trade association for manufacturers of generic and biosimilar prescription medicines. AAM argues that widespread access to naloxone has been shown to reduce opioid-related mortality, and restrictions on these products hinder public health efforts to combat opioid misuse. Patients and providers rely on these medications and California should not artificially limit access to them. AAM supports open and fair competition when the state is seeking to partner with a manufacturer for any drug product. However, the limitation against contracting with a manufacturer that participated in a negotiated opioid settlement could lead to shortages of opioid antagonists. While the bill seems to be drafted to address one particular contract, it limits any state agency from entering contracts with most entities engaged in the opioid antagonist supply chain. AAM states based on a review of 2024 sales data, prohibiting the state from contracting with a manufacturer that entered a negotiated opioid settlement would exclude nearly 50 percent of naloxone products available in the U.S. today. AAM says limiting access to such a large percentage of these essential medicines could lead to significant localized shortages depending on where wholesalers and distributors move a particular manufacturer's product.

4) PREVIOUS LEGISLATION.

a) AB 118 (Committee on Budget), Chapter 42, Statutes of 2023 extends the authority of CHHSA to enter into exclusive or nonexclusive contracts on a bid or negotiated basis, for

purposes of the California Affordable Drug Manufacturing Act of 2020, indefinitely and requires CHHSA to enter into partnerships for the procurement of general prescription drugs.

b) SB 137 (Committee on Budget and Fiscal Review) Chapter 191, Statutes of 2023 expands the authority of HCAI to enter partnerships to develop, manufacture, or distribute an over-the-counter version of a naloxone nasal product.

c) SB 184 (Committee on Budget and Fiscal Review), Chapter 47, Statutes of 2022 creates the OSF to be administered DHCS, and requires the moneys in the OSF to be used for opioid remediation in accordance with the terms of the judgment or settlement from which the funds were received. Requires DHCS to produce periodic written reports.

d) SB 838 (Pan), Chapter 603, Statutes of 2022 requires the CHHSA to enter into a partnership to manufacture at least one form of insulin, to be made available at production and dispensing costs, requires this partnership to include representation and involvement with the governance of the contractor entity, and requires CHHSA, upon appropriation by the Legislature, to develop a California-based manufacturing facility for generic drugs.

e) SB 852 (Pan), Chapter 207, Statutes of 2020 requires CHHSA to enter into partnerships to increase competition, lower prices, and address shortages in the market for generic prescription drugs, to reduce the cost of prescription drugs for public and private purchasers, taxpayers, and consumers, and, to increase patient access to affordable drugs.

5) POLICY COMMENTS.

a) **Unintended consequences**. The author's stated intent to ensure that companies are not profiting from solutions to the opioid epidemic they may have helped create is laudable. As noted in b) of the Background section, under the contract with Amneal the state is paying 40% less than the previous supplier of the NDP. Currently, a two pack of Narcan is available for purchase online and in person through various pharmacies, or through Amazon, for $44.99. Walgreens sells generic naloxone nasal spray in a two pack for $34.99. Despite what seems like a positive outcome for the state in achieving expanded access to naloxone at a lower price, the contract would be void under this bill. There is no guarantee that a new contract would present better financial value to the state, or better access to a lifesaving drug. The process of awarding this contract is allowed by law, and the Legislature's intent is clearly laid out in statute that "any manufacturing that is done under this section is intended to benefit the residents of this state by ensuring adequate supplies and access to generic prescription drugs and lowering health care costs through savings to public health care programs and private health insurance coverage."

If this contract is void, there are several practical implications to consider about what happens to naloxone products that have already been manufactured with the CalRx branding and whether this will disrupt the state's immediate access to this lifesaving drug. While the author contends that any manufacturer would still be eligible to bid for the contract, it would be happening in the context of a voided agreement with the state's supplier to the NDP. The NDP has distributed 6.1 million kits of naloxone, which have been used to reverse more than 355,000 overdoses. DHCS has approved applications from 14,995 entities to receive NDP distributions of naloxone as of April 2025, 19% of

which are from law enforcement, 17% from schools and colleges, and 12% from community-based organizations.

If DHCS loses its primary supplier for NDP naloxone, HCAI would likely be incentivized to address this gap as expediently as possible with a new CalRx contract, which would be unlikely through a full and thorough bid process that the author cites as an option. Should this bill move forward, the author may wish to consider how to minimize the potential risks posed by reduced access to naloxone.

b) **Which entities benefit by placing requirements specifically on participants in settlements?** In September 2023, *The Washington Post* reported that Emergent BioSolutions refused to allow Narcan to be sold over the counter, frustrating health experts and workers on the epidemic's front lines who saw making Narcan and other naloxone-based medicines easier to buy as a way to save lives[1]. The article says that Robert Califf, former head of the Food and Drug Administration, blamed Narcan's over-the-counter delay on Emergent's pursuit of profits. "I think the problem is that the financial model doesn't appear to be working for the company, so they're not motivated to do it," Califf said at a 2022 conference. The article notes that Narcan's list price hadn't gone up since its debut in 2016 and that public agencies receive discounts. Through legal action, Emergent was able to delay generic competition by four years, until 2022. While this bill proposes restricting how a contractor that was part of an opioid settlement can engage in securing a CalRx naloxone contract with the state, other behaviors by companies can also prove harmful, but their ability to secure contracts would not be impacted by this bill.

Opposition notes that in January 2025, Hikma entered into an exclusive commercial partnership with Emergent for the sale of its Kloxxado naloxone nasal spray in the U.S. and Canada. Under the six year agreement, Emergent will incorporate Kloxxado into its naloxone product portfolio and handle all North American sales and marketing. Hikma will continue manufacturing the 8 mg naloxone nasal spray as the exclusive supplier to Emergent. Unlike Hikma and Amneal, Emergent is not involved in an opioid settlement. The opponents argue that Emergent is now positioned to have a disproportionate share of the market, controlling both Narcan and Kloxxado. This partnership between Hikma and Emergent could sidestep the proposed restrictions for companies implicated in opioid settlements to profit further and capture the market on naloxone.

Under this bill, any participant in a settlement would be allowed to enter into a CalRx naloxone contract, provided that contract is not established through a noncompetitive bid process. However, existing law already requires that any contract entered into by CHHSA or HCAI under CalRx increase competition, lower prices, and address shortages in the market for generic prescription drugs, reduce the cost of prescription drugs for public and private purchasers, taxpayers, and consumers, and increase patient access to affordable drugs. Should this bill move forward, the author may wish to consider how it could unintentionally benefit companies that may also have contributed to overdose deaths, but

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[1] Frankel, Todd, " How one company profited while delaying Narcan's drugstore debut," *The Washington Post*, 18 September 2023, https://www.washingtonpost.com/business/2023/09/18/narcan-over-the-counter-delays-emergent-biosolutions/

are not a part of a settlement, and how these market forces may conflict with HCAI's required considerations.

REGISTERED SUPPORT / OPPOSITION:

Support

None on file

Opposition

Association for Accessible Medicines
California Syringe Exchange Program (CASEP) Coalition
Drug Policy Alliance
End the Epidemics: Californians Mobilizing to End HIV, Viral Hepatitis, STIs, and Overdose
Hope in The Valley
National Harm Reduction Coalition
Treatment on Demand Coalition
Two individuals

Analysis Prepared by: Logan Hess / HEALTH / (916) 319-2097

Date of Hearing: April 29, 2025

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 1326 (Ahrens) – As Amended April 3, 2025

SUBJECT: Masks: individual or public health.

