# California State Assembly

## HEALTH

**MIA BONTA**
CHAIR



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## AGENDA

Tuesday, April 9, 2024
1:30 p.m. -- 1021 O Street, Room 1100

BILLS HEARD IN FILE ORDER
TESTIMONY MAY BE LIMITED:
2 WITNESSES PER SIDE, 2 MINUTES EACH

| | | | |
|---|---|---|---|
| 1. | AB 1915 | Arambula | Pupil health: drug education: opioid overdose training program. |
| 2. | AB 1970 | Jackson | Mental Health: Black Mental Health Navigator Certification. |
| 3. | AB 1977 | Ta | Health care coverage: behavioral diagnoses. |
| 4. | AB 1996 | Alanis | Opioid antagonists: stadiums, concert venues, and amusement parks: overdose training. |
| 5. | AB 2043 | Boerner | Medi-Cal: nonmedical and nonemergency medical transportation. |
| 6. | AB 2058 | Weber | Automated decision systems. |
| 7. | AB 2110 | Arambula | Medi-Cal: Adverse Childhood Experiences trauma screenings: providers. |
| 8. | AB 2129 | Petrie-Norris | Immediate postpartum contraception. |
| 9. | AB 2161 | Arambula | The Early Psychosis Intervention Plus Program. |
| 10. | AB 2169 | Bauer-Kahan | Prescription drug coverage: dose adjustments. |
| 11. | AB 2237 | Aguiar-Curry | Children and youth: transfer of specialty mental health services. |
| 12. | AB 2258 | Zbur | Health care coverage: cost sharing. |
| 13. | AB 2297 | Friedman | Hospital and Emergency Physician Fair Pricing Policies. |

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| 14. | AB 2356 | Wallis | Medi-Cal: monthly maintenance amount: personal and incidental needs. |
| 15. | AB 2365 | Haney | Public health: kratom. |
| 16. | AB 2390 | Arambula | Social Media Harm Reduction Pilot Program. |
| 17. | AB 2411 | Wendy Carrillo | Local Youth Mental Health Boards. |
| 18. | AB 2428 | Calderon | Medi-Cal: Community-Based Adult Services. |
| 19. | AB 2549 | Gallagher | Patient visitation. |
| 20. | AB 2550 | Gabriel | Business establishments: building standards: retail food safety. |
| 21. | AB 2657 | Arambula | Social Media Commission. |
| 22. | AB 2700 | Gabriel | Emergency medical services: alternate destinations. |
| 23. | AB 2701 | Villapudua | Medi-Cal: dental cleanings and examinations. |
| 24. | AB 2749 | Wood | California Health Benefit Exchange: financial assistance. |
| 25. | AB 2871 | Maienschein | Overdose fatality review teams. |
| 26. | AB 2899 | Gabriel | General acute care hospitals: licensed nurse-to-patient ratios. |
| 27. | AB 2998 | McKinnor | Minors: consent to medical care. |
| 28. | AB 3030 | Calderon | Health care services: artificial intelligence. |
| 29. | AB 3129 | Wood | Health care system consolidation. |
| 30. | AB 3161 | Bonta | Health and care facilities: patient safety and antidiscrimination. |
| 31. | AB 3218 | Wood | Unflavored Tobacco List. |
| 32. | AJR 10 | Irwin | Food date labeling. |

Date of Hearing: April 9, 2024

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 1915 (Arambula) – As Amended April 1, 2024

**SUBJECT**: Pupil health: drug education: opioid overdose training program.

**SUMMARY**: Requires the State Department of Public Health (DPH) to develop by July 1, 2026, a training program and toolkit for public school pupils in grades nine to 12, to gain skills in how to identify and respond to an opioid overdose, including the administering of a federally approved opioid overdose reversal medication. Specifically, **this bill**:

1) Requires the DPH to develop by July 1, 2026, a training program and program toolkit for public school pupils in grades nine to 12, inclusive, to gain skills in how to identify and respond to an opioid overdose, including the administering of a federally approved opioid overdose reversal medication.

2) Requires DPH, by July 1, 2026, to notify public high schools of the availability of the program toolkit.

3) Requires DPH to provide the program toolkit upon request to public high schools that opt to host the program on their campuses.

4) Requires DPH, in establishing the program, to collaborate with local, state, and national organizations, which may include community health centers, community health experts, and nonprofits with related expertise, to provide pupils with integrated, comprehensive, accurate, and unbiased educational materials on opioid and drug overdose prevention, opioid and drug safety, and stigma reduction.

5) Authorizes the program to include, but not be limited to, the following:

    a) Informational videos, graphics, or in-person training on what to do and how to respond during a drug or opioid overdose. Authorizes DPH to use any existing content or other relevant materials already developed, or develop new materials;
    b) Information on how to recognize signs of a drug or opioid overdose; and,
    c) Information on how to respond in an emergency involving a drug or opioid overdose.

6) Requires the program toolkit to encourage and support opioid overdose training instruction in person at public high schools from appropriately trained instructors from local, state, and national organizations, which may include community health centers, community health experts, nonprofit organizations with related expertise, and school staff. Requires instructors who are not employed by the school to undergo state-approved background checks.

7) Requires the program to provide resource materials related to drug and opioid use and or prevention, appropriate for use with students of all races, genders, sexual orientations, and ethnic and cultural backgrounds, students with disabilities, and English learners.

8) Requires any school district, county office of education (COE), or charter school, serving students in grades nine to 12, that chooses to make naloxone hydrochloride (NH) or another

opioid antagonist available on campus to ensure that it is placed in an appropriate location, as determined by the governing board or body, that is widely known and easily accessible, both during school hours and after school hours. Requires that the NH or another opioid antagonist is located in at least one of the following locations on campus:

a) School nurse's office;
b) Athletic trainer's office;
c) Front office;
d) Performing arts auditorium;
e) Library;
f) Cafeteria; or,
g) Athletic gym.

**EXISTING LAW**:

1) Establishes DPH, directed by a state Public Health Officer (PHO), to be vested with all the duties, powers, purposes, functions, responsibilities, and jurisdiction as they relate to public health disease prevention, as specified. Gives the PHO, broad authority to detect, monitor, and prevent the spread of communicable disease in the state. [Health & Safety Code (HSC) §131050 and §120130, *et seq*.]

2) Authorizes the DPH, in order to reduce the rate of fatal overdose from opioid drugs including heroin and prescription opioids, to award funding to local health departments, local government agencies, or on a competitive basis to community-based organizations, regional opioid prevention coalitions, or both, to support or establish programs that provide naloxone, or any other opioid antagonist that is approved by the United States Food and Drug Administration (FDA) for the treatment of an opioid overdose, to first responders and to at-risk opioid users through programs that serve at-risk drug users, including, but not limited to, syringe exchange and disposal programs, homeless programs, and substance use disorder (SUD) treatment providers. [HSC §1179.80]

3) Establishes within the California Health and Human Services Agency a grant program to reduce fentanyl overdoses and use throughout the state by providing six one-time grants: two in northern California, two in the central valley, and two in southern California. [Welfare and Institutions Code §3200]

4) Permits a pharmacy to furnish NH or another opioid antagonist to a school district, COE, or charter school pursuant to existing law if certain requirements are met. [Business and Professions Code (BPC) §4119.8]

5) Authorizes a pharmacy, wholesaler, or manufacturer to furnish NH or other opioid antagonists to a law enforcement agency if specified conditions are met. [BPC §4119.9]

6) Classifies controlled substances under the California Uniform Controlled Substances Act, into five schedules and places the greatest restrictions and penalties on the use of those substances placed in Schedule I. Classifies the drug fentanyl in Schedule II. [HSC §11054-11058]

7) Establishes ongoing funding for COEs to purchase and maintain sufficient stock of emergency NH or another opioid antagonist for local educational agencies within its jurisdiction. [Education Code (EDC) §49414.8]

8) Authorizes school districts, COEs, and charter schools to provide emergency NH or another opioid antagonist to school nurses or trained volunteer personnel for the purpose of providing emergency medical aid to persons suffering, or reasonably believed to be suffering, from an opioid overdose. [EDC §49414.3 *et seq.*]

9) Authorizes public and private elementary and secondary schools to voluntarily determine whether or not to make emergency NH or another opioid antagonist and trained personnel available at its school. Requires a school to evaluate the emergency medical response time to the school and determine whether initiating emergency medical services is an acceptable alternative to NH or another opioid antagonist and trained personnel. [EDC §49414.3 (c)]

10) Requires the Superintendent of Public Instruction (SPI) to establish minimum standards of training for the administration of NH or another opioid antagonist and to review the minimum standards of training every five years, or sooner, as deemed necessary. Requires the SPI to consult with organizations and providers with expertise in administering NH or another opioid antagonist and administering medication in a school environment, including, the California Society of Addiction Medicine, the Emergency Medical Services Authority, the California School Nurses Organization, the California Medical Association, and the American Academy of Pediatrics. [EDC §49414.3(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, the fentanyl and opioid crisis is a state and nationwide public health emergency that has taken the lives of so many young people. Fentanyl prevention, education, and training on how to assist someone who is experiencing an opioid overdose is lifesaving. According to DPH, in 2021 there were 7,175 deaths because of an opioid overdose. The state can take a leadership role to inform people of how to treat those who undergo a potentially fatal overdose. This bill will establish a training program and toolkit for high school pupils. It will outline key methods on how to support a peer experiencing an opioid overdose, with the use of NH nasal sprays. The author concludes that through comprehensive and evidence-based training, students can prepare and learn ways to support their peers experiencing a drug-related overdose.

2) **BACKGROUND.** California is facing an overdose epidemic. According to a California Health Care Foundation report, 9% of Californians have met the criteria for a SUD within the last year. While the health care system is moving toward acknowledging SUDs as a chronic illness, only about 10% of people with an SUD within the last year received treatment. 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 DPH, fentanyl-related overdose deaths increased 625% among youth ages 10 to 19 from 2018 to 2020. DPH's Opioid Overdose Dashboard reported there were 177 fentanyl-related overdose deaths and 1,165 opioid-related overdose emergency department visits among youth ages 10 to 19 years old in 2022.

**a) Fentanyl.** Fentanyl is a potent synthetic opioid drug approved by the FDA for use as an analgesic and anesthetic. It is approximately 50 times stronger than heroin and 100 times stronger than morphine. First developed in 1959, it was introduced in the 1960's as an intravenous anesthetic. Fentanyl is legally manufactured and distributed in the US; however, there are two types of fentanyl: pharmaceutical fentanyl and illicitly manufactured fentanyl. Both are considered synthetic opioids. Pharmaceutical fentanyl is prescribed by doctors to treat severe pain, especially after surgery and for advanced-stage cancer. Most recently, cases of fentanyl-related overdoses are linked to illicitly manufactured fentanyl that is distributed through illegal drug markets for its heroin-like effect. It is often added to other drugs because of its extreme potency, which makes drugs cheaper, more powerful, more addictive, and more dangerous.

The California Department of Education, in conjunction with DPH, provides local educational agencies with resources and information that they can provide to parents and students. The Fentanyl Awareness and Prevention toolkit page offer information about the risks of fentanyl and how to prevent teen use and overdoses. In addition to the toolkit, DPH's Substance and Addiction Prevention branch also provides resources for parents, guardians, caretakers, educators, schools, and youth-serving providers.

**b) Reversing opioid overdoses.** NH is the generic name for an opioid antagonist that rapidly reverses an opioid overdose. It attaches to opioid receptors and reverses and blocks the effects of other opioids. NH can quickly restore normal breathing to a person if their breathing has slowed or stopped because of an opioid overdose. NH comes in two FDA-approved forms: injectable and prepackaged nasal spray. Narcan nasal spray was first approved by the FDA in 2015 as a prescription drug.

According to the FDA, in accordance with a process to change the status of a drug from prescription to nonprescription, the manufacturer of Narcan provided data demonstrating that the drug is safe and effective for use as directed in its proposed labeling. The manufacturer also showed that consumers can understand how to use the drug safely and effectively without the supervision of a healthcare professional. The application to approve Narcan nasal spray for over-the-counter (OTC) use was granted priority review status and was the subject of an advisory committee meeting in February 2023, where committee members voted unanimously to recommend it be approved for marketing without a prescription.

As of July 2023 the FDA approved Narcan and RiVive, for OTC, nonprescription use. These are the first NH products approved for use without a prescription. This approval will allow the medications to be sold directly to consumers in drug stores, grocery stores, as well as online. According to an FDA Commissioner, "The approval of OTC NH nasal spray will help improve access to NH, increase the number of locations where it's available and help reduce opioid overdose deaths throughout the country. We encourage the manufacturer to make accessibility to the product a priority by making it available as soon as possible and at an affordable price."