SUMMARY: States that an individual has the right to wear a mask on their face in a public place for the purpose of protecting their individual health or the public health, with regard to communicable disease, air quality, or other health factors. Provides this right would not be construed as limiting or otherwise modifying the application or implementation of certain requirements for the removal of a mask relating to, among other contexts, security protocols to identify an individual, a bona fide occupational qualification, or emergency health care protocols, as specified. Specifically, **this bill**:

1) States that an individual has the right to wear a mask on their face in a public place for the purpose of protecting their individual health or the public health, with regard to communicable disease, air quality, or other health factors, subject to any limitations described in this bill.

2) Prohibits 1) above from being construed as limiting or otherwise modifying the application or implementation of any of the following:

    a) Any requirement to temporarily remove a mask for identification purposes through facial recognition, as part of security regulations, procedures, or protocols under federal or state law, or as part of the policy of a public place if identification of an individual is required for entry into the public place and removal of the mask is necessary for that identification;

    b) Any requirement to avoid obstruction of vision while operating a vehicle. States the intent of the Legislature that a mask worn as described in this chapter is in the form of covering an individual's mouth and nose and not an individual's eyes;

    c) Any requirement to remove a mask for purposes of a bona fide occupational qualification; and,

    d) Any health care protocols to remove a mask as necessary to access an individual's face in order to perform a health care treatment or procedure on an emergency basis.

    e) Existing law 4) below.

3) Defines, for purposes of this bill, the following:

    a) "Mask" to mean any of the following masks for placement on an individual's face:

        i) A filtering facepiece respirator, such as an N95 or KN95 mask;

        ii) A surgical mask;

        iii) A cloth mask; and,

iv) Another mask within the scope of personal protective equipment (PPE), as described in 1) in existing law below.

b) "Public place" to mean any of the following:

i) A place of business that is open to the general public for the sale of goods or services;

ii) Another place of public accommodation, as defined in existing law 5) below or within the scope of entities that are subject to existing law 3) below;

iii) A governmental or public building or place open to the general public;

iv) A street, road, plaza, park, or other outdoor space open to the general public;

v) A mode of public transportation;

vi) A clinic, a hospital or other health facility, a care facility, or other health care setting;

vii) An academic institution or other educational setting; and,

viii) An employment setting or other workplace.

EXISTING LAW:

1) Defines "personal protective equipment" or "PPE" means protective equipment for eyes, face, head, and extremities, protective clothing, respiratory devices, and protective shields and barriers, including, but not limited to, N95 and other filtering facepiece respirators, face masks, surgical masks, and face shields, among other items, as provided. [Health and Safety Code § 131021]

2) Requires an employer to maintain a stockpile of the following equipment in the amount equal to three months of normal consumption: N95 filtering facepiece respirators; surgical masks, among other items, as provided. [Labor Code § 6403.3]

3) States that all persons within the jurisdiction of this state are free and equal, and no matter what their sex, race, color, religion, ancestry, national origin, disability, medical condition, genetic information, marital status, sexual orientation, citizenship, primary language, or immigration status are entitled to the full and equal accommodations, advantages, facilities, privileges, or services in all business establishments of every kind whatsoever. [California Civil Code § 51]

4) States that it is unlawful for any person to wear any mask, false whiskers, or any personal disguise (whether complete or partial) for the purpose of: evading or escaping discovery, recognition, or identification in the commission of any public offense; or, concealment, flight, or escape, when charged with, arrested for, or convicted of, any public offense. Makes violation of this provision punishable by a misdemeanor. [Penal Code § 185]

5) Defines public accommodation as any inn, hotel, motel, or other establishment which provides lodging to transient guests, other than an establishment located within a building which contains not more than five rooms for rent or hire and which is actually occupied by the proprietor of such establishment as their residence; any restaurant, cafeteria, lunchroom,

lunch counter, soda fountain, or other facility principally engaged in selling food for consumption on the premises, including, but not limited to, any such facility located on the premises of any retail establishment; or any gasoline station; any motion picture house, theater, concert hall, sports arena, stadium or other place of exhibition or entertainment; and, any establishment which is physically located within the premises of any establishment otherwise covered by this definition, as specified. [Title 42, United States Code § 2000A]

FISCAL EFFECT: This bill is keyed non-fiscal.

COMMENTS:

1) **PURPOSE OF THIS BILL.** According to the author, this bill aims to establish a clear legal right for individuals to wear masks to protect their health and the health of others. The author continues that individuals may face discrimination when making personal health choices without this legal safeguard. The author states that this this issue relates to bodily autonomy. The author concludes that if statutory protection is not provided, policies or ordinances restricting or banning the use of masks could be implemented.

2) **BACKGROUND.**

   a) **Use of Face Masks in the Pandemic Mitigation Strategy.** According to an article titled, "*Local, state, and federal mask mandates during the COVID-19 pandemic,"* on April 3, 2020, the Centers for Disease Control and Prevention (CDC) released a recommendation that public citizens should wear "nonmedical cloth masks" while in public places to help prevent the spread of SARS-CoV-2, the virus which causes COVID-19. The initial rationale behind this recommendation was for "source control," to limit the emission of virus-containing respiratory droplets from infected people during their contagious period. As the viral transmission dynamics were better understood, another pandemic challenge was realized: up to 40% of infected people are asymptomatic but can shed high levels of SARS-CoV-2 from their respiratory tracts, and they contribute to more than half of viral transmissions. Thus, the universal use of face masks for source control among the general public became a top priority in the pandemic mitigation strategy.

   A 2023 rapid systematic review of evidence titled, "*Effectiveness of face masking for reducing transmission of SARS-CoV-2"* found that masks wearing masks reduced the transmission of SARS-CoV-2.

   In April 2020, the State Department of Public Health (DPH) recommended wearing face coverings. In June of 2020, DPH issued guidance that required Californians to wear a face-covering in high-risk settings, including but not limited to public spaces, healthcare settings, public workplaces, in retail food settings, driving when passengers are present, and outdoors in public spaces when maintaining a physical distance of six feet from persons who are not members of the same household or residence is not feasible. This guidance included limited exemptions including but not limited to children two and under and people with disabilities which prevent wearing a face covering. Throughout 2020 and into early 2022, the state issued various guidelines and requirements regarding mask usage in public spaces, healthcare settings, and areas where social distancing was not feasible. Cities like Los Angeles and San Francisco enforced stricter rules than state mandates, depending on local COVID-19 infection rates.

In January of 2021, President Joseph R. Biden issued Executive Order 13991 requiring on-duty or on-site Federal employees, on-site Federal contractors, and other individuals in Federal buildings and on Federal lands to wear masks, maintain physical distance, and adhere to other public health measurers, as provided in CDC guidelines.

b) Mask Bans. In 2024, Nassau County in New York has passed a bill banning masks in public spaces. According to the text of the law, titled the "Mask Transparency Act", the county legislature of stated the purpose of the law is to prohibit wearing masks or facial coverings for the purposes of concealing an individual's identity in public places, unless such mask is worn for purposes of protecting the wearer's health or safety or for religious or celebratory purposes. In 2024, Los Angeles Mayor Karen Bass indicated that she was in discussions regarding a mask ban for protests with the City Attorney.

California state law makes it a misdemeanor to wear a mask with the intent to conceal one's identity, punishable by up to 180 days in jail, community service, fines, and other probation conditions.

This bill seeks to enshrine the right of wearing a mask in a public place in state law. The author contends that since pandemic-related mandates have expired, many institutions, employers, and even government entities have begun to restrict or discourage mask-wearing. The author further notes that many individuals have worn masks during protest demonstrations, and these policies seem to target these individuals as a means of suppression. This bill seeks to establish legal protections for individuals wearing masks for personal health reasons.

3) **SUPPORT.** Disability Rights California (DRC) supports this bill and states by codifying the right to wear a mask for health protection, this bill removes ambiguity and helps to destigmatize the use of masks, especially for individuals with chronic health conditions, compromised immune systems, or who are protecting vulnerable family members. DRC continues that people with certain health conditions and disabilities may need to wear P95 masks in public to reduce their risk of infection or exposure to harmful particles, including: individuals with weakened immune systems due to cancer treatments, organ transplants, or HIV/AIDS; those with chronic respiratory diseases such as asthma, chronic obstructive pulmonary disease (COPD), or cystic fibrosis; and people with cardiovascular conditions like heart disease, which can be worsened by air pollution or respiratory infections. DRC continues that individuals with certain disabilities that affect their ability to fight infections or that require close contact with caregivers may also rely on high-filtration masks like P95s for protection. DRC states that California has long led the nation in advancing public health and environmental protections. DRC concludes that this bill continues that leadership by ensuring that health-conscious individuals are not penalized, harassed, or denied services for making responsible choices to protect themselves and others in public spaces.

4) **RELATED LEGISLATION.** AB 596 (McKinnor) prohibits an employer from preventing any employee from wearing a face covering, including a respirator, unless it would create a safety hazard. AB 596 passed the Assembly Committee on Labor and Employment with a vote of 6-0 on March 19, 2025 and is pending on the Assembly Floor.

5) PREVIOUS LEGISLATION.

a) AB 73 (Rivas), Chapter 322, Statutes of 2021, expands the definition of essential workers to include agricultural workers for the purpose of accessing the personal protective equipment (PPE) stockpile for emergencies established by DPH and the Office of Emergency Services. Directs the Division of Occupational Safety and Health (Cal/OSHA) to review and update the content of wildfire smoke training in existing regulations. Requires training provided by employers to be in a language and manner readily understandable by employees.

6) Policy Comment. This bill is drafted to prohibit the right to wear a mask from being construed as limiting or otherwise modifying the application or implementation of existing law 4) above, which makes it unlawful, punishable by a misdemeanor, to wear any mask, false whiskers, or any personal disguise (whether complete or partial) for the purpose of: evading or escaping discovery, recognition, or identification in the commission of any public offense; or, concealment, flight, or escape, when charged with, arrested for, or convicted of, any public offense. As this bill moves forward, to address potential safety concerns that may arise, the author may wish to consider specifying legislative intent that a "mask" does not mean a mask that completely obscures an individual's face except within the scope of personal protective equipment as described in existing law 1) above.

REGISTERED SUPPORT / OPPOSITION:

Support

Disability Rights California
One individual

Opposition

None on file

Analysis Prepared by: Eliza Brooks / HEALTH / (916) 319-2097

Date of Hearing: April 29, 2025

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 1386 (Bains) – As Introduced February 21, 2025

SUBJECT: Health facilities: perinatal services.

SUMMARY: Requires, beginning on an unspecified date, perinatal services to be included as a required basic hospital service. Requires, on or before an unspecified date, the Department of Public Health (DPH) to establish a process to approve or deny a "perinatal service compliance plan" to meet the requirement to provide perinatal services. Requires, on or before an unspecified date, any general acute care hospital (GACH) that does not provide perinatal services to submit a perinatal service compliance plan to DPH, with specified information. Specifically, **this bill**:

1) Requires, beginning _____, perinatal services to also be considered a basic service.

2) Requires, on or before ____, DPH to establish a process to approve or deny a "perinatal service compliance plan" to meet the requirement to provide perinatal services. Requires on or before ____, any GACH that does not provide perinatal services to submit a "perinatal service compliance plan" to DPH including, at a minimum, all of the following:

   a) Maintenance of written transfer agreements with one or more GACHs that provide perinatal services;

   b) A financial report demonstrating the hospital's lack of financial capacity to establish perinatal services;

   c) A description of measures taken to establish perinatal services at the hospital; and,

   d) Other requirements, as determined by DPH.

EXISTING LAW:

1) Licenses and regulates hospitals, including GACHs, by DPH. Permits GACHs, in addition to the basic services all hospitals are required to offer (medical, nursing, surgical, anesthesia, laboratory, radiology, pharmacy, and dietary services), to be approved by DPH to offer special services, including, among other services, an emergency department (ED) and maternity services. [Health and Safety Code [HSC] § 1250 and § 1255, *et seq*.]

2) Defines supplemental service to mean an organized inpatient or outpatient service which is not required to be provided by law or regulation. [Title 22, California Code of Regulations, § 70067]

3) Requires a hospital, not less than 120 days prior to eliminating a supplemental service of either an inpatient psychiatric unit or a perinatal unit, to provide public notice of the proposed elimination of the supplemental service, including a notice posted at the entrance to all affected facilities, a notice to all contracted Medi-Cal managed care plans, and a notice to DPH and the board of supervisors of the county in which the hospital is located. Requires the health facility to conduct at least one noticed public hearing within 60 days of providing public notice of the proposed elimination of the supplemental service. [HSC § 1255.25(a)(3)]

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

COMMENTS:

1) **PURPOSE OF THIS BILL.** According to the author, California is facing a maternal health crisis, exacerbated by the alarming trend of hospital maternity ward closures. The author states that this bill is a critical piece of legislation that ensures all communities have access to essential perinatal care by requiring GACHs to maintain maternity services as a basic health care offering. The closure of maternity wards disproportionately affects low-income families and communities of color, forcing expectant mothers to travel long distances for care or rely on emergency rooms ill-equipped for childbirth. Research consistently shows that access to comprehensive maternity care reduces complications, premature births, and maternal mortality—outcomes that are essential for the well-being of California families. The author concludes that this bill not only safeguards maternal and infant health but also strengthens our health care system by supporting the labor and delivery workforce.

2) **BACKGROUND.** In the past decade, more than 50 labor and delivery wards have closed in California hospitals. As a result, large areas of California are without access to birthing facilities or maternity care providers. The absence of access to maternity care has disproportionally impacted California's low-income, Black, Latinx, and Indigenous populations, and those living in rural communities. When maternity wards close, particularly in rural counties, birthing people receive less prenatal care and rates of preterm birth increase. Currently, twelve California counties, most of them rural, do not have any hospitals delivering babies.

   a) **Perinatal units.** With some exceptions, GACHs are required to provide eight basic services: medical, nursing, surgical, anesthesia, laboratory, radiology, pharmacy, and dietary. Beyond these basic services, hospitals can be authorized to offer supplemental services, including outpatient services such as emergency services, or inpatient services such as intensive care, cardiovascular surgery, psychiatric units, and perinatal units, among other supplemental services.

      Perinatal units are defined in regulations as a maternity and newborn service of the hospital for the provision of care during pregnancy, labor, delivery, postpartum, and neonatal periods with appropriate staff, space, equipment and supplies. The regulations pertaining to perinatal units establish a number of staffing requirements, including the following:

      i) A physician certified or eligible for certification by the American Board of Obstetrics and Gynecologists or the American Board of Pediatrics must have overall responsibility of the unit. If a physician with those qualifications is not available, a physician with training and experience in obstetrics and gynecology or pediatrics is permitted to administer the service, while a physician with the necessary qualifications provides consultation at a frequency that will assure high quality service;

      ii) The physician must be responsible for providing continuous obstetric, pediatric, anesthesia, laboratory, and radiologic coverage, among other requirements;

iii) One registered nurse on duty on each shift must be assigned to the labor and delivery suite, with sufficient additional trained personnel to assist the family, monitor and evaluate labor and assist with the delivery;

iv) One registered nurse must be on duty for each shift assigned to the antepartum and postpartum areas; and,

v) A registered nurse who has had training and experience in neonatal nursing must be responsible for the nursing care in the nursery.

b) Recent increase in maternity unit closures. On November 15, 2023, *CalMatters* published an investigative report focusing on the increase in maternity unit closures in California, titled "*As Hospitals Close Labor Wards, Large Stretches of California Are Without Maternity Care*." According to this report, from 2012 to 2019, at least 19 hospitals stopped offering labor and delivery services (six of those were because the hospitals closed completely). In an acceleration, 16 more closed maternity services from 2020 to 2022. By the time of publication, 11 more had announced maternity closures in 2023, including one hospital that closed completely (Madera Community Hospital). CalMatters reported that after El Centro Regional Medical Center closed its maternity service in January of 2023, Imperial County was left with only one hospital doing births for the approximately 2,500 babies born every year in Imperial County. In total, according to CalMatters analysis, at least 46 California hospitals have shut down or suspended labor and delivery since 2012, and 27 of those have taken place in the last three years. Twelve rural counties do not have any hospitals delivering babies, and Latino and low-income communities have been hit hardest by losses. CalMatters noted that the closures come as the country and state contend with a maternal mortality crisis, with pregnancy-related deaths reaching a ten-year high in 2020 in California.