**c) NH Availability in California school districts.** The 2023-24 state Budget appropriated $3.5 million annually for COEs to purchase and maintain a sufficient stock of emergency opioid antagonists for school districts and charter schools within their jurisdiction, and to maintain a minimum of two units at each middle school, junior high school, high school,

and adult school site. As a condition of receiving the funding, each school or charter school must ensure two staff members meet minimum training standards.

**d) DPH statewide standing order for NH.** NH can help reduce opioid overdose deaths in California, but many organizations find it difficult to obtain the required standing order to obtain NH from health care providers. According to DPH, of the 7,175 opioid-related overdose deaths in 2021, 83% or 5,961 were related to fentanyl. The number of deaths each year involving fentanyl increased dramatically between 2012 and 2021. During this time period fentanyl related overdose deaths increased by more than 7,250% from 82 to 5,961 in 2021. DPH issued a standing order, in 2017, to address this need and support equitable NH access. The standing order:

**i)** Allows community organizations and other entities in California that are not currently working with a physician, to distribute NH 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 NH 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 NH under the order are colleges and universities. An individual at risk of experiencing an 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 NH must be trained. They are also required to provide training to individuals who receive NH 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 due to its OTC status, all other formulations remain available by prescription only and require a standing order to distribute and administer.

**e) Naloxone Distribution Project.** A separate distribution program administered through the Department of Health Care Services (DHCS), the Naloxone Distribution Project (NDP) allows various entities, including schools, universities and colleges, to apply for and obtain NH at no cost to the institution. As of February 20, 2024 the NDP has approved more than 10,800 applications for NH (17% of which are from schools and universities), distributed more than 3.8 million kits of NH and reversed more than 245,000 opioid overdoses. DHCS reports that less than one percent of the overdose reversals reported in the NDP occurred in schools and universities.

3) **SUPPORT.** Generation Up (GENup) is a sponsor of this bill, stating they are committed to student safety, and the explosion in youth opioid overdoses is a serious threat to student well-being. GENup continues that students aren't taught how to deal with stigma and safety around opioid use, and this bill counters that shortfall by prioritizing youth accessibility to medication and knowledge that can save the lives of their peers, families, and communities. GENup argues that equipping and empowering students to deliver care in emergency situations may mean the difference between life and death.

**4) RELATED LEGISLATION.**

**a)** AB 1996 (Alanis) requires DPH to develop an opioid overdose training program for stadium, concert venue, and amusement park staff. AB 1996 is pending in Assembly Health Committee.

**b)** AB 3271 (Joe Patterson) requires each individual public school operated by a school district, county office of education, or charter school that has elected to make a school nurse or trained personnel available at the school to maintain at least two units of naloxone hydrochloride or another opioid antagonist on campus. AB 3271 is pending in Assembly Health Committee.

**c)** AB 2998 (McKinnor) permits minors 12 years of age and above to consent to receiving, carrying, and administering NH or another opioid antagonist if approved by a physician. AB 2998 is pending in Assembly Health Committee.

**5) PREVIOUS LEGISLATION.**

**a)** AB 915 (Arambula) of 2023 was substantially similar to AB 1915. AB 915 was held in the Senate Appropriations Committee suspense file.

**b)** AB 1748 (Mayes), Chapter 557, Statutes of 2016, authorizes school nurses and other trained personnel to use NH or another opioid antagonist to provide emergency medical aid to persons suffering, or reasonably believed to be suffering, from an opioid overdose.

**c)** SB 1438 (Pavley), Chapter 491, Statutes of 2014, required the development of training and other standards for the administration of NH by emergency medical technicians and other pre-hospital emergency care personnel.

**d)** AB 635 (Ammiano), Chapter 707, Statutes of 2013, revised certain provisions from a pilot program authorizing prescription of opioid antagonists for treatment of drug overdose and limiting civil and criminal liability, expanded these provisions statewide, and removed the 2016 sunset date for the pilot program. Permits a licensed health care provider who is authorized by law to prescribe an opioid antagonist, if acting with reasonable care, to prescribe and subsequently dispense or distribute an opioid antagonist to a person at risk of an opioid-related overdose or a family member, friend, or other person in a position to assist the person at risk, and limited the professional and civil liability of licensed health care providers and persons who possess or distribute opioid antagonists.

**6) DOUBLE REFERRAL.** This bill is double referred, it passed the Assembly Committee on Education with a 7-0 vote on March 20, 2024.

**REGISTERED SUPPORT / OPPOSITION**:

**Support**

Generation Up (sponsor)
Alameda County Office of Education
American Academy of Pediatrics, California
California Academy of Child and Adolescent Psychiatry
California Federation of Teachers AFL-CIO

County Health Executives Association of California
Los Angeles County Office of Education

**Opposition**

None on file.

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

Date of Hearing: April 9, 2024

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 1970 (Jackson) – As Amended April 1, 2024

**SUBJECT**: Mental Health: Black Mental Health Navigator Certification.

**SUMMARY**: Requires the Department of Health Care Access and Information (HCAI) to develop, as a component of an existing Community Health Worker (CHW) certificate program, criteria for a specialty certificate program and specialized training requirements for a Black Mental Health Navigator Certification, and report related program data. Specifically, **this bill**:

1) Requires HCAI to develop criteria for a specialty certificate program and specialized training requirements for a Black Mental Health Navigator Certification.

2) Includes, in the criteria developed pursuant to 1) above, comprehensive training in mental health resources and awareness, including, but not limited to, entry-level assessments, crisis intervention training for nonemergency cases, navigation support, and Afrocentric practices relative to delivering public health and mental health assistance to help connect individuals with state resources, licensed mental health professionals, and wellness services.

3) Requires HCAI to solicit stakeholder feedback on criteria for the certificate and allows HCAI to engage a community-based organization with relevant expertise about mental health and wellness in Black communities to advise on or to develop the criteria.

4) Requires HCAI to collect and regularly publish data, not less than annually, on the number and overall demographics of individuals who earn a certificate, including a specialty certificate, as well as the number of individuals who are actively employed in a community health worker role.

**EXISTING LAW**:

1) Specifies CHW services as a covered benefit under Medi-Cal. [Welfare & Institutions Code (WIC) § 14132.36]

2) Defines CHW to mean a liaison, link, or intermediary between health and social services and the community to facilitate access to services and to improve the access and cultural competence of service delivery. States that a CHW is a frontline health worker either trusted by, or who has a close understanding of, the community served, and requires a CHW's lived experience to align with and provide a connection to the community being served. [WIC § 18998]

3) States that CHWs include Promotores, Promotores de Salud, community health representatives, navigators, and other nonlicensed health workers, including violence prevention professionals. [*ibid.*]

4) Requires HCAI to develop statewide requirements for CHW certificate programs in consultation with stakeholders, including, but not limited to, the Department of Health Care

Services (DHCS), the California Department of Public Health, CHWs, Promotores and Promotores de Salud, or representative organizations. [*ibid.*]

5) Requires, as part of 4), above, HCAI to determine criteria for specialty certificate programs and specialized training requirements that build on the lived experience of CHWs. [*ibid.*]

6) Allows HCAI to, in consultation with stakeholders, request that an individual who is either enrolled in, or who has completed, a community health worker certificate program submit data, and allows HCAI to determine the frequency and manner of data submission. [*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, California must ensure equal access and quality healthcare for our African American communities. The author notes studies consistently highlight disparities in health outcomes among people of color, particularly within our Black communities—an inequity that stems partly from a lack of cultural competency among healthcare providers. This bill aims to address these disparities by implementing better training and data reporting on CHWs, paving the way for long-term policy solutions. California Black Health Network is this bill's sponsor.

**2) BACKGROUND.**

**a) Mental Health Disparities in Black/African American Communities.** Racial and ethnic disparities in health and health care remain a persistent challenge in the United States. Compared with non-Hispanic whites, Black and African Americans with any mental illness have lower rates of any mental health service use including prescription medications and outpatient services, but higher use of inpatient services. Black people are also less likely to utilize psychiatric services, and if they receive care, it is usually of lower quality than care provided to white people. Consequently, unmet need for mental health care is greater among Black and African Americans than white people.

Unfortunately, unmet need for mental health care can manifest itself in crises. According to the Centers for Disease Control and Prevention, rates of mental health-related emergency department (ED) visits by race and Hispanic ethnicity were highest among non-Hispanic Black adults (96.8 visits per 1,000 adults), followed by non-Hispanic white (53.4) and Hispanic (36.0) adults. Rates of ED visits for specific mental health disorders, including substance use disorders, anxiety disorders, and mood disorders, were also highest among non-Hispanic Black adults.

According to KFF's "Key Data on Health and Health Care by Race and Ethnicity," among adults with any mental illness, Black (39%), Hispanic (36%), and Asian (25%) adults were less likely than white (52%) adults to receive mental health services as of 2021. Overall rates of mental illness and substance use disorder were lower for people of color compared to white people but could be underdiagnosed among people of color. Research suggests that a lack of culturally sensitive screening tools that detect mental illness, coupled with structural barriers could contribute to underdiagnosis of mental illness among people of color.

**b) Barriers to Mental Health Care.** According to the federal Substance Abuse and Mental Health Services Administration, Black and African Americans and other minority groups experience barriers to behavioral health services and care including:

**i)** Experiences of bias, stemming from historical, structural, and systemic racism, and discrimination;
**ii)** Mental health stigma which hinders Black and African Americans from seeking help;
**iii)** Mistrust of the health care system, access barriers and negative encounters with care professionals;
**iv)** Provider shortage due to the limited from diverse racial/ethnic backgrounds (only 2% of psychiatrists and 4% of psychologists in the United States are Black); and,
**v)** Lack of culturally competent providers to meet cultural, social, and language-related needs.

According to the American Psychiatric Association, other common barriers reported in the Black population include the importance of family privacy, lack of knowledge regarding available treatments, and denial of mental health problems. Concerns about medications, not receiving appropriate information about services, and dehumanizing services have also been reported to hinder Black and African Americans from accessing mental health services.

**c) CHWs.** According to the National Association of Community Health Workers, "CHW" is used as an umbrella term to describe community health representatives, promotores de salud or promotoras, outreach workers, and many other different work titles. CHWs share life experience with the people they serve and have firsthand knowledge of the causes and impacts of health inequity. In the United States (US), the majority of CHWs serve communities that have experienced structural oppression and who are marginalized by traditional health care systems, including Black, Latinx, American Indian/Alaska Native, and Asian/Pacific Islander communities, as well as rural and low-income communities.

According to the American Public Health Association (APHA), CHWs are frontline public health workers who are trusted members of and/or have an unusually close understanding of the community served. This trusting relationship enables CHWs to serve as a liaison between health/social services and the community to facilitate access to services and improve the quality and cultural competence of service delivery. CHWs also build individual and community capacity by increasing health knowledge and self-sufficiency through a range of activities such as outreach, community education, informal counseling, social support and advocacy. APHA's definition is commonly cited by other organizations. California's Welfare and Institutions Code Section 18998 contains a similar definition, and emphasizes that a CHW's lived experience aligns with and provides a connection to the community being served. Although CHW is commonly used as an umbrella term, promotores and Community Health Representatives (CHRs) have distinct histories and footprints in California. Promotores. Promotores de salud, or promotores, are lay health workers who most often provide culturally congruent services informed by their lived experiences to Spanish-speaking communities, while CHRs serve in tribal communities.

Although CHWs leverage their own language, culture, and lived experience to relate to the people they serve, CHWs are distinct from peer support specialists common in the

behavioral health field. Peer support specialists are distinguished by having direct experience with recovery from and treatment of their own mental health condition or substance use; furthermore, they are specifically trained how to make use of their personal experience to assist others in recovery.

CHWs can and do work in the behavioral health field alongside peer support specialists and licensed clinicians. However, they are not limited to behavioral health—they can address a variety of different health conditions in addition to behavioral health, including infectious and chronic disease, oral health, maternal and child health, among others. Many CHWs specialize in working with specific populations or in a specific topical area, including behavioral health.