The CalMatters report stated that hospital administrators cite a number of reasons for the closures, including high costs, labor shortages, and declining birth rates. In the past 30 years, the number of births have dropped by half in California, and the birth rate is at its lowest level on record. CalMatters noted that the trend is not unique to California, with labor and delivery units closing across the country. Many closures result from hospital systems consolidating maternity care into one location, which hospitals argue can help maintain staff training and provide a higher level of care. According to CalMatters, labor and delivery units are often the second-most expensive department for hospitals to run, second only to emergency rooms. The report quoted a health researcher as stating that obstetrics units are often unprofitable for hospitals to operate.

c) Maternity care in California. According to the California Health Care Foundation's 2023 Health Care report, "Maternity Care in California," access to quality maternal care is essential for positive birth outcomes. In California, 46,000 women age 15 to 44 live in counties with no hospitals with obstetrics care or birth centers, and an additional 76,000 live in counties with only one hospital with obstetrics care or a birth center. Fifty-one thousand women age 18 to 44 live in counties with fewer than 29 obstetricians or certified nurse midwives per 10,000 births.

In 2021, births to Latina/x mothers and birthing people made up nearly half of all births in the state, at just under 200,000 births. About three in 10 births in California were to mothers or birthing people born outside the US.

California's pregnancy-related mortality rate has fluctuated since 2009. It increased by 45% from 2019 to 2020, possibly due to COVID-19. About one in four deaths occurred on the day of delivery between 2018 and 2020. A recent Centers for Disease Control and Prevention analysis found that more than four in five pregnancy-related deaths were preventable. Between 2009 and 2020, the pregnancy-related mortality rate for Black mothers and birthing people was three to four times higher than the rate for mothers and birthing people of other races/ethnicities. This variation cannot be explained by factors such as age, income, education, and health insurance coverage. Research shows that implicit bias and racism are key causes of disparate outcomes for Black mothers and birthing people.

d) **Nine Basic Services?** As noted in existing law, and a) of the Background, above, hospitals are required to provide eight basic services. This bill would add perinatal services as a basic service at a date uncertain and would require DPH to define criteria for hospitals' compliance plans. This would require DPH to promulgate regulations through the standard regulations process, which DPH estimates would take about three years to complete. If a hospitals' compliance plan was not approved, DPH would most likely require the hospital to submit a plan of correction detailing how it planned to meet the compliance plan requirement. If DPH did not approve the hospital's plan of correction, or a subsequently revised compliance plan, the hospital would be required to provide perinatal services. Since this bill would make perinatal services a required basic service, DPH would be compelled to suspend or revoke the license of the hospital if it did not provide the service and did not have an exemption.

   DPH would also need to revise its licensure and re-licensure surveys to reflect the addition of perinatal services to the required basic services. DPH would inspect a hospitals' perinatal service during all periodic surveys.

3) **SUPPORT.** The California Nurses Association/National Nurses United (CNA) is the sponsor of this bill and states that hospitals are the backbone of comprehensive perinatal services in our communities, providing specialized expertise, staffing, and resources to manage high-risk pregnancies and to handle complications during the birthing process. Yet, there are no guardrails to ensure all communities have access to basic and essential maternity services. Despite nearly 98% of all births in California occurring in a hospital, perinatal services are considered only a supplemental service and consequently not protected under state law. CNA contends that the lack of statutory protections for perinatal services has allowed hospitals to selectively close these vital services based on profit maximization and that the result has been a systemic erosion of hospital-based maternity care in California, disproportionately affecting vulnerable populations and exacerbating health disparities.

   CNA argues that the burden of hospital maternity service closures has fallen most heavily on low-income families, rural communities, and communities of color, with closures primarily of for-profit hospitals that predominantly service low-income Black and Latino communities. The closure of hospital maternity wards in California's rural communities has led to increased travel distances for expectant mothers, with 6.4% of women in the state residing more than 30 minutes away from a birthing hospital. CNA points to research that shows that there is a direct correlation between obstetric unit closures and increased rates of severe maternal morbidity, particularly for Black and Latino mothers. Black women in California already face a maternal mortality rate nearly four times higher than their white counterparts, and the

elimination of hospital-based maternity services only deepens these inequities. This pattern of closures has effectively created a two-tiered system of maternity care, where wealthier communities retain access to hospital-based perinatal services while low-income and rural communities – predominantly communities of color – are left to navigate a landscape of diminished and fragmented care, a form of medical redlining that endangers the lives of mothers and infants.

CNA states that this bill seeks to correct the crisis in access to comprehensive maternity care by reclassifying perinatal services as a mandatory component of hospital care under current law. For GACHs that currently provide perinatal services, this bill would require that the hospital maintains these services as a basic service. Hospitals that have closed their labor and delivery units, or do not currently provide these services, must submit a compliance plan to DPH detailing solutions to ensure continued access to maternity care. CNA concludes that this bill will hold hospitals accountable to their communities and prevent financially-motivated decisions to close maternity services that come at the expense of maternal and infant health.

4) **OPPOSE UNLESS AMENDED.** The California Hospital Association (CHA) is opposed to this bill unless it is amended and states that three primary factors are behind California's reduced capacity for hospital deliveries: lower birth volume, workforce shortages, and hospitals' financial instability. CHA argues that this bill, which would require perinatal services (those provided by Labor & Delivery (L&D) units) to be offered at all California hospitals, fails to acknowledge any of these factors.

   CHA contends that maintaining labor and L&D services is particularly challenging in areas with low birth volumes and significant workforce shortages. Many regions in California — especially lower-income communities — face a severe lack of OB/GYNs, with eight counties having no licensed OB/GYNs at all. These workforce constraints make it difficult — especially for hospitals facing significant financial distress — to ensure the specialized, around-the-clock staffing needed to safely operate an L&D unit.

   CHA notes that when considering solutions to maintaining L&D services in hospitals, any approach must address the factors underlying access challenges and recognize that every community is unique and requires a resolution tailored to its needs. Legislation requiring every hospital to open a labor and delivery unit is not feasible and would only come at the cost of other services being cut — especially for the more than 50% of California hospitals that lose money every day caring for patients.

   CHA has offered amendments, including:

   a) The establishment of a statewide Obstetrical Coverage Program and a Statewide Obstetrical Nurse Staffing Pool to ensure equitable access to specialized care in communities unable to support an OB/GYN practice or hospital-based maternity unit; and,

   b) Requirements that health plans, including all Medi-Cal managed care plans, reimburse GACHs for perinatal services at rates sufficient to cover direct and indirect costs of providing those services.

5) RELATED LEGISLATION.

a) SB 32 (Weber Pierson) would require, on or before July 1, 2027, the Department of Managed Health Care, the Department of Insurance, and the Department of Health Care Services (DHCS) to consult together and with stakeholders to develop and adopt standards for the geographic accessibility of perinatal units to ensure timely access for enrollees and insureds, as specified. The bill's provisions would become inoperative on July 1, 2033, and be repealed on January 1, 2034. SB 32 is currently pending in the Senate Health Committee.

b) SB 669 (McGuire) would establish a 5-year pilot project to allow critical access and individual and small system rural hospitals to establish standby perinatal medical services, as defined. The bill would require a hospital, to qualify for participation in the pilot project, to meet specified requirements, including, among others, that the hospital (1) be greater than 60 minutes from the nearest hospital providing full maternity services, (2) not have closed a full maternity or labor and delivery department within the past 3 years, and (3) agree to provide routine labor and delivery services or have an agreement with a freestanding birth center. SB 669 is pending in the Senate Health Committee.

6) PREVIOUS LEGISLATION.

a) AB 1895 (Weber) of 2024 would have required a GACH that operates a perinatal unit and determines those services are at risk of closing in the next six months to report specified information to the Department of Health Care Access and Information (HCAI). Would have required HCAI, DPH, and DHCS to assess the potential impact to the community and develop recommendations for how to resolve the perinatal units' challenges. AB 1895 was vetoed by Governor Newsom, who stated in part, "…current law already requires hospitals to provide public notice in advance of a supplemental service elimination, and much of the information in the proposed community impact report is duplicative. Further, this bill creates costly administrative burdens for the state that are unlikely to change hospitals' business decisions."

b) SB 1300 (Cortese), Chapter 894, Statutes of 2024, extends the public notice requirement, when a health facility eliminates or closes either inpatient psychiatric services or perinatal services, from 90 days prior to elimination of the service to 120 days; expands the notice of closure to include data on the patients served and a justification for the decision to eliminate services; and requires the hospital to hold a public hearing within 60 days of providing the notice.

c) Senate Bill 413 (Beilenson), Chapter 1201, Statutes of 1973, among other provisions, established standards for licensure of GACHs, including the 8 basic services a hospital is required to maintain.

7) POLICY COMMENT. As noted by the author, sponsors, and opposition to this bill, access to maternity care in California is rapidly decreasing, placing birthing people in immediate jeopardy of adverse outcomes. While agreement on the scope of the problem is universal, proposed solutions differ widely. Making the conversations even more difficult, the State is facing a potential budget shortfall in the billions of dollars, not even accounting for looming federal cuts to health care spending. Moving forward, the stakeholders are encouraged to engage in long-term and meaningful conversations as to how access to safe birthing options

in California can be preserved, and even expanded, in creative and cost effective ways. The author is also encouraged to engage with stakeholders to establish an implementation date for the bill that promotes safe and accessible maternal care.

REGISTERED SUPPORT / OPPOSITION:

Support

California Nurses Association/National Nurses United (sponsor)
Black Women for Wellness Action Project
California Federation of Labor Unions, AFL-CIO
California Pan - Ethnic Health Network

Opposition

None on file

Analysis Prepared by: Lara Flynn / HEALTH / (916) 319-2097

Date of Hearing: April 29, 2025

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 1429 (Bains) – As Amended April 2, 2025

SUBJECT: Behavioral health reimbursement.

SUMMARY: Requires, on or after May 1, 2022, the Kaiser Foundation Health Plan (Kaiser) to fully reimburse an enrollee who incurs out-of-pocket costs for behavioral health care services or mental health prescription medication obtained from non-Kaiser providers, facilities, or pharmacies until the Department of Managed Health Care (DMHC) certifies to the Legislature that Kaiser has successfully completed implementation of the corrective action work plan (CAWP) resulting from its 2023 settlement agreement with DMHC. Specifically, **this bill**:

1) Requires, on or after May 1, 2022, Kaiser to fully reimburse an enrollee who incurs out-of-pocket costs for behavioral health care services or mental health prescription medication obtained from non-Kaiser providers, facilities, or pharmacies until DMHC certifies to the Legislature that Kaiser has successfully completed implementation of the CAWP resulting from its 2023 settlement agreement with DMHC.

2) Requires reimbursement to be provided within 60 days of an enrollee's submission of documented expenses.

3) Requires an enrollee to submit all of the following in order to receive reimbursement:

    a) Receipts or invoices showing actual costs paid;

    b) Documentation that the service or medication was prescribed or recommended by a licensed mental health provider; and,

    c) A signed statement affirming that the expense was incurred due to the enrollee's inability to obtain timely and appropriate care through Kaiser.

4) Requires Kaiser, if they fail to provide reimbursement, to pay the original amount plus 10% per annum interest to the enrollee and a $5,000 fine per incident.

5) Requires Kaiser to establish procedures for all of the following actions:

    a) Enrollee submission of reimbursement requests in either online or paper form;

    b) Kaiser's processing of reimbursement requests;

    c) Appeals of denied reimbursement requests in either online or paper form; and,

    d) Statistical monitoring of submitted, approved, and denied reimbursement requests.

6) Requires DMHC to review and determine if Kaiser has fulfilled the requirements in 4) above.

7) Requires Kaiser to submit a monthly report to DMHC that includes:

a) The number of reimbursement requests received;

b) Total amount reimbursed;

c) Average processing time for reimbursement requests; and,

d) Number of denied reimbursement requests and reasons for denial.

8) Defines "behavioral health care" as behavioral health services, psychiatric services, psychological services, counseling, addiction services, and related prescription medications that are offered by Kaiser.

9) Defines "out-of-pocket costs" as any expenses paid directly by an enrollee, including:

a) Copayments;

b) Deductibles;

c) Prescription medication costs;

d) Provider visit fees;

e) Telehealth consultation fees; and,

f) Transportation costs directly related to obtaining behavioral health care.

EXISTING LAW:

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

2) Requires health plans to meet specified requirements regarding facilities, personnel, equipment, and services as a condition of licensure. [HSC § 1367]

3) Establishes California's Essential Health Benefits (EHBs) benchmark under the Patient Protection and Affordable Care Act (ACA) as the Kaiser Small Group Health Maintenance Organization. Establishes existing California health insurance mandates and the 10 ACA mandated benefits, including mental health and substance use disorder coverage. [HSC § 1367.005]

4) Requires every health plan that provides hospital, medical, or surgical coverage to provide coverage for medically necessary treatment of mental health and substance use disorders, under the same terms and conditions applied to other medical conditions, as specified. [HSC § 1374.72]

5) Requires a health plan that provides hospital, medical, or surgical coverage to base any medical necessity determination or the utilization review criteria that the plan, and any entity acting on the plan's behalf, applies to determine the medical necessity of health care services and benefits for the diagnosis, prevention, and treatment of mental health and substance use disorders on current generally accepted standards of mental health and substance use disorder care, as specified. Requires a health plan or insurer to apply the criteria and guidelines set

forth in the most recent versions of treatment criteria developed by the nonprofit professional association for the relevant clinical specialty in conducting utilization review of all covered health care services and benefits for the diagnosis, prevention, and treatment of mental health and substance use disorders in children, adolescents, and adults. [HSC § 1374.721]

6) Requires health plans to ensure that all services be readily available at reasonable times to each enrollee consistent with good professional practice, and to the extent feasible, a health plan to make all services readily accessible to all enrollees consistent with existing law on timely access to health care services. [HSC § 1367]

7) Requires DMHC to develop and adopt regulations to ensure that enrollees have access to health care services in a timely manner, regarding:

   a) Waiting times for appointments, including primary and specialty care physicians;

   b) Care in an episode of illness, including timeliness of referrals and obtaining other services, as needed; and,

   c) Waiting time to speak to a physician, registered nurse, or other qualified health professional trained to screen or triage. [HSC § 1367.03]

8) Requires, in developing these standards, DMHC to consider the clinical appropriateness, the nature of the specialty, the urgency or care, and the requirements of law governing utilization review. [HSC § 1367.03]