**d) Recent State Efforts.** In recent years, the state has enacted two major initiatives related to CHWs, promotoras, and community health representatives (CHW/P/Rs): First, DHCS added CHW services as a Medi-Cal benefit starting in July 1, 2022, and has leveraged CHW/P/Rs in specific roles under the Medi-Cal transformation project called California Advancing and Innovating Medi-Cal (CalAIM). Under Medi-Cal, supervising providers can bill for the services CHW/P/Rs provide, including health education, navigation, limited screening and assessment to determine need for services, and individual support and advocacy across a wide range of health conditions, including behavioral health.

Second, the 2022 Budget Act included $281.4 million over three years to support a new program administered by HCAI to recruit, train, and certify 25,000 new CHW/P/Rs by 2025, including those with specialized training to work with specific populations or on specific issues. Both initiatives are still in the early stages of implementation.

**e) HCAI Statutory Requirements**. SB 184 (Committee on Budget and Fiscal Review), Chapter 47, Statutes of 2022, the 2022 Health Trailer Bill, described the HCAI CHW initiative. It required HCAI to develop statewide requirements for CHW certificate programs in consultation with stakeholders. Specifically, it required HCAI to do the following:

**i)** Consult evidenced-based and community-defined materials;

**ii)** Determine necessary curriculum to meet certificate program objectives;

**iii)** Determine criteria for specialty certificate programs and specialized training requirements that build on the lived experience of CHWs;

**iv)** Determine a structure of statewide oversight that reduces barriers to training;

**v)** Determine how past experience as a CHW may provide a pathway to certification, and how to verify past experience; and,

**vi)** Approve statewide requirements for the development of certificate programs for CHWs, approve the curriculum for such programs, and review, approve, or renew evidence-based curricula and community-defined curricula for core competencies, specialized programs, and training. The statute allows organizations to submit an application for HCAI approval of a CHW certificate program.

**f)** **Current Status and Stakeholder Work**. In July 2023, following a series of stakeholder consultation sessions, HCAI issued a guidance letter implementing the requirements described above. However, the guidance letter has since been "paused" as HCAI collects more robust stakeholder input. The state team comprised of the California Health and Human Services Agency, DHCS, and HCAI has been working since late 2023 to design a further stakeholder engagement process, which launched in February. This work is planned to conclude in June 2024. In late February, the agencies convened an ad hoc advisory group that will continue to advise to ensure the process is comprehensive, relevant, and appropriate.

**g)** **Implementation of this Bill**. As noted above, statute requires HCAI to determine criteria for specialty certificate programs and specialized training requirements that build on the lived experience of CHWs. HCAI has not yet adopted curricula for specialty certificates. This bill would require adoption of a specialty certificate specific to the mental health needs of Black/African American people, as described above, and require reporting on the number of people who earn certificates, including the specialty certificates. Once the state approves the curriculum, training entities make available the applicable training, and individuals earn the certificates, then providers, including community-based organizations, can employ these trained CHWs who are trained and possess the Black Mental Health Navigator Certification. Providers would then be able to bill Medi-Cal through the CHW benefit for provision of covered CHW services, including navigation, screening and assessment, health education, and individual support and advocacy, to Medi-Cal eligible individuals.

**3)** **SUPPORT.** National Association of Social Workers California Chapter writes in support that this bill directs attention to a particular demographic and emphasizes the importance of delivering services with competence by mandating a thorough understanding of who our clients are and what social conditions have historically impacted their trajectory through multiple generations. The California Pan-Ethnic Health Network indicates providing targeted mental health support tailored to the specific needs and experiences of Black communities is essential for addressing disparities and promoting overall well-being. The California State Association of Psychiatrists writes that while they support the bill and its intentions, changing the language to Behavioral Health would be more inclusive and allow for a more accurate and comprehensive representation of the individuals the legislation is aimed at helping.

**4)** **RELATED LEGISLATION.**

**a)** AB 2250 (Weber) requires a health plan, health insurer, and Medi-Cal to provide coverage for, and provider reimbursement of, social determinants of health (SDOH) screenings. Requires a health plan or insurer to provide to physicians who provide primary care services with adequate access to peer support specialists, lay health workers, social workers, or CHWs, as defined. Provides for reimbursement of SDOH screenings at the Medi-Cal fee-for-service rate for federally qualified health centers and rural health clinics. AB 2250 passed the Assembly Health Committee on April 2, 2024, on a vote of 15 to 0.

**b)** AB 2110 (Arambula), also pending in this committee, allows doulas, as well as community-based organizations and local health jurisdictions that provide health services

through CHWs, to provide Adverse Childhood Experiences trauma screenings (ACEs screening) and makes them eligible for Medi-Cal reimbursement for the screening.

**5) PREVIOUS LEGISLATION.**

**a)** AB 85 (Weber) of 2023 was similar to AB 2250 (Weber), above, and required the Department of Health Care Access and Information to convene a working group. AB 85 was vetoed by Governor Newsom, who expressed support for the overall goal of this proposal, but that it is duplicative of existing efforts, such as ACEs screenings and the work DHCS is doing through the CalAIM initiative. The Governor also cited that the bill may be premature given a standardized SDOH tool does not yet exist.

**b)** AB 2697 (Aguiar-Curry), Chapter 488, Statutes of 2022, codifies CHW services as a covered Medi-Cal benefit.

**c)** SB 184 codified the HCAI CHW workforce initiative.

**REGISTERED SUPPORT / OPPOSITION**:

**Support**

California Family Resource Association
California Pan - Ethnic Health Network
California State Association of Psychiatrists
Child Abuse Prevention Center
National Association of Social Workers California
Prevent Child Abuse California
Safe Kids California

**Opposition**

None on file.

**Analysis Prepared by**: Lisa Murawski / HEALTH / (916) 319-2097

Date of Hearing: April 9, 2024

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 1977 (Ta) – As Amended April 1, 2024

**SUBJECT**: Health care coverage: behavioral diagnoses.

**SUMMARY**: Prohibits a health plan contract or health insurance policy issued, amended, or renewed on or after January 1, 2025 from requiring an enrollee or insured previously diagnosed with pervasive developmental disorder (PDD) or autism to be reevaluated or review a new behavioral diagnosis to maintain coverage for behavioral health treatment (BHT) for PDD or autism. Clarifies that this bill does not prohibit a treating provider from reevaluating an enrollee or insured for purposes of determining the appropriate treatment.

**EXISTING LAW**:

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

2) Requires every health plan contract and health insurance policy that provides hospital, medical, or surgical coverage to cover BHT for PDD or autism. Requires the coverage to be provided in the same manner and to be subject to the same requirements as provided in California's mental health parity law. [HSC §1374.73 and INS §10144.51]

3) Defines BHT for purposes of 2) above as professional services and treatment programs, including applied behavior analysis and evidence-based intervention programs, that develop or restore, to the maximum extent practicable, the functioning of an individual with PDD or autism and that meet specified criteria regarding the treatment plan, the professionals who can prescribe (physicians and psychologists) and supervise treatment, and administer a treatment plan. Defines BHT to mean specified services provided by, among others, a qualified autism service professional (QASP) or qualified autism service paraprofessional (QASPP) supervised and employed by a qualified autism services (QAS) provider. [HSC §1374.73 (d)(1) and INS §10144.51(d)(1)]

4) Defines the following BHT providers:
   a) QASP to mean an individual that meets specified criteria, including is supervised by a QAS provider; provides treatment pursuant to a treatment plan developed and approved by a QAS provider; is either a behavioral service provider as specified in regulations or a clinical provider as defined and regulated by the Board of Behavioral Sciences or the Board of Psychology; has training and experience in providing services for PDD or autism; and, is employed by the QAS provider responsible for the autism treatment plan;
   b) Defines a QASPP an unlicensed and uncertified individual who meets specified criteria, including supervision by a QAS provider or QASP at a level of clinical supervision that meets professionally recognized standards of practice, provides treatment and implements services pursuant to a treatment plan developed and approved by the QAS provider; and meets the education and training qualifications described in regulations; and,
   c) Defines a QAS provider to mean either of the following:

i) A person who is certified by a national entity, such as the Behavior Analyst Certification Board, with a certification that is accredited by the National Commission for Certifying Agencies, and who designs, supervises, or provides treatment for PDD or autism, provided the services are within the experience and competence of the person who is nationally certified; or,
ii) A person licensed as a physician and surgeon, physical therapist, occupational therapist, psychologist, marriage and family therapist, educational psychologist, clinical social worker, professional clinical counselor, speech-language pathologist, or audiologist under the Business and Professions Code, who designs, supervises, or provides treatment for PDD or autism, provided the services are within the experience and competence of the licensee. [HSC §1374.73(c) and INS §10144.51(c)]

5) Requires the treatment plan to have measurable goals over a specific timeline that is developed and approved by the QAS provider for the specific patient being treated. Requires the treatment plan to be reviewed no less than once every six months by the QAS provider and modified whenever appropriate, and requires the QAS provider to do all of the following:
   a) Describes the patient's behavioral health impairments or developmental challenges that are to be treated;
   b) Designs an intervention plan that includes the service type, number of hours, and parent participation needed to achieve the plan or insurer's goal and objectives, and the frequency at which the patient's progress is evaluated and reported;
   c) Provides intervention plans that utilize evidence-based practices, with demonstrated clinical efficacy in treating PDD or autism; and,
   d) Discontinues intensive behavioral intervention services when the treatment goals and objectives are achieved or no longer appropriate. [HSC §1374.73(c)(1)(C) and INS §10144.51(c)(1)(C)]

**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 end the unnecessary practice of requiring families to undergo burdensome autism reevaluations every two to three years. These reevaluations, for a lifelong condition, pose a constant hurdle for families of children with autism or PDD, placing the child's access to critical BHT at risk and imposing additional costs on behavioral health providers. The author concludes that the Legislature should end this outdated practice and allow parents to decide the best time for their children to be reevaluated, instead of fixing them to an arbitrary, stressful, and difficult reevaluation process.

**2) BACKGROUND.** According to the California Health Benefits Review Program, autism spectrum disorder (ASD) is a developmental disability characterized by deficits in social interactions and communication, sensory processing, stereotypic (repetitive) behaviors or interests, and sometimes cognitive function. The symptoms of ASD fall along a continuum, ranging from mild impairment to profound disability. ASD diagnoses are often made early in life, as individuals often demonstrate symptoms in early childhood. ASD can sometimes be detected by the age of 18 months, with reliable diagnoses by age two. The cause (or causes) of ASD remain unknown, and research into genetic etiology, as well as environmental

factors, continues to be explored. There is no cure for ASD; however, there is evidence that treatment, including BHT, may improve some symptoms. California law requires BHT coverage and requires a QAS provider to review a treatment plan no less than once every six months by the QAS provider and modified whenever appropriate.

**a) ASD screening and diagnosis.** According to the Centers for Disease Control and Prevention, ASD can be difficult to identify because there is no medical test, like a blood test, to diagnose the disorder. Doctors look at the child's developmental history and behavior to make a diagnosis. ASD can sometimes be detected at 18 months of age or younger. By age two, a diagnosis by an experienced professional can be considered reliable. However, many children do not receive a final diagnosis until much older. Some people are not diagnosed until they are adolescents or adults. This delay means that people with ASD might not get the early help they need. Diagnosing children with ASD as early as possible is important to make sure children receive the services and supports they need to reach their full potential.

- **i)** Developmental Monitoring. Developmental monitoring is an active, ongoing process of watching a child grow and encouraging conversations between parents and providers about a child's skills and abilities. Developmental monitoring involves observing how a child grows and whether a child meets the typical developmental milestones, or skills that most children reach by a certain age, in playing, learning, speaking, behaving, and moving.
- **ii)** Developmental Screening. Developmental screening takes a closer look at how a child is developing. Developmental screening is more formal than developmental monitoring. It is a regular part of some well-child visits even if there is not a known concern. The American Academy of Pediatrics (AAP) recommends developmental and behavioral screening for all children during regular well-child visits at nine months, 18 months, and 30 months. In addition, AAP recommends that all children be screened specifically for ASD during regular well-child visits at 18 months and 24 months.
- **iii)** Developmental Diagnosis. A brief test using a screening tool does not provide a diagnosis, but it can indicate whether a child is on the right development track or if a specialist should take a closer look. If the screening tool identifies an area of concern, a formal developmental evaluation may be needed. This formal evaluation is a more in-depth look at a child's development and is usually done by a trained specialist such as a developmental pediatrician, child psychologist, speech-language pathologist, occupational therapist, or other specialist. The specialist may observe the child give the child a structured test, ask the parents or caregivers questions, or ask them to fill out questionnaires. The results of this formal evaluation highlight a child's strengths and challenges and can inform whether they meet criteria for a developmental diagnosis. A diagnosis of ASD now includes several conditions that used to be diagnosed separately; autistic disorder, PDD not otherwise specified, and Asperger syndrome. The results of a formal developmental evaluation can also inform whether a child needs early intervention services. In some cases, the specialist might recommend genetic counseling and testing for a child.

**b) SB 946.** SB 946 (Steinberg and Evans), Chapter 650, Statutes of 2011, imposes a set of rules regarding BHT that health plans and health insurers in California must cover for individuals with autism and PDD. SB 946 also identifies the required qualifications of individuals who provide BHT, and permits individuals who are not licensed by the state

to provide BHT, as long as the detailed criteria set forth in SB 946 are met. Additionally, SB 946 specifies requirements of treatment plans, including measurable goals for a specific patient and review no less than once every six months and modified whenever appropriate. This bill prohibits a health plan from requiring an enrollee to be reevaluated or receive a new behavioral health diagnosis to maintain BHT coverage. Recent amends clarify that a treating provider may reevaluate an enrollee to determine the appropriate treatment.

**c) SB 855.** SB 855 (Wiener), Chapter 151, Statutes of 2020, requires commercial health plans and insurers to provide full coverage for the treatment of all mental 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. California law requires health care coverage of behavioral health and wellness screenings.

**3) SUPPORT.** The Council of Autism Service Providers (CASP) writes that ASD is a complex, lifelong disorder. Once diagnosed with autism, treatment should begin as soon as possible. Ample evidence has established that early intervention can improve social and communication skills, and this has the potential to significantly help improve the child's later development and independence while reducing the need for costly supports in school and across the lifespan. CASP concludes that delays and disruptions to treatment can adversely affect the overall outcome.

**4) OPPOSITION.** The California Association of Health Plans (CAHP), the Association of California Life and Health Insurance Companies (ACLHIC), and America's Health Insurance Plans (AHIP), are concerned this bill, as it is currently drafted, is too broad. Specifically, this bill could potentially negatively impact patients' quality of care by prohibiting plans/insurers from reevaluating an enrollee/insureds' treatment plan. The opposition states that this bill may have unintended consequences that could be detrimental to the quality of care they receive.

**5) RELATED LEGISLATION.** AB 2449 (Ta) clarifies that the Qualified Applied Behavior Analysis Credentialing Board is also a national entity that may certify a QAS provider, and authorizes the certification to be accredited by the American National Standards Institute. AB 2499 is pending in Assembly Health Committee.

**6) PREVIOUS LEGISLATION.**

**a)** SB 805 (Portantino), Chapter 635, Statutes of 2023, expands the criteria for a QASP to include a psychological associate, an associate marriage and family therapist, an associate clinical social worker, or an associate professional clinical counselor, as specified. Requires those positions to meet the criteria for a Behavioral Health Professional, as provided. Requires the Department of Developmental Services (DDS) to adopt regulations, on or before July 1, 2026, to address the use of Behavioral Health Professionals and Behavioral Health Paraprofessionals in BHT group practice. Requires DDS to establish rates and the educational or experiential qualifications and professional

supervision requirements necessary for these positions to provide behavioral intervention services, as specified.

**b)** SB 562 (Portantino) of 2021 would have revised the definition of BHT to require the services and treatment programs provided to be based on behavioral, developmental, relationship-based, or other evidence-based models. Would have revised the definition of a QASP to include a registered, certified, or licensed associate or assistant regulated by one of a list of specified professional boards, and supervised by a QAS provider practicing in the associate's or assistant's field of medicine. Would have revised the training requirements for a QASPP by authorizing training to be provided by a QAS provider practicing the evidence-based treatment modality that the QASPP will administer. Would have required the QAS provider to design an intervention plan that includes parent or caregiver participation, when clinically appropriate, that is individualized to the patient, or to develop an alternative plan if a parent or caregiver cannot participate, as specified. Would have prohibited using the lack of parent or caregiver participation, implementation of an alternative plan, or the setting, location, or time of treatment as a reason to deny or reduce coverage for medically necessary services. SB 562 was vetoed by Governor Newsom, who stated in part:

"Early diagnosis of ASD and subsequent participation in evidence-based intervention and therapies, provided by licensed and certified individuals, make all the difference in an individual's long-term health outcomes. Research finds that Black and Latino children are often misdiagnosed and diagnosed later with ASD than their white peers. It is incumbent upon us to ensure that any intervention is medically-necessary, evidence-based and grounded in research that is conducted to reduce disparities."

**REGISTERED SUPPORT / OPPOSITION**:

**Support**

American Academy of Pediatrics, California
Association of Regional Center Agencies
California Health Coalition Advocacy
Educate. Advocate.
SCDD
The Arc & United Cerebral Palsy California Collaboration
The Council of Autism Service Providers

**Opposition**

America's Health Insurance Plans (AHIP)
Association of California Life & Health Insurance Companies
California Association of Health Plans

**Analysis Prepared by**: Kristene Mapile / HEALTH / (916) 319-2097

Date of Hearing: April 9, 2024

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 1996 (Alanis) – As Introduced January 30, 2024

**SUBJECT**: Opioid antagonists: stadiums, concert venues, and amusement parks: overdose training.

**SUMMARY**: Requires the State Department of Public Health (DPH) to develop an opioid overdose training program for stadium, concert venue, and amusement park staff. Specifically, **this bill**:

1) Requires DPH to develop an opioid overdose training program for stadium, concert venue, and amusement park staff to effectively identify and respond to an opioid overdose, including how to administer naloxone hydrochloride (NH) or other opioid antagonists.

2) Requires stadiums, concert venues, and amusement parks to ensure that NH or another opioid antagonist on site is easily accessible and its location is widely known.

**EXISTING LAW**:

1) Establishes DPH, directed by a state Public Health Officer (PHO), to be vested with all the duties, powers, purposes, functions, responsibilities, and jurisdiction as they relate to disease prevention, as specified. Gives the PHO, broad authority to detect, monitor, and prevent the spread of communicable disease in the state. [Health & Safety Code (HSC) § 131050 and § 120130, *et seq.*]

2) Authorizes the DPH, in order to reduce the rate of fatal overdose from opioid drugs including heroin and prescription opioids, to award funding to local health departments, local government agencies, or on a competitive basis to community-based organizations, regional opioid prevention coalitions, or both, to support or establish programs that provide NH, or any other opioid antagonist that is approved by the United States Food and Drug Administration (FDA) for the treatment of an opioid overdose, to first responders and to at-risk opioid users through programs that serve at-risk drug users, including, but not limited to, syringe exchange and disposal programs, homeless programs, and substance use disorder (SUD) treatment providers. [HSC § 1179.80]

3) Requires stadiums, concert venues, and amusement parks to maintain unexpired doses of an opioid antagonist on site and ensure that at least two employees are aware of the location. Provides indemnification for anyone who administers NH or another opioid antagonist, in good faith, on the premises of a stadium, concert venue, or amusement park. [HSC § 11871]

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

**COMMENTS**:

1) **PURPOSE OF THIS BILL.** According to the author, California communities continue to be ravaged by opioid overdoses. Families are being ripped apart while access to this poison continues to grow. The author states that this bill is a step toward helping our communities

better understand and respond to signs of overdoes in places where people gather by focusing on the expanded training of public venue employees' ability to understand the signs of an opioid overdose and respond appropriately using approved opioid counter agents like Narcan. The author concludes that by expanding this training, we can ensure a wider net of protection for all members of the community.

2) **BACKGROUND.** California is facing an overdose epidemic. According to a California Health Care Foundation report, 9% of Californians have met the criteria for a SUD within the last year. While the health care system is moving toward acknowledging SUDs as a chronic illness, only about 10% of people with an SUD within the last year received treatment. 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 ten-fold increase in fentanyl related deaths between 2015 and 2019. DPH's Opioid Overdose Dashboard reported 7,385 deaths related to "any" opioid overdose in 2022, with 6,473 (87.7%) of those deaths fentanyl related.

   a) **Fentanyl.** Fentanyl is a potent synthetic opioid drug approved by the FDA for use as an analgesic and anesthetic. It is approximately 50 times stronger than heroin and 100 times stronger than morphine. First developed in 1959, it was introduced in the 1960s as an intravenous anesthetic. Fentanyl is legally manufactured and distributed in the United States; however, there are two types of fentanyl: pharmaceutical fentanyl and illicitly manufactured fentanyl. Both are considered synthetic opioids. Pharmaceutical fentanyl is prescribed by doctors to treat severe pain, especially after surgery and for advanced-stage cancer. Most recently, cases of fentanyl-related overdoses are linked to illicitly manufactured fentanyl that is distributed through illegal drug markets for its heroin-like effect. It is often added to other drugs because of its extreme potency, which makes drugs cheaper, more powerful, more addictive, and more dangerous.

   b) **Reversing opioid overdoses.** NH is the generic name for an opioid antagonist that rapidly reverses an opioid overdose. It attaches to opioid receptors and reverses and blocks the effects of other opioids. NH can quickly restore normal breathing to a person if their breathing has slowed or stopped because of an opioid overdose. NH comes in two FDA-approved forms: injectable and prepackaged nasal spray. Narcan nasal spray was first approved by the FDA in 2015 as a prescription drug.

      According to the FDA, in accordance with a process to change the status of a drug from prescription to nonprescription, the manufacturer of Narcan provided data demonstrating that the drug is safe and effective for use as directed in its proposed labeling. The manufacturer also showed that consumers can understand how to use the drug safely and effectively without the supervision of a healthcare professional. The application to approve Narcan nasal spray for over-the-counter (OTC) use was granted priority review status and was the subject of an advisory committee meeting in February 2023, where committee members voted unanimously to recommend it be approved for marketing without a prescription.

      As of July 2023 the FDA has approved Narcan and RiVive, for OTC, nonprescription use. These are the first NH products approved for use without a prescription. These approvals allow the medications to be sold directly to consumers in drug stores, grocery stores, as well as online. According to an FDA Commissioner, "The approval of OTC

NH nasal spray will help improve access to NH, increase the number of locations where it's available and help reduce opioid overdose deaths throughout the country. We encourage the manufacturer to make accessibility to the product a priority by making it available as soon as possible and at an affordable price."

**c) Existing DPH education and training materials.** DPH's Substance and Addiction Prevention Branch maintains numerous resources for the public on NH and overdose prevention on their Opioid Prevention Initiative webpages. These webpages include two DPH developed training videos, in English and Spanish, to educate the general public on how to administer NH. The webpages also host two recorded NH webinar trainings from 2018, one targeted for professionals who educate laypersons about opioid overdose and distributing NH, the other for program managers and others in charge of implementing NH distribution systems and the Overdose Education and Naloxone Distribution program in their community. The webpages also provide links to general information on opioids and NH, how to recognize and respond to an overdose, where to get NH, disposal guidance, and multiple outside resources on NH and overdose response.

**3) SUPPORT.** The California Public Defenders Association (CDPA) supports this bill, stating that it addresses the alarming rise in fentanyl overdoses by requiring staff at stadiums, concert venues, and amusement parks to undergo training in identifying and treating overdoses, and ensuring the accessibility of opioid antagonists. CDPA argues that with a staggering 1,030% increase in fentanyl-related deaths over the past six years, California faces a pressing public health crisis. CDPA continues that this bill offers a proactive approach to saving lives and safeguarding attendees by equipping venue staff with the necessary tools and training to respond effectively to opioid overdoses, thereby enhancing public safety and health. CPDA welcomes legislative efforts treating opioid overdoses as a health issue, rather than relying on criminal penalties. Their clients and their families are members of the community attending sporting events, concerts, and amusement parks whose lives may be saved.

**4) RELATED LEGISLATION.** AB 1915 (Arambula) requires DPH to develop by July 1, 2026, a training program and toolkit for public school pupils in grades nine to 12 to gain skills in how to identify and respond to an opioid overdose, including the administering of a federally approved opioid overdose reversal medication. This bill is currently pending in Assembly Health Committee.

**5) PREVIOUS LEGISLATION.**

**a)** SB 234 (Portantino), Chapter 596, Statutes of 2023, requires stadiums, concert venues, and amusement parks to maintain unexpired doses of an opioid antagonist on its premises and ensure that at least two employees are aware of the location and provides indemnification, as specified.

**b)** AB 915 (Arambula) would have required DPH to create an opioid overdose training program and program toolkit to train high school students on how to identify and respond to an opioid overdose. This bill also would have required any local educational agency, county office of education, and charter school that voluntarily determines to make naloxone hydrochloride or another opioid antagonist available on campus to be placed in

an appropriate location, as specified. AB 915 was held in the Senate Appropriations Committee.