9) Requires every plan to establish procedures in accordance with DMHC regulations for continuously reviewing the quality of care, performance of medical personnel, utilization of services and facilities, and costs, as specified. [HSC § 1370]

10) Requires DMHC to conduct examinations of the fiscal and administrative affairs of any health plan, and each person with whom the plan has made arrangements for administrative, management, or financial services, as often as deemed necessary to protect the interest of subscribers or enrollees, but not less frequently than once every five years [HSC § 1382]

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

COMMENTS:

1) **PURPOSE OF THIS BILL.** According to the author, this bill is a necessary response to Kaiser's persistent and systemic failure to provide timely and adequate behavioral health care to its enrollees, despite repeated citations, fines, and mandated corrective actions. The author states that Kaiser's integrated healthcare model, which combines insurance coverage and service delivery, creates significant barriers for patients seeking external care when Kaiser's services fall short. The author continues that enrollees often face lengthy delays, inadequate treatment options, and an inability to access out-of-network providers without incurring significant personal costs. The author argues that this bill addresses these injustices by requiring Kaiser to cover the full cost of out-of-network behavioral health services when it fails to meet state and federal standards. The author notes that by shifting the financial burden from patients to Kaiser, this bill provides immediate relief for those struggling to access critical mental health care and ensures that Kaiser is held accountable until it fully

complies with the law. The author concludes that legislation is essential to protecting patient rights and improving behavioral health outcomes across California.

2) **BACKGROUND.** Kaiser is the largest health plan in California with 9.4 million members across the state. Kaiser operates under an integrated care model, meaning their members primarily receive care at Kaiser Foundation Hospitals and through providers with two exclusively contracted medical groups, The Permanente Medical Group and Southern California Permanente Medical Group. Collectively the health plan, hospitals, and medical groups are referred to as "Kaiser Permanente."

   a) **Mental Health Parity.** Federal Mental Health Parity laws require if a health plan includes services for mental health and substance use disorders as part of their benefits that those services must be covered under the same terms and conditions as other medical services. The ACA also specifies coverage of the 10 EHBs, including mental health and substance use disorder treatment services. The ACA went beyond existing federal law by mandating coverage instead of requiring parity only if coverage is provided.

      SB 855 (Wiener), Chapter 151, Statutes of 2020, requires commercial health plans and insurers in California to provide full coverage for the treatment of all mental health conditions and substance use disorders. SB 855 also establishes specific standards for what constitutes medically necessary treatment and criteria for the use of clinical guidelines. SB 855 applies to all state-regulated health plans and insurers that provide hospital, medical, or surgical coverage, and to any entity acting on the plan or insurer's behalf. A health plan cannot limit benefits or coverage for mental health or substance use disorder treatments or services when medically necessary.

   b) **Timely access laws.** SB 221 (Wiener) Chapter 724, Statutes of 2021, codified DMHC regulations requiring health plans to meet a set of standards, including specific time frames under which enrollees must be able to access care. These requirements provide health plan members the right to behavioral health appointments within the following time frames:

      i) Urgent care without prior authorization: **within 48 hours**;

      ii) Urgent care with prior authorization: **within 96 hours**;

      iii) Non-urgent psychiatrist appointments **within 15 business days**, and non-physician mental health or substance use disorder providers **within 10 business days**; and,

      iv) Non-urgent follow-up appointments with a non-physician mental health care or substance use disorder provider **within 10 business days** of the prior appointment for those undergoing a course of treatment for an ongoing mental health or substance use disorder condition.

   c) **History of behavioral health complaints against Kaiser.** DMHC is charged with enforcing behavioral health laws, including mental health parity and timely access laws. The National Union of Healthcare Workers (NUHW), sponsors of this bill, provided a timeline of complaints that NUHW has filed with DMHC, surveys and investigations that DMHC has conducted, and settlement agreements that DMHC has reached regarding Kaiser's delivery of behavioral health services. In November of 2011, NUHW therapists

filed their first complaint against Kaiser to DMHC, including a 34-page analysis of problems affecting Kaiser's behavioral health services. From 2011 to 2021, DMHC conducted various investigations and surveys of Kaiser, resulting in citations, fines, and settlements.

In May of 2022, DMHC announced that it was initiating a non-routine survey of Kaiser after receiving complaints from enrollees, providers, and other stakeholders concerning Kaiser's mental health and substance use disorder operations. Key issues included Kaiser's internal and external provider network, timely access to care, process for intake and follow-up appointments, appointment scheduling processes, levels of care and associated decision-making processes, medical record documentation and retention practices, and monitoring of urgent appointments. In August of 2022, DMHC launched an additional targeted enforcement investigation against Kaiser after receiving complaints that Kaiser was failing to schedule mental health appointments within the timely access standards set forth by state law.

In October of 2023, DMHC and Kaiser announced a $200 million settlement for both the enforcement investigation and non-routine survey. Collectively, the investigation and survey identified several violations and 20 deficiencies across Kaiser's plans. The settlement included $50 million in fines, a $150 million commitment to invest in programs that improve behavioral health services for all Californians beyond Kaiser's existing obligations, and a requirement that Kaiser take corrective action to address deficiencies in their delivery and oversight of behavioral health care to their members.

d) CAWP. The settlement agreement identified areas of concern with corresponding corrective action areas (CAAs). The agreement further stipulated that Kaiser would hire consultants to develop a CAWP to address the eight CAAs outlined in the agreement, which include:

i) Oversight;

ii) Access;

iii) Network and Referrals;

iv) Grievance and Appeals;

v) Future Strike Contingency;

vi) Mental Health Parity;

vii) Member Communications; and,

viii) Continuous Improvement and Comprehensive Review.

On August 15, 2024 Kaiser submitted their initial CAWP to DMHC. An updated version was released on March 12, 2025.

e) Claim reimbursement requirement. Under the third CAA, network and referrals, the settlement dictates that Kaiser is required to develop a process for identifying members who attempted, but were unable to, obtain timely and clinically appropriate behavioral

health care services in-network and, as a result self-referred to an out-of-network provider. The settlement further requires Kaiser to develop a process for evaluating enrollee out-of-network claims for reimbursement. The settlement states that the terms of such reimbursement will be subject to agreement between Kaiser and DMHC. This bill seeks to codify a claims reimbursement into state law.

3) **SUPPORT.** The National Union of Healthcare Workers (NUHW), sponsor of this bill, states that despite nearly two decades of escalating regulatory sanctions, Kaiser's behavioral health services remain sorely understaffed and frequently fail to provide access to timely and appropriate care. NUHW states that as a result, patients often experience lengthy delays in obtaining services, an overreliance on group therapies, and frustrating obstacles that push many to forgo care or seek treatment elsewhere at their own expense. NUHW continues that this bill ensures that Kaiser patients are not held hostage by a provider that has failed to deliver adequate care and consistently broken state behavioral health laws. NUHW argues that until Kaiser fully implements its CAWP, which DMHC expects to take up to five years, Kaiser patients will continue to suffer from lack of timely access to behavioral health services and a substandard grievance and appeals process. NUHW continues that this bill provides relief to Kaiser enrollees by requiring Kaiser to cover costs such as copayments, deductibles, prescription medication costs, provider visit fees, telehealth consultation fees, and transportation costs directly related to obtaining behavioral health care from non-Kaiser providers when Kaiser fails to provide timely and appropriate care, based solely upon the enrollees' written attestation to Kaiser's failure and submission of receipts and documentation that the services were prescribed or recommended by a licensed mental health provider. NUHW concludes that this bill ensures that Kaiser patients receive the behavioral health care they need and are entitled to under California law.

4) **OPPOSITION.** Kaiser Permanente is opposed to this bill, stating that it is unnecessary and generally duplicative of current law. Kaiser Permanente notes that this bill raises possible quality and patient safety concerns. Kaiser continues that while this bill resembles their settlement agreement and CAWP with the DMHC, the bill does not require their enrollees to attempt to access care within Kaiser Permanente’s network first before going outside of network. Kaiser Permanente states that this is inconsistent with current law and common practice in a managed care environment. Kaiser Permanente further states that this bill is costly, allowing providers and pharmacies to charge their members without limit since there is no agreed-upon rate. Kaiser Permanente argues that the bill is an “any willing provider or pharmacy” mandate which is counterproductive to access since it would undermine their ability to contract with external providers. Kaiser Permanente continues that under this bill, care would be provided outside the medical home, causing fragmentation and possible quality and patient safety issues, such as overprescribing of addictive, dangerous or scheduled drugs. Kaiser Permanente notes that the pharmacy component of this bill is also unnecessary and will be costly and difficult to administer, stating that medication access is not an issue or a noted deficiency for them.

5) **PREVIOUS LEGISLATION.**

   a) SB 221 (Wiener), Chapter 724, Statutes of 2021 codifies existing timely access to care standards for health plans and insurers, applies these requirements to Medi-Cal Managed Care plans, and adds a standard for non-urgent follow-up appointments for nonphysician

mental health care or substance use disorder providers that is within 10 business days of the prior appointment.

b) SB 855 (Wiener), Chapter 151, Statutes of 2020 revises and recasts California's Mental Health Parity provisions, and requires a health plan contract or disability insurance policy issued, amended, or renewed on or after January 1, 2021, to provide coverage for medically necessary treatment of mental health and substance use disorder, as defined, under the same terms and conditions applied to other medical conditions and prohibits a health plan or disability insurer from limiting benefits or coverage for mental health and substance use disorder to short-term or acute treatment. Specifies that if services for the medically necessary treatment of a mental health and substance use disorder are not available in network within the geographic and timely access standards in existing law, the health plan or insurer is required to arrange coverage to ensure the delivery of medically necessary out of network services and any medically necessary follow up services, as specified.

6) **PROPOSED AMENDMENT.** The committee may wish to make technical amendments to the definition of "Kaiser."

7) **POLICY COMMENT.** This bill aims to codify the claims reimbursement process, required under the DMHC/Kaiser settlement and CAWP, outside of an agreement between Kaiser and DMHC. In background provided to the committee, the author of this bill states that Kaiser's track record of underinvesting in mental health and repeated violations raises questions about the appropriateness of their oversight and administration of a program that would not be necessary had they been in compliance with the law.

   While there is merit in the author's goal for patient, provider, and legislator perspectives to be considered as the claims reimbursement process is established, there are concerns with pursing a legislative proposal that is likely to come into conflict with the process established through the CAWP.

   According to the timelines and detailed plans published in the CAWP, the claims reimbursement process is set to be completed in Q2 of 2025. If these timelines are met, the claims reimbursement process established between DMHC and Kaiser would be in effect and implemented well before the provisions of this bill. It is unclear how the terms of the process established through the CAWP and settlement agreement would interact with a new state law. Would one supersede the other? Or would they both exist, even if they are in conflict?

   DMHC and Kaiser may wish to work with the author and sponsors, to the extent possible, to find pathways for the Legislature and stakeholders to provide input on the pending claims reimbursement process being established through the CAWP to minimize consumer confusion and ensure a thorough, patient-centered process is implemented as swiftly as possible.

REGISTERED SUPPORT / OPPOSITION:

Support

National Union of Healthcare Workers (sponsor)

California Alliance for Retired Americans
California Alliance of Child and Family Services
California Federation of Labor Unions, AFL-CIO
California OneCare Education Fund
California Pan - Ethnic Health Network
County Behavioral Health Directors Association (CBHDA)
Courage California
Health Care for All - California
Healthy California Now
Mental Health America of California
National Association of Social Workers – California Chapter
Physicians for a National Health Program -- California Chapter
U.S. Pain Foundation
Unite Here International Union, AFL-CIO
Western Center on Law & Poverty

Opposition

Cal Asian Chamber of Commerce
California African American Chamber of Commerce
California Asian Pacific Chamber of Commerce
California Association of Health Plans
California Chamber of Commerce
California Hispanic Chambers of Commerce
California Medical Association (CMA)
Chino Valley Chamber of Commerce
Kaiser Permanente
Oakland Chamber of Commerce
Sacramento Hispanic Chamber of Commerce
Sacramento Metro Chamber of Commerce
Southwest California Legislative Council
The Greater Coachella Valley Chamber of Commerce
Tri County Chamber Alliance

Analysis Prepared by: Riana King / HEALTH / (916) 319-2097

Date of Hearing: April 29, 2025

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 1495 (Valencia) – As Introduced February 21, 2025

SUBJECT: Home health aides: training and certification.

SUMMARY: Requires that either a registered nurse (RN) or a licensed vocational nurse (LVN), as specified, provide the classroom or supervised practical training required for qualification as a certified home health aide (HHA). Requires an online or distance learning training program for HHA certification or in-service training for certified HHAs to include specific requirements, including, among others, requiring a trainee to sign an affidavit attesting under penalty of perjury to confirm their identity while completing the program. Specifically, **this bill**:

1) Requires a person who provides classroom and supervised practical training for a home health aide, to be either of the following:

    a) An RN who possesses a minimum of two years nursing experience, at least one year of which is in home health care; or,

    b) An LVN under the general supervision of an RN who meets the requirements of a) above.

2) Prohibits, notwithstanding any other law, an RN from being required to hold a teaching credential to provide instruction as part of a HHA certification program.

3) Requires an online or distance learning training program for HHA certification or in-service training to comply with all of the following requirements:

    a) Provide online instruction in which the trainee and their approved instructor are online at the same or similar times and allows them to use real-time collaborative software that combines audio, video, file sharing, or any other forms of approved interaction and communication;

    b) Require the use of a personal identification number or personal identification information that confirms the identity of a trainee or instructor, including, but not limited to, having a trainee sign an affidavit attesting under penalty of perjury as to their identity while completing the program;

    c) Provide safeguards to protect personal information;

    d) Include policies and procedures to ensure that instructors are accessible to trainees outside of the normal instruction times;

    e) Include policies and procedures for equipment failures, student absences, and completing assignments past original deadline;

    f) Provide a clear explanation on its internet website of all technology requirements to participate in and complete the program; and,

g) Provide the Department of Public Health (DPH) with statistics about the performance of trainees in the program, including, but not limited to, exam pass rate and the rate at which trainees repeat each module of the program, and any other information requested by DPH regarding trainee participation in and completion of the program.

4) Requires, in addition to the requirements set forth in 3) above, an online or distance learning training program or in-service training for certified HHAs to meet the same standards as a traditional, classroom-based program, and comply with any other standard established by DPH for online or distance learning HHA training programs.

5) Authorizes DPH to, notwithstanding any other law, without taking any regulatory actions pursuant to implement, interpret, or make specific the provisions of this bill by means of an All Facilities Letter (AFL) or similar instruction.

6) Requires as a condition of approval by DPH, an online or distance learning training program or in-service training for HHA certification to provide DPH with access rights to the program for the purposes of verifying that the program complies with all requirements and allowing DPH to monitor online or distance learning sessions.