**c)** AB 1233 (Waldron), Chapter 570, Statutes of 2023, requires the Department of Health Care Services (DHCS) to conduct outreach to each of the tribal governments in California for the purpose of advising them of the availability of NH or another opioid antagonist through DHCS' Naloxone Distribution Project.

**d)** AB 33 (Bains), Chapter 887, Statutes of 2023, establishes the Fentanyl Addiction and Overdose Prevention Task Force to undertake specified duties relating to fentanyl abuse.

6) **DOUBLE REFERRAL.** This bill is double referred, upon passage of this Committee, it will be referred to the Assembly Committee on Arts, Entertainment, Sport, and Tourism Committee.

7) **SUGGESTED AMENDMENT.** DPH's Opioid Prevention Initiative has produced numerous resources and trainings for the public on NH and overdose prevention. All of the initiative's materials are available to the public on DPH's website. It is unclear what DPH would need to develop separately for stadium, concert venue, and amusement park staff, and neither the author's office nor representatives for the sites impacted in this bill have been able to detail what additional resources are needed. The Committee may wish to amend this bill to instead direct DPH to create an overdose training toolkit for stadium, concert venue, and amusement park staff. The amendments could include guidelines for what types of content the toolkit should include and authorize DPH to use existing content or develop new materials as needed.

**REGISTERED SUPPORT / OPPOSITION**:

**Support**

California Association of Alcohol and Drug Program Executives
California District Attorneys Association
California Medical Association
California Public Defenders Association
Everyday Responder Project

**Opposition**

None on file.

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

Date of Hearing: April 9, 2024

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 2043 (Boerner) – As Amended April 1, 2024

**SUBJECT**: Medi-Cal: nonmedical and nonemergency medical transportation.

**SUMMARY**: Requires the Department of Health Care Services (DHCS) to ensure the fiscal burden of transporting Medi-Cal beneficiaries is not unfairly placed on public paratransit service operators (public transit operators or transit agencies). **Specifically,** this bill:

1) Requires DHCS to ensure that the fiscal burden of transporting beneficiaries via nonemergency medical transportation or nonmedical transportation is not unfairly placed on public transit operators.

2) Allows DHCS to ensure compliance with 1), above, by directing Medi-Cal managed care plans to reimburse public paratransit service operators who are enrolled as Medi-Cal providers at DHCS's fee-for-service (FFS) rates for the trip.

3) Requires DHCS to engage with transit agencies and issue guidance related to the requirement in 1), above.

4) Makes various findings and declarations that clarify this bill's purpose, including:

    a) Support of public transportation as a state concern;

    b) Transit agencies' responsibility under the federal Americans with Disabilities Act of 1990 to provide complementary paratransit services to people with disabilities;

    c) The status of complementary paratransit services as highly subsidized by public transit operators for the public benefit of eligible riders;

    d) The ability of transit agencies to seek reimbursement for Medi-Cal transportation before and after the inclusion of the transportation benefit in Medi-Cal managed care; and,

    e) A 2023 Centers for Medicare and Medicaid Services (CMS) guidance that advises state Medicaid agencies to explore partnerships with transit agencies and should ensure that the fiscal burden of transporting Medicaid beneficiaries is not unfairly placed on paratransit services.

**EXISTING LAW**:

1) Requires, under federal regulations issued by CMS, states to ensure necessary transportation for beneficiaries to and from providers. [Title 42, Code of Federal Regulations (CFR) §431.53]

2) 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*.]

3) Establishes a schedule of benefits under the Medi-Cal program, which includes federally required and optional Medicaid benefits. [WIC §14132]

4) Defines, under state regulations, a nonemergency medical transportation (NEMT) as ambulance, litter van, and wheelchair van services, which are to be provided when the beneficiary's medical and physical condition is such that transport by ordinary means of public or private conveyance is medically contraindicated, and transportation is required for the purpose of obtaining needed medical care. [Title 22, California Code of Regulations §51151.7]

5) Requires Medi-Cal to cover nonmedical transportation (NMT), subject to utilization controls and permissible time and distance standards, for a beneficiary to obtain covered Medi-Cal services. [*Ibid*]

6) States that NMT includes, at a minimum, round trip transportation for a beneficiary to obtain covered Medi-Cal services by passenger car, taxicab, or any other form of public or private conveyance, and mileage reimbursement when conveyance is in a private vehicle arranged by the beneficiary and not through a transportation broker, bus passes, taxi vouchers, or train tickets. [*Ibid*]

7) Excludes from NMT the transportation of the sick, injured, invalid, convalescent, infirm, or otherwise incapacitated beneficiaries by ambulance, litter van, or wheelchair van licensed, operated, and equipped in accordance with state and local statutes, ordinances, or regulations. [*Ibid*]

8) Requires NMT to be provided for a beneficiary who can attest that other currently available resources have been reasonably exhausted. Provides that for beneficiaries enrolled in a managed care plan, NMT must be provided by the plan. Requires, for Medi-Cal FFS beneficiaries, DHCS to provide NMT when those services are not available to the beneficiary. [*Ibid*]

9) Requires NMT to be provided in a form and manner that is accessible in terms of physical and geographic accessibility, for the beneficiary and consistent with applicable state and federal disability rights laws. [*Ibid*]

10) States it is the intent of the Legislature to affirm federal requirements, in which DHCS is required to provide necessary transportation, including NMT, for recipients to and from covered services, and that the addition of statutory requirements are not to be interpreted to add a new benefit to the Medi-Cal program. [*Ibid*]

11) States, prior to the effective date of any necessary federal approvals, NMT was not a Medi-Cal managed care benefit with the exception of when provided as an Early and Periodic Screening, Diagnostic, and Treatment service. [*Ibid*]

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

**COMMENTS**:

1) **PURPOSE OF THIS BILL.** This bill is sponsored by the San Diego Metropolitan Transit System (MTS) to ensure Medi-Cal reimbursement for public transit operators despite enrollment of individuals into Medi-Cal managed care plans. According to the author, public transit operators provide NMT and NEMT for medically necessary Medi-Cal covered services, for which the transit operators are supposed to be reimbursed. The author asserts that pursuant to AB 2394 (Garcia), Chapter 615, Statutes of 2016, transportation costs were being built into Medi-Cal managed care plan rates, but the bill has an unintended consequence because it did not include a corresponding requirement to reimburse public transit operators. With no requirement or incentive to reimburse public transit operators for Medi-Cal transportation services the plan is responsible to pay for, the author states operators are often left with little recourse to recoup the costs for their services. This bill seeks to correct this imbalance by requiring DHCS to take specific steps to ensure the fiscal burden of transporting Medi-Cal beneficiaries is not unfairly placed on public paratransit service operators, pursuant to recent federal Medicaid guidance.

2) **BACKGROUND.**

   a) **Medi-Cal Transportation Coverage**. Medi-Cal is California's safety net health care program, covering about one-third of the state's population. Medi-Cal covers a comprehensive set of health benefits. Pursuant to federal regulation, Medi-Cal also covers both medical and nonmedical transportation that is needed in order to access other covered benefits.

      i) **Medical transportation**. Medical transportation can be either emergency medical transportation or NEMT, as described below:

         **(1)** Emergency medical transportation is a typical "ambulance ride" and may involve the emergency medical system. Per Medi-Cal guidance, it is provided when necessary to obtain program covered benefits when the beneficiary's condition is acute and severe, necessitating immediate medical diagnosis and treatment in order to prevent death or disability. It does not require prior authorization and is always by ambulance.

         **(2)** NEMT is provided when necessary to obtain program covered medical services and when the beneficiary's medical and physical condition is such that transport by ordinary means of private or public conveyance is medically contraindicated. This type of medical transportation is subject to prior authorization. Each authorization request for such transportation must be accompanied by either a prescription or order signed by a physician, dentist, or podiatrist, which describes the medical reasons necessitating the use of NEMT. Authorization is granted only for the lowest cost type of medical transport that is adequate for the patient's medical needs and is available to transport the patient at the time transportation is required. NEMT is specialized transportation by ambulance, litter van, and wheelchair van services.

      ii) **NMT**. NMT is the transportation of members to access covered services by passenger car, taxicabs, or other forms of public or private transport. The term "NMT" can be confusing, as NMT is covered when it is used to transport people to a medical

service, such as an office visit or an outpatient surgery. However, unlike emergency and nonemergency *medical* transportation, the transportation itself is "nonmedical" in that is does not require specialized vehicles, equipment, or personnel.

**b) Other State Medicaid Programs**. According to a Kaiser Family Foundation issue brief, "Medicaid Non-Emergency Medical Transportation: Overview and Key Issues in Medicaid Expansion Waivers," state Medicaid agencies have considerable latitude in how they administer NEMT/NMT benefits. Most states use third-party brokerage firms to coordinate transportation for beneficiaries in return for a capitated payment, while some states deliver services directly via FFS reimbursements, and still others rely on a mix of capitated brokerage, direct delivery, and public transit voucher programs as appropriate based on geographic and beneficiary needs. States may also contract with managed care plans to provide transportation for their enrollees.

Pursuant to recent federal guidance discussed further below, the Centers for Medicare and Medicaid Services (CMS), which oversees state Medicaid programs, notes that while states can engage vendors and managed care plans, and can delegate the many aspects of the operation of transportation programs to other entities, the single state Medicaid agency ultimately is responsible for ensuring transportation that meets all statutory and regulatory requirements, regardless of whether the beneficiary receives necessary transportation through a Medicaid FFS or managed care delivery system.

According to the Medicaid and Children's Health Insurance Program Payment and Access Commission (MacPAC), a federal entity that tracks and advises on Medicaid policy, use of public transportation for NEMT/NMT purposes varies considerably across states and even within states as public transportation is not available in all areas. MacPAC indicates although the scope of the benefit varies by state, NEMT/NMT generally covers a broad range of transportation services including trips in taxis, buses, vans, and personal vehicles belonging to beneficiaries and their family or friends.

**c) Federal Americans with Disabilities Act (ADA) requirements.** Independent of Medi-Cal, the federal ADA obligates public transit operators to ensure that their policies and practices do not discriminate against individuals with disabilities. This includes offering so-called demand-responsive services such as dial-a-ride and paratransit services that are comparable to the level of service provided to individuals without disabilities who use the fixed route system.

**d) Experience of California Public Transit Operators**. According to the sponsor of this bill, public transit operators provide both NMT and NEMT to Medi-Cal managed care plan enrollees to access medically necessary Medi-Cal covered services, such as travel to appointments for medically necessary covered services; picking up drug prescriptions that cannot be mailed directly to the enrollee; or, picking up medical supplies such as prosthetics, orthotics, and other equipment.

According to MTS, the sponsor of this bill, before the enactment of AB 2394, which specified managed care plans were responsible for providing NMT to their beneficiaries, public transit operators billed Medi-Cal FFS directly for covered transportation services. However, MTS asserts that since the responsibility was transferred to managed care plans, and plans do not appear required to reimburse transit providers, plans are placed

under little to no pressure at all to partner with transportation providers. For some operators, transportation reimbursement has been a sizable revenue source, providing hundreds of thousands to several millions of dollars that enable them to continue offering NMT and NEMT services. Without it, operators absorb the costs of these services, which may impact other services.

According to recent reporting, public transit ridership in California has fully not recovered since plummeting during the pandemic. Public transit operators have been experiencing a drop in ridership and revenue. Combined with the end of federal aid, many operators expect without additional public subsidies, they need to impose higher fares and/or service cuts. Transit operators more reliant on revenue collected from passenger fares to fund operations are at higher financial risk. Significantly increasing public transit trips is also key to reducing vehicle-miles traveled and meeting the state's climate goals.

The role of public transit operators is unique. From a fiscal perspective, there are significant public subsidies inherent in the public transit system. For instance, this bill's sponsor indicates a transit agency may charge a rider $5 for a paratransit ride that costs the agency $60 to provide. The balance of the cost to the transit agency is generally covered by local, state, and federal revenue. This dynamic creates some level of murkiness about whether appropriate reimbursement from a plan is what the transit agency charges a consumer, which is heavily subsidized, or something closer to the actual cost of providing the service. Recent federal guidance addressed this question, as discussed further below.

Transit operators also have independent mandates to ensure the availability of nondiscriminatory transportation to individuals with disabilities under ADA. This distinguishes these operators from private providers such as taxis or Uber, and may, as this bill's sponsors suggest, undermine the ability of these operators to negotiate and reach contractual agreements with plans because, by definition, these operators must provide requested services pursuant to federal requirements, regardless of another payer's responsibility to cover the service.

**e) DHCS Guidance**. On May 18, 2022, DHCS issued All Plan Letter (APL) 22-008 to provide Medi-Cal managed care health plans with guidance regarding NEMT and NMT services. The APL:

- **i)** Details coverage requirements for NMT and NEMT, generally restating statutory and regulatory requirements for transportation coverage, and clarifying processes and plan responsibility for monitoring and oversight;
- **ii)** Requires plans to provide transportation to Medi-Cal covered services, whether the covered service is covered by the plan or by a different delivery system, like a county;
- **iii)** Specifies plans may subcontract with transportation brokers for the provision of the NEMT or NMT services;
- **iv)** States NEMT services are subject to prior authorization, with some exceptions, and allows plans to require prior authorization for NMT; and,
- **v)** Requires plans to authorize, at a minimum, the lowest cost type of NEMT service, and requires the NMT service requested to be the least costly method of transportation that meets the member's needs.

Although it seems reasonable to infer the least costly method would at times be the public transit agency, the APL does not specifically address availability of public transit for Medi-Cal beneficiaries or specify whether the plan has a responsibility to contract with or reimburse public transit operators.

**f)** **Federal Guidance**. On September 28, 2023, CMS issued State Medicaid Director letter # 23-006: "Assurance of Transportation: A Medicaid Transportation Coverage Guide" to serve as a consolidated and comprehensive compilation of both current and new Medicaid transportation policy, providing a one-stop source of guidance on federal requirements and state flexibilities. As it relates to the issues raised by this bill, the CMS letter offers the following guidance to states:

**i)** States should ensure that the fiscal burden of transporting Medicaid beneficiaries is not unfairly placed on paratransit services.
**ii)** State departments of transportation and Medicaid agencies should explore partnerships to better serve the Medicaid population, including considering how public providers and Medicaid agencies can work together to understand transit and Medicaid policies and definitions.
**iii)** Recognizing the higher costs of operating a paratransit system, Medicaid may pay more than the rate charged to individuals with disabilities for a paratransit ride.

With respect to iii) above, the bill's sponsor reiterates the rate charged to individuals with disabilities for a paratransit ride is a subsidized rate designed to make the ride accessible to a public rider paying directly for the service, and is not equal to and does not cover the cost of providing the paratransit services. CMS appears to acknowledge this point, in explicitly authorizing Medicaid to reimburse paratransit operators more than the rate charged to individuals with disabilities.

**g)** **Implementation of this Bill.** This bill requires DHCS to ensure, per federal guidance, that the fiscal burden of transporting Medicaid beneficiaries is not unfairly placed on paratransit services. It authorizes, but does not require, DHCS to do so by directing Medi-Cal managed care plans to reimburse public paratransit service operators who are enrolled as Medi-Cal providers at the DHCS's FFS rates for the trip. Although the state generally does not mandate payment levels and arrangements between Medi-Cal managed care plans and their contracted providers, federal regulations allow states to establish minimum fee schedules for providers in managed care (42 CFR §438.6). DHCS is also authorized to implement the bill without setting a minimum fee schedule requiring plans to pay paratransit operators at the FFS Medi-Cal rate, as long as DHCS ensures by some means that the fiscal burden of transporting Medicaid beneficiaries is not unfairly placed on paratransit services. However, requiring reimbursement at the FFS level for Medi-Cal enrolled paratransit providers seems a reasonable approach that would ensure a consistent level of reimbursement and address the unique needs of transit agencies, including addressing the imbalance in negotiating power between managed care plans and public transit operators based on the latter's obligations under ADA.

**3)** **SUPPORT.** Transit operators and advocates support this bill to ensure public transit operators can be reimbursed for providing covered services that Medi-Cal managed care plans are financially responsible to provide. Eastern Sierra Transit Authority (ESTA) writes that in Bishop, California, the public transit system carries hundreds of Medi-Cal passengers

every year. Under current law, ESTA writes, managed care plans are placed under little to no pressure at all to partner with public paratransit service operators, who are not legally allowed to turn away customers, because there is no requirement to reimburse these operators and plans can retain the funds instead of reimbursing operators.

**4) PREVIOUS LEGISLATION.**

**a)** AB 719 (Boerner) of 2023 attempted to address the same issue as this bill. AB 719 would have required Medi-Cal managed care plans that are contracted to provide nonemergency medical transportation or nonmedical transportation to contract with public paratransit service operators who are enrolled Medi-Cal providers, for the purpose of establishing reimbursement rates for nonemergency medical transportation and nonmedical transportation trips provided by a public paratransit service operator. AB 719 was vetoed by Governor Newsom, who expressed support for more public paratransit service operators enrolling as nonmedical transportation providers in Medi-Cal, but contended that the bill required DHCS to pursue a series of federal approvals that are not currently allowable under federal guidance and was thereby not a prudent use of state resources.

**b)** AB 2394 added to the schedule of benefits nonmedical transportation, as defined, effective July 1, 2017, subject to utilization controls and permissible time and distance standards, for a beneficiary to obtain covered Medi-Cal services.

**c)** AB 1231 (Wood) of 2015 was substantially similar to AB 2394 and would have added NMT as a Medi-Cal benefit. Along with five other bills, AB 1231 was vetoed by the Governor, who stated that, "These bills unnecessarily codify certain existing health care benefits or require the expansion or development of new benefits and procedures in the Medi-Cal program. Taken together, these bills would require new spending at a time when there is considerable uncertainty in the funding of this program. Until the fiscal outlook for Medi-Cal is stabilized, I cannot support these measures."

**REGISTERED SUPPORT / OPPOSITION**:

**Support**

AARP
Access Services
California Special Districts Association
Eastern Sierra Transit Authority
Orange County Transportation Authority
Stanislaus Regional Transit Authority

**Opposition**

None on file.

**Analysis Prepared by**: Lisa Murawski / HEALTH / (916) 319-2097

Date of Hearing: April 9, 2024

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 2058 (Weber) – As Amended March 18, 2024

**SUBJECT**: Automated decision systems.

**SUMMARY**: Requires a medical device to have a legible disclosure on the product, the packaging, or within informational material included with the packaging for the device to include known limitations on the effectiveness of the device because of certain characteristics of the patient using the device or of the patient on which the medical device is being used, including, but not limited to age, color, disability, ethnicity, gender, or race.

**EXISTING LAW**:

1) Regulates, under the Sherman Food, Drug, and Cosmetic Law, regulates the packaging, labeling, and advertising of drugs and devices and is administered by the State Department of Public Health (DPH). Makes a violation of that law a crime. [Health and Safety Code (HSC) § 109875-111915]

2) Authorizes the DPH to establish performance standards for devices designed to provide reasonable assurance of safe and effective performance and, where appropriate, requiring the use and prescribing the form and content of labeling for the proper installation, maintenance, operation, or use of the device. [HSC § 11245]

3) Provides any drug or device is misbranded if its labeling is false or misleading in any particular. [HSC § 111330]

4) Provides that any device is misbranded if it the labeling fails to reveal facts concerning the food, drug, device or cosmetic or consequences of consumer use. [HSC § 111335]

5) Provides that any drug or device is misbranded unless its labeling bears all of the following information:

    a) Adequate directions for use. If DPH determines that

    b) Such adequate warnings against use in pathological conditions or by children where its use may be dangerous to health.

    c) Adequate warning against unsafe dosage or methods or duration of administration or application.

    d) Warnings must be in a manner and form as are necessary for the protection of users. If DPH determines that any requirement of subdivision (a), as applied to any drug or device, is not necessary for the protection of the public health, the department may adopt regulations exempting the drug or device from these requirements.

    e) Any drug or device exempted under federal law governing misbranded drugs and devices exempt from the requirement of this section. DPH is authorized adopt any regulation including a drug or device within, or excluding a drug or device from the requirements of

this section, whether or not the inclusion or exclusion of the drug or device is in accord with federal law. [HSC § 111375]

6) Provides that any drug or device is misbranded unless it bears a label containing all of the following information:
   a) The name and place of business of the manufacturer, packer, or distributor.
   b) An accurate statement of the quantity of the contents in terms of weight, measure, or numerical count. Authorizes reasonable variations from these requirements.
   c) Requirements for placement and prominence of the information and exemptions as to small packages shall be established in accordance with existing regulations. [HSC § 11340]

7) Provides that any drug or device is misbranded if any word, statement, or other information required by or under this part to appear on the label or labeling is not prominently placed on the label or labeling with conspicuousness, as compared with other words, statements, designs, or devices in the labeling, and in terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use. [HSC § 111345]

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

**COMMENTS**:

1) **PURPOSE OF THIS BILL.** According to the author, medical technologies are the technologies that diagnose, treat and improve a person's health and wellbeing, and include both low- and high-risk medical devices. These products may vary from tongue depressors, bedpans and medical thermometers to insulin pumps, complex pacemakers and in vitro diagnostics. Advancements in medical technology have resulted in significant positive impacts for patients, and the healthcare industry as a whole. The author states that these technologies and devices are not without flaw; studies have shown that both pulse oximeters and forehead thermometers are less accurate on individuals with darker skin. The author continues that these types of inaccuracies can lead to delays in diagnoses or drug administration, and could possibly have fatal implications. The author concludes that for these reasons, this bill requires a medical device manufacturer to include a disclosure on the device or its packaged materials, on the known limitations of the effectiveness of the device due to certain characteristics of the patient using the device or of the patient on which the medical device is being used, including, but not limited to age, color, gender, or race.

2) **BACKGROUND.**

   a) **Racial disparities in the use of medical devices.** The final California Reparations Task Force Report, released in June 2023, highlighted the disparities that exist within the use of medical devices. The report stated that: "a 2020 study on pulse oximeters, a medical device used especially in the COVID-19 pandemic to monitor patients' oxygen levels, detailed that the devices are less accurate among patients with darker skin and could even increase risk of adverse health outcomes for those patients. A 2022 retrospective study found that patients of color, likely due to this known bias, received less supplemental oxygen than White patients, contributing to their morbidity." A recent study by Emory University found that forehead thermometers were significantly less accurate (26% lower) than oral thermometers in detecting fevers for Black patients.

**b) U.S. Food and Drug Administration (FDA) Guidance.** In April 2022, the FDA updated its latest draft guidance to improve diversity in clinical trials, including the requirement that device applications must report clinical trial demographic data. On December 29, 2022, President Biden signed into law the Consolidated Appropriations Act of 2023 which included a requirement that clinical trial sponsors submit to the Secretary of the U.S. Department of Health and Human Services, a "diversity action plan" for certain late-stage drug trials, as well as most medical device studies.

**c) FDA discussion.** On November 16, 2023, the FDA Center for Devices and Radiological Health published a discussion paper, *"*Approach for Improving the Performance Evaluation of Pulse Oximeter Devices Taking Into Consideration Skin Pigmentation, Race and Ethnicity." The intent of the discussion paper was not to communicate the FDA's regulatory expectations, but to advance a broader discussion among stakeholders on this topic. The discussion paper highlighted a summary of three systematic reviews on the topic of potential bias of pulse oximetry in people with darker skin pigmentation published in 2022.

**i)** Cabanas, et al. (2022) identified 41 references published between 1976 and 2022, which included 34 prospective and retrospective studies. Nine studies were considered at high risk of bias due to unstandardized classification of skin pigmentation such as "dark," "black," "light," or "white." The authors reported that there was a considerable upsurge of publications in 2021, due to the COVID-19 pandemic as well as increased concern about pulse oximeter performance across skin types. They concluded that "there is growing evidence that pulse oximeters are less accurate in dark-skinned individuals at lower saturation resulting in overestimations" and also that "a more accurate method for classifying the research participants into categories by degree of skin pigmentation should be employed in these studies.

**ii)** Shi, et al. (2022) identified 32 references published between 1985 and 2021. Meta-analysis of 15 studies using skin pigmentation levels and 22 studies using race/ethnicity showed that pulse oximetry probably overestimates oxygen saturation in people with high level of skin pigmentation and people described as Black/African American, although this evidence was considered moderate to low certainty. The authors concluded that "Pulse oximetry may overestimate blood oxygen saturation levels for people with dark skin in hospital settings compared with gold standard SaO2 measures. The evidence for the measurement bias identified for other levels of skin pigmentation or ethnicities is more uncertain. Whilst the extent of measurement bias and overall accuracy meet current international thresholds, the variation of pulse oximetry measurements appears unacceptably wide. Such a small overestimation may be crucial for some patients: particularly at the threshold that informs clinical decision-making.

**iii)** Poorzargar, et al. (2022) identified 22 references published between 1988 and 2020, looking specifically at pulse oximetry accuracy under poor perfusion conditions (including hypothermia, vasoactive drug use, or other factors not reported). Only one study controlled for skin pigmentation, by excluding participants with darker skin. The authors reported that most oximeter models were accurate in patients with poor perfusion, newer models were more accurate than older models, and earlobe

placement was more accurate than fingertip. They also concluded that more trials are needed that incorporate FDA guidelines for a diverse range of skin pigmentation.

Research makes clear that there are accuracy differences in the performance of medical devices such as pulse oximeter devices based on certain characteristics of the patient, such as skin color. It stands to reason that these types of inaccuracies can lead to delays in patient treatment, whether it be the diagnoses or the administration of drugs. This bill will provide necessary information regarding known limitations of device specific to characteristics such as their race, color, ethnicity, age, disability, or gender.

3) **PREVIOUS LEGISLATION.** SB 605 (Eggman) of 2021 would have required manufacturers of powered medical devices to make the documentation, software, and parts necessary to maintain and repair such devices available to a hospital and an independent service organization engaged by the hospital, on fair and reasonable terms, so that the hospital or its engaged repair service can conduct its own maintenance and repairs. SB 605 was held on the Senate Appropriations suspense file.

4) **DOUBLE REFFERAL.** This bill is double-referred, upon passage of this Committee, it will be referred to the Assembly Committee on Privacy and Consumer Protection.

**REGISTERED SUPPORT / OPPOSITION**:

**Support**

None on file.

**Opposition**

None on file.

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

Date of Hearing: April 9, 2024

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 2110 (Arambula) – As Introduced February 5, 2024

**SUBJECT**: Medi-Cal: Adverse Childhood Experiences trauma screenings: providers.

**SUMMARY**: Allows doulas, as well as community-based organizations (CBOs) and local health jurisdictions (LHJs) that provide health services through community health workers (CHWs), to provide Adverse Childhood Experiences trauma screenings (ACEs screening) and makes them eligible for Medi-Cal reimbursement for the screening. Specifically, **this bill** requires the Department of Health Care Services (DHCS) to:

1) Include CBOs/LHJs and doulas as providers of ACE screenings.

2) File a state plan amendment and seek any federal approvals it deems necessary to implement the bill, and conditions implementation on the availability of federal financial participation and receipt of any necessary federal approvals.

3) Update its internet website and the ACEs Aware website to reflect the addition of the Medi-Cal providers described in subdivision (a) as qualified to provide ACEs trauma screenings.

**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) Establishes a schedule of benefits under the Medi-Cal program. [WIC §14132]

3) Establishes CHW services as a Medi-Cal benefit. [WIC §14132.36]

4) Requires DHCS to convene a workgroup to examine the implementation of the Medi-Cal doula benefit and to, by July 1, 2025, publish a report on utilization of the benefit that identifies any barriers that impede access to doula services and make recommendations to reduce any identified barriers. [WIC §14132.24]

5) For services provided on or after July 1, 2022, allows General Fund or other state funds to be used to maintain payment levels for ACEs screenings under Medi-Cal at the payment levels in effect on December 31, 2021, inclusive of supplemental payments established under Proposition 56, an initiative measure approved in 2016. [WIC §14105.197]

6) Requires DHCS, in consultation with the State Department of Social Services (DSS) and stakeholders, to convene an advisory working group to update, amend, or develop, if appropriate, tools and protocols for the screening of children for trauma, within the Early and Periodic Screening, Diagnostic and Treatment benefit, consistent with existing law and this section. [WIC §14132.19]

7) Defines trauma as the result of an event, series of events, or set of circumstances that is experienced by an individual as physically or emotionally harmful or threatening and that has lasting adverse effects on the individual's functioning and physical, social, emotional, or spiritual well-being. [*Ibid.*]

8) Requires a health care service plan contract issued, amended, or renewed on or after January 1, 2022, that provides coverage for pediatric services and preventive care, to include coverage for ACEs screenings. [Health & Safety Code Section 1367.34]

9) Permits the Department of Managed Health Care (DMHC) to adopt guidance to health care service plans to implement 8) above. Requires DMHC's guidance to apply the rules and regulations for screening for trauma as set forth in the Medi-Cal program as the minimum ACEs coverage requirements for health care service plans. Specifies that this provision does not prohibit a health care service plan from exceeding the Medi-Cal program's rules and regulations for trauma screening. [*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, all Californians should have access to trauma-informed ACEs screenings by health care providers they trust. ACEs can have life-long negative impact on physical and behavioral health. The author indicates ACEs screenings enable providers to identify patients who are at higher risk for toxic stress and develop a trauma-informed care plan. Accordingly, because CHWs and doulas are trusted messengers in the communities they serve, this bill will authorize them to receive Medi-Cal reimbursement for ACEs screenings. This bill is sponsored by the BLACK Wellness & Prosperity Center (BWPC) and the Fresno Community Health Improvement Partnership (FCHIP).

**2) BACKGROUND.**

**a) ACES.** Addressing ACEs has been a signature state initiative of the California Office of the Surgeon General (CA-OSG). According to the CA-OSG, the term "ACEs" refers to 10 categories of childhood experience across three domains that were identified in a landmark 1998 study by the Centers for Disease Control and Prevention (CDC) and Kaiser Permanente. The experiences measured by ACEs screening, by domain, are abuse (physical, emotional, or sexual abuse), neglect (physical or emotional), and "household dysfunction" (parental incarceration, mental illness, substance dependence, parental separation or divorce, and intimate partner violence).

According to a 2023 CDC article in the *Morbidity and Mortality Weekly Report*, "Prevalence of Adverse Childhood Experiences Among U.S. Adults — Behavioral Risk Factor Surveillance System, 2011–2020," among U.S. adults from all 50 states and the District of Columbia surveyed during 2011–2020, approximately two thirds reported at least one ACE; one in six reported four or more ACEs. ACEs were highest among women, persons aged 25 to 34 years, non-Hispanic American Indian or Alaska Native adults, non-Hispanic multiracial adults, adults with less than a high school education, and adults who were unemployed or unable to work. The prevalence of individual and total number of ACEs varied across jurisdictions.

According to the California ACEs Aware initiative, ACEs screening has been successfully integrated into a wide range of clinical settings, including pediatric primary care, adult primary care, family medicine, and women's health and prenatal care. Prominent health care and public health organizations, such as the National Academies of Science, Engineering, and Medicine, CDC, and American Academy of Pediatrics now recommend screening for ACEs.

**b) Why are ACEs Important to Health Care?** CA-OSG indicates understanding the science of ACEs and toxic stress, and how it can manifest in the body, is critical to effective treatment planning for patients. High levels of adversity, without the buffering protections of trusted caregivers and safe, stable environments, lead to changes in brain structure and function, how genes are read, functioning of the immune and inflammatory systems, and growth and development. These changes comprise the "toxic stress response."

According to the Harvard Center for the Developing Child (Center), toxic stress response can occur when a child experiences strong, frequent, and/or prolonged adversity. Toxic stress is distinguished from "positive stress responses," which are normal and essential part of healthy development, characterized by brief increases in heart rate and mild elevations in hormone levels, and "tolerable stress response," in which the body's alert systems are activated to a greater degree as a result of more severe, longer-lasting difficulties, such as the loss of a loved one, a natural disaster, or a frightening injury. If the activation from tolerable stress response is time-limited and buffered by relationships with adults who help the child adapt, the brain and other organs recover from what might otherwise be damaging effects.

The Center indicates the more adverse experiences in childhood, the greater the likelihood of developmental delays and later health problems, including heart disease, diabetes, substance abuse, and depression.

While the mechanism of exactly how toxic stress impacts the brain and body are still somewhat unclear, ACEs have been described as having a dose-response effect where higher ACE scores are more strongly associated with poor health outcomes at a population level. In adults, experiencing four or more ACEs is associated with significantly increased risk for nine out of 10 leading causes of death in adulthood, such as heart disease, stroke, cancer, chronic obstructive pulmonary disease, diabetes, Alzheimer's, and suicide. Research indicates ACEs can follow a generational pattern, where children of parents of ACEs can be at greater risk themselves. For children, having two or more ACEs has been associated with poor health, sleep disturbance, somatic complaints, reduced cognitive ability, childhood obesity, asthma symptoms and hospitalization, higher likelihood of being bullied, higher probability of affected males perpetrating bullying, reduced levels of school engagement, and being more likely to repeat a grade in school.

Although ACEs are associated with a high number of negative health outcomes at a population level, screening for ACEs has not yet shown an ability to predict risk for negative health outcomes on an *individual* basis. While health conditions associated with ACEs can precede, coincide with, or follow ACEs occurring, the California Health Benefits Review Program notes that none of these studies have identified a direct, causal

link between an ACE and a particular health outcome. Rather, the cumulative effect of an elevated stress response over an extended period of time can put individuals at higher risk for a variety of poor outcomes.

**c) ACEs Aware Initiative.** The ACEs Aware Initiative offers Medi-Cal providers training and clinical protocols for screening children and adults for ACEs. The training educates Medi-Cal providers about the importance of incorporating ACE screenings into their clinical practices, how to conduct ACE screenings, how to use clinical protocols to determine treatment plans, and best practices in providing trauma-informed care.

According to the ACEs Aware training materials, non-licensed providers like CHWs often play important roles in facilitating the screenings, which are often provided in a team-based care environment. For example, non-licensed staff can review records to determine if the ACEs screen is indicated, provide the questionnaire to the patient or caregiver, and transcribe the ACEs score into the medical record. Staff then transmit this information to a licensed clinician (the billing provider) who documents that the completed screen was reviewed, interprets the results (including assessing whether the patient has any ACE-Associated Health Conditions), discusses the results with the patient, and integrates this ACE screening information into the treatment plan for the patient.

ACEs Aware also provides an "ACEs and Toxic Stress Risk Assessment Algorithm" that helps a provider assess whether a patient is at low, intermediate, or high risk of a toxic stress physiology, based on the ACE score and the presence or absence of ACE-associated health conditions. According to the algorithm, a patient with an ACEs score of one to three *without* associated health conditions is at intermediate risk, while a patient with an ACEs score of one to three *with* associated health conditions is at high risk, of toxic stress. A patient's status as intermediate risk or high risk, and the presence or absence of ACE-associated health conditions, has implications for the education and guidance that is offered by the provider after the assessment, and it also informs treatment planning and follow-up care. In other words, the algorithm indicates that conducting the Pediatric ACEs and Related Life-events Screener (PEARLS) or other assessment tool is just a portion of the ACEs screening—the other portions include the clinical assessment of the interplay between ACEs, risk of toxic stress, and ACE-associated health conditions, incorporation of the results into the patient's care plan, and documentation of the results in the patient's medical record along with the provider's notes.

**d) ACEs Medi-Cal Screening Data.** On January 1, 2020, California became the first state to screen for ACEs through the state's Medi-Cal program. Medi-Cal reimburses for ACEs screenings for both children and adults up to 65 years of age.

According to the February 2024 ACE Screening and Clinician Training Data Quarterly Progress Report, between the launch of ACEs Aware Initiative in December 2019 and March 31, 2023, Medi-Cal clinicians conducted more than 2.3 million ACE screenings of over 1.5 million unique Medi-Cal members. More than 35,000 individuals completed the Becoming ACEs Aware in California training, including approximately 17,100 Medi-Cal clinicians who are ACEs Aware-certified and eligible to receive Medi-Cal payment for conducting ACE screenings.

Of the 1.2 million unique Medi-Cal members ages 0 to 20 screened for ACEs, 5% had an ACE score of four or more. Of the nearly 300,000 unique Medi-Cal members ages 21 to 64 screened for ACEs, 15% had an ACE score of four or more.

**e) Current Medi-Cal Reimbursement Policy for ACEs.** Providers must meet the requirements of the billing code in order to be reimbursed for Medi-Cal covered services. DHCS defines these requirements as follows:

**i) Billing Codes and Required Components.** To be reimbursed for ACEs screening, providers bill one of the following Healthcare Common Procedure Coding System (HCPCS) codes:

**(1)** G9919: ACEs score of four or greater, high risk. Screening performed – result indicates patient at high risk for toxic stress; education and interventions (as necessary) provided; or,

**(2)** G9920: ACEs score of 0 to three, lower risk. Screening performed – result indicates patient at lower risk for toxic stress; education and interventions (as necessary) provided.

Providers must document the following: completed screen was reviewed, appropriate tool was used, ACEs screening results, interpretation of results, discussion with the beneficiary and/or family, and any appropriate actions taken. This documentation should remain in the beneficiary's medical record and be available upon request. Clinical risk assessment and management should be pursued according to the ACEs Aware Screening Clinical Workflows, ACEs and Toxic Stress Risk Assessment Algorithm, and ACE-Associated Health Conditions guidelines.

DHCS notes, in a training presentation on ACEs screening, that the clinical response to identification of ACEs and increased risk of toxic stress should include the following:
**(1)** Applying principles of trauma-informed care;
**(2)** Identification and treatment of ACE-associated health conditions;
**(3)** Patient education about toxic stress and buffering interventions, including supportive relationships, mental health treatment, exercise, sleep hygiene, healthy nutrition, and mindfulness and medication practices;
**(4)** Validation of existing strengths and protective factors;
**(5)** Referral to patient resources; and,
**(6)** Follow-up as necessary.

**ii) Providers.** Screening is reimbursable for providers who have taken a certified training and self-attested to their completion of the training. ACE screening is reimbursable in all inpatient and outpatient settings in which billing occurs through Medi-Cal fee-for-service (FFS) or to network providers of a Medi-Cal managed care plan (MCP). Providers who are eligible to bill for ACEs screening include the following; however, the provider must meet all requirements of the billing code:

**(1)** Certified Nurse Midwife;
**(2)** Certified Nurse Practitioner;
**(3)** Group Certified Nurse Practitioners;

**(4)** Early and Periodic Screening, Diagnostic, and Treatment Services Providers;
**(5)** Licensed Clinical Social Worker – Individual, Group;
**(6)** Licensed Nurse Midwife;
**(7)** Licensed Professional Clinical Counselor – Individual, Group;
**(8)** Marriage and Family Therapist – Individual, Group;
**(9)** Physician;
**(10)** Physician Group;
**(11)** Psychologist;
**(12)** County Hospital – Outpatient;
**(13)** County Clinics not associated with a Hospital;
**(14)** Indian Health Services/Memorandum of Agreement;
**(15)** Otherwise Undesignated Clinic;
**(16)** Outpatient Heroin Detox Center;
**(17)** Rehabilitation Clinic;
**(18)** Rural Health Clinic (RHC)/Federally Qualified Health Center (FQHC); and,
**(19)** In-state and border providers.

**iii) Screening Tools.** For children, providers must use the PEARLS tool. There are versions of the tool based upon age: PEARLS for children ages 0 to 11, to be completed by a caregiver; PEARLS for teenagers 12 to 19, to be completed by a caregiver; and PEARLS for teenagers 12 to 19, self-reported. For adults, providers must use the ACE Assessment Tool adapted from the work of Kaiser Permanente and the CDC, or a similar alternative.

**iv) Frequency Limits.** Children under age 21 may receive periodic rescreening as determined appropriate and medically necessary, not more than once per year, per provider, or per provider per managed care plan (for beneficiaries enrolled in plans) Adults age 21 and over may be screened once in their adult lifetime up to age 65, per provider, or per provider per managed care plan (for beneficiaries enrolled in plans).

**v) Payments.** Providers can bill and be reimbursed at a rate of $29 by FFS Medi-Cal and by MCPs. ACEs screenings performed in federally qualified health centers, rural health clinics, and certain Indian Health Services clinics are paid at the $29 rate.

**f) CHWs and Doulas.** In an effort to improve health equity and outcomes, Medi-Cal recently began covering the services of CHWs and doulas through the CHW and doula Medi-Cal benefits. These new provider types and benefits can often offer a more tailored and culturally relevant care experience. CHWs and doulas can also improve health equity by offering support, education, advocacy and linkages to resources to Medi-Cal enrollees who may be at particular risk for worse health outcomes. Although there is some overlap in the allowable services, CHWs and doulas are distinct in their training and experience, as well as the specific services Medi-Cal covers under each benefit. Key provisions of both benefits, as described in the Medi-Cal provider manual, are listed below. Neither CHW services or doula services are required to be covered by commercial plans and insurers, although statute encourages coverage for doulas as part of required maternal mental health programs, and AB 2250 (Weber), which is currently under consideration in the Legislature, would require commercial plans and insurers to provide access to CHWs.

**i)** **Doula Services**. Doulas are defined as birth workers who provide health education, advocacy, and physical, emotional and nonmedical support for pregnant and postpartum persons before, during and after childbirth (perinatal period) including support during miscarriage, stillbirth and abortion. Doulas are not licensed or clinical providers, and they do not require supervision.

Doula services encompass health education, advocacy, and physical, emotional and nonmedical support provided before, during and after childbirth or end of a pregnancy, including throughout the postpartum period. Doulas offer various types of support, including perinatal support and guidance; health navigation; evidence-based education and practices for prenatal, postpartum, childbirth, and newborn/infant care; lactation support; development of a birth plan; and linkages to community-based resources. Coverage also includes comfort measures and physical, emotional, and other nonmedical support provided during labor and delivery and for miscarriage and abortion.

Doulas bill as independent providers, or as part of a group. Doulas are allowed to bill, for a single pregnancy: One initial visit; Up to eight additional visits that may be provided in any combination of prenatal and postpartum visits; Support during labor and delivery (including labor and delivery resulting in a stillbirth), abortion or miscarriage; and up to two extended three-hour postpartum visits after the end of a pregnancy.

Doula services are defined as a "preventive service" under federal regulation; therefore, services must be recommended by a licensed health care provider. To increase access to services, on November 1, 2023, the DHCS Medical Director, Karen Mark, MD, PhD, issued a standing recommendation for doula services, which fulfills the requirement for a recommendation for an individual who is pregnant or was pregnant within the past year.

**ii)** **CHW Services**. DHCS added CHW services, including violence prevention services, as a Medi-Cal benefit starting July 1, 2022. The benefit was codified through AB 2697 (Aguiar-Curry), Chapter 488, Statutes of 2022. CHW services are defined to include those delivered by promotores, community health representatives who work in tribal communities, navigators, and other non-licensed public health workers. Like doula services, CHW services are also defined as preventive services and services must therefore be recommended by a licensed health care provider. There is no standing recommendation in place for CHW services, but CHW services are defined as medically necessary for individuals with a broad range of health conditions.

With respect to billing procedures, the supervising provider, who submits claims for services, is an enrolled Medi-Cal provider who oversees the services provided and ensures a CHW meets the defined qualifications. The supervising provider can be a licensed provider, a hospital, an outpatient clinic, a LHJ, or a CBO. CBO or LHJ do not need a licensed provider on staff in order to supervise CHWs. CHWs cannot bill independently; CHW services are always billed by the supervising provider.

CHW services include health education; navigation to health care and other community resources that address health-related social needs; screening and

assessment that does not require a license and that assists a beneficiary to connect to appropriate services to improve their health; and individual support and advocacy that assists a beneficiary in preventing a health condition, injury, or violence.

CHWs can address a range of health conditions, including but not limited to control and prevention of chronic conditions or infectious diseases; mental health conditions and substance use disorders; perinatal health conditions; sexual and reproductive health; environmental and climate-sensitive health issues; child health and development; oral health; aging; injury; domestic violence; and violence prevention.

**iii) CHW and Doula Qualification**s. Unlike most health care professionals, there are no required qualifications for CHWs or doulas at the state level, such as a license or certificate. Accordingly, minimum qualifications for CHWs and doulas were defined through the Medi-Cal State Plan Amendment that added the service.

CHWs must demonstrate minimum qualifications through either earning a certificate of completion that attests to skills and/or training in defined core competencies, or meeting the requirements for an experience pathway based on 2,000 hours of work, whereby an experienced individual can provide services for a maximum of 18 months without a certificate of completion. A Violence Prevention Certificate allows individuals to provide CHW violence prevention services. CHWs must also have lived experience that aligns with and provides a connection between the CHW and the community being served.

Similarly, doulas must prove qualification either through a training pathway that includes 16 hours of training and providing support at a minimum of three births, or an experience pathway that requires at least five years of active doula experience and attestation to skills in prenatal, labor, and postpartum care as demonstrated by client testimonial letters or professional letters of recommendation from a health care provider or CBO.

These qualifications only apply to CHWs and doulas for purposes of Medi-Cal billing; there are no minimum qualifications one must meet to work as a CHW or doula outside of Medi-Cal.

**g) Social Determinants of Health (SDOH) Screening versus ACEs Screening.** SDOH screening is another type of screening that identifies social challenges that create barriers to good health. It is useful to understand and contrast the two types of screening, particularly in the context of considering the ability of nonclinical personnel like CHWs and doulas to conduct, interpret, and act on these different types of screening.

With respect to SDOH screening, various tools have been developed to help identify patients' "health-related social needs" (HRSN) and their risks for developing social needs. According to the Agency for Healthcare Research and Quality (AHRQ), health care systems are increasingly trying to assess the specific social needs of their patients and help meet those needs. AHRQ notes SDOH can be categorized into five domains:

**i)** Social context;
**ii)** Economic context;
**iii)** Education;

**iv)** Physical infrastructure; and,
**v)** Healthcare context.

HRSN can be, for instance, physical safety issues, need for mold remediation, or lack of housing. AHRQ indicates that once needs are identified, clinical-community linkages help to connect healthcare providers, community organizations, and public health agencies improve patients' access to services.

Although experience of ACEs can be considered a social determinant, or driver, of health outcomes, screenings for ACEs and SDOH have different purposes. SDOH screening is designed to assess and address present or recent HRSN that pose barriers to good health. Some SDOH screens also assess violence and psychological abuse, but the questions are generally designed to assess the patient's current situation and identify appropriate resources, in contrast to ACEs screenings, which, for an adult, are a retrospective assessment of one's traumatic childhood experiences, including abuse. SDOH screenings can help providers address the present needs of the "whole person," for instance, offer referrals to other health care or community resources or programs; assist in developing an effective treatment plan, such as addressing transportation barriers that would prevent someone from receiving twice-weekly infusions; and ensure health care system and providers understand the overall complexity of the patient's needs and the level of resources the patient will need to maintain and improve their health. ACEs screening, in contrast, can identify the role of toxic stress in ACEs-associated health conditions, assist with mitigation of toxic stress, and inform treatment planning and follow-up care.

For children, ACEs screenings may have more overlap with SDOH screenings, as identifying traumatic experiences a child is experiencing may offer a chance to intervene. After all, an ultimate goal of the state's ACEs-related efforts—providing ACEs screenings and building provider and community awareness of the impact of ACEs on health outcomes— is to prevent childhood trauma and its later health impacts, including preventing multigenerational trauma. Some traumatic experiences measured by the screening tool, such as parental incarceration, can also trigger a HRSN, such as the need to maintain stable housing in the face of a loss household income associated with the incarceration. The close relation of ACEs and SDOH screening for children is also demonstrated in the PEARLS screening tool, which includes two parts: Part 1, produces the ACEs "score" and is mandatory for children's ACEs screening, and Part 2, which is a SDOH screening and is not required to be used with the ACEs screening.

In conclusion, ACEs and SDOH screenings share some similar features, in that they both offer additional information to clinical providers that allow them to contextualize a patient's conditions and better care for the patient. This is especially true in a pediatric setting, given the potential ability to intervene to prevent or mitigate the effects of trauma. However, they are distinct in that they ask different questions and have different goals; while SDOH screenings are used primarily to identify HRSN, connect patients with resources, and inform differential diagnostics and treatment planning, ACEs screening is focused on identifying and mitigating the effects of toxic stress. Finally, as discussed above, CHWs and doulas in Medi-Cal can both provide navigation and linkage to community-based resources, such as those that may be identified through SDOH screening, under their scope of services as defined in the applicable Medi-Cal provider manual.

3) **SUPPORT.** This bill is supported by a large number of consumer, public health, children's and ethnic-focused health advocacy groups. Cosponsors BWPC and the FCHIP write in support that this bill can enhance access to mental health services, reduce the stigma associated with mental health, and promote healthier communities. Cosponsors note CHWs and doulas offer culturally and linguistically appropriate care and are uniquely positioned to conduct ACEs screenings. They note many provider types, such as physicians, psychologists, and certified nurse practitioners, can bill for ACEs screenings to help providers assess patient risk of toxic stress and that although CHWs and Doulas are not eligible for Medi