EXISTING LAW:

1) Licenses and regulates home health agencies, under DPH, to provide skilled nursing services to patients in the home. [Health and Safety Code (HSC) § 1725 *et seq.*]

2) Defines HHA as an aide who has completed a state-approved training program, is employed by a home health agency or hospice program, and provides personal care service in a patient's home. Defines home health aide services as personal care services provided within a plan of treatment prescribed by a licensed doctor or surgeon. Specifies that services which do not involve personal care services provided under a plan of treatment prescribed by a physician may be provided by a person who is not a certified HHA. [HSC § 1727]

3) Permits a home health agency to also provide therapeutic services, in addition to skilled nursing services, which include physical, speech, occupational therapy, medical social services, or HHA services. [HSC § 1727.1]

4) Authorizes the certification of an applicant for a HHA certification if the applicant has done the following:

   a) Successfully completed a training program with a minimum of 75 hours or an equivalent competency evaluation program as determined by DPH;

   b) Obtains a clear criminal record clearance by electronically submitting fingerprint images and related information to the Department of Justice; and,

   c) Provides DPH with their individual taxpayer identification number or social security number for purposes of applying for certification and/or renewal of the certificate. [HSC § 1736.1]

5) Requires a certified HHA to renew their certification and obtain criminal record clearance every two years. [HSC § 1736.2]

6) Establishes in regulation the basic training for an HHA certificate program to be 120 hours and to consist of, at a minimum, the following:

   a) Introduction (four hours): including, but not limited to: definition of functions and responsibilities as a home health aide and interpretations of the employing agencies polices, as defined;

   b) Interpretation of medical and social needs of people being served (20 hours);

   c) Personal care services (70 hours): including, but not limited to, assisting patients with personal hygiene, assisting patients in self-care activities, and assisting with mobility;

   d) Cleaning and care tasks in the home (10 hours); including, but not limited to: home safety measures, handling laundry, and principles of general cleanliness of environment; and,

   e) Nutrition (16 hours): including, but not limited to, meal planning and serving and food preparation, sanitation, and storage. [22 California Code of Regulations (CCR) § 74747]

7) Requires in regulation, the training to include 20 hours of clinical experience of which at least 15 hours are personal services, two hours are in cleaning and care, and three hours are in nutrition. Clarifies the in-classroom lecture to only consist of 75 hours of the overall required training. [22 CCR § 74747]

8) Requires a HHA receive at least 12 hours of in-service training during each 12-month period. Permits in-service training to occur while an aide is furnishing care to a patient. [Title 42 Code of Federal Regulations (CFR) § 484.80 (d)]

9) Requires classroom and supervised practical training to be performed by an RN who possesses a minimum of two years nursing experience, at least one year of which must be in home health care, or by other individuals under the general supervision of the RN. [Title 42 CFR § 484.80 (e)]

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

COMMENTS:

1) **PURPOSE OF THIS BILL.** According to the author, this bill is a crucial step toward addressing California's growing caregiving crisis. This bill empowers DPH to permit online or distance learning training programs for HHA training programs. The author states that by 2030, one in four Californians will be aged 60 or older, with many relying on HHAs to meet their basic needs yet, we are expecting a shortfall of 600,000 to 3.2 million direct care workers by the same year. The author argues that this bill will expand opportunities for individuals to obtain certification, ensuring we have a larger, qualified pool of HHAs to provide essential services for seniors and others who rely on in-home care. The author concludes that with this bill, we have the opportunity to make meaningful progress in addressing this shortage and ensuring that Californians have the support they deserve.

2) **BACKGROUND.**

   a) **Home health aides**. According to AARP, a recent analysis estimates that 56% of people turning 65 between 2021 and 2025 will need long term services and supports (LTSS) in

their lifetime and millions of people need (or will need) LTSS before they reach age 65. Those trends are fueling rapid growth in the home health care field. According to the most recent data from the federal Bureau of Labor Statistics (BLS), there were more than 3.9 million HHAs and personal care aides working nationwide in 2023, up from 3.5 million three years earlier. The BLS projects their ranks to swell by 21% by 2033, much faster than the average across all occupations. The median wage for a personal care or home health aide in 2023 was $16.78 an hour, or about $34,900 a year, according to BLS.

b) **Home health aide training**. While statute requires a minimum of 75 hours of training to be a certified home health aide, current regulations actually require the basic training program for certification to be a minimum of 120 hours, with the classroom hours limited to 75 hours. DPH approves two different types of training programs: a shorter 40-hour training program for applicants that are already certified nurse assistants (CNAs), and therefore have already completed some related training, and the full 120-hour program for applicants without prior certification as a nurse assistant. DPH approves and maintains a list of postsecondary education institution HHA training programs in the state. Currently there are 164 approved programs located at California Community Colleges, for-profit institutions, and non-profit institutions throughout the state. These programs only offer the 40-hour HHA training program that is taken after a prospective student has completed the CNA certificate. DPH's training website indicates that there are only 20 training programs that offer the 120-hour course in just 11 counties.

c) **Master Plan on Aging.** In January 2021, the Newsom Administration published its Master Plan for Aging, which is intended to be a ten-year blueprint for state government, local government, the private sector, and philanthropy to prepare the state for the coming demographic changes and "continue California's leadership in aging, disability, and equity." The Master Plan for Aging outlines five goals, 23 strategies, and over 100 initiatives. Goal two of the Master Plan, "Health Reimagined," focuses on ensuring that older adults have access to the care and services needed to optimize health and quality of life and continue to live where they choose. The Master Plan notes that over half of older adults, especially women, will eventually need home care or adult day health care to assist with daily activities such as meal preparation, physical activity, and bathing. One of the key strategies outlined under "Health Reimagined" is "Bridging Health Care with Home," including testing models of health care delivery that maximize access to services and avoid unnecessary institutionalization. Goal three of the Master Plan, "Inclusion and Equity, not Isolation," focuses on opportunities for community engagement and protection from isolation.

3) **SUPPORT.** The Alzheimer's Association (AA) supports this bill and states that HHAs provide an integral service to individuals living with Alzheimer's disease or other dementia by assisting them with Activities of Daily Living. This also provides caregivers with some respite from their responsibilities for their own personal care, which prevents caregiver fatigue. AA argues that under this bill HHAs will receive training to provide quality care to individuals who are living at home with their condition. This training will give caregivers a sense of comfort when leaving their loved one, which can be a guilt-ridden and anxiety inducing experience. AA concludes that this bill provides access to a profession that is badly needed especially as California's population is aging in a critical mass.

The California Association for Health Services at Home (CAHSAH) also supports this bill stating California's allied health workforce is critically in need of more certified HHAs as California's senior population continues to grow exponentially each year. CAHSAH says home health agencies are experiencing more hospital referrals for patients who need home health services. California must be ready with a qualified workforce to meet the growing demands of individuals who wish to receive care in their homes. CAHSAH is especially pleased that this bill contains provisions to authorize certified home health aides to complete their continuing education units online. With the growing advancements in online training and the requirement for an RN or LVN to provide the classroom or supervised practical training required for qualification as a certified HHA, CAHSAH is confident the right bill provisions are in place to ensure quality care. Certified HHA training programs are very limited throughout the state and many counties do not offer training programs. CAHSAH concludes that' creating the authorization for completing training online will greatly improve access to training throughout the entire state and especially in California's rural areas.

4) PREVIOUS LEGISLATION.

a) AB 2069 (Villapudua) of 2022 would have established a scholarship program at the Department of Health Care Access and Information (HCAI), with awards of $1,500 for 1,000 people, for costs related to training to become a certified home health aide. Required scholarship recipients to work for one year as a home health aide or repay 25% of the scholarship award. This bill was vetoed by the Governor.

b) AB 1306 (Arambula) of 2021 would have authorized HCAI to address barriers to entry in health professions for students from underrepresented background by establishing pilot programs, internships, and fellowships at public universities throughout California. AB 1306 was held on the Senate Appropriations Committee suspense file.

REGISTERED SUPPORT / OPPOSITION:

Support

Alzheimer's Association
California Association for Health Services At Home

Opposition

None on file

Analysis Prepared by: Logan Hess / HEALTH / (916) 319-2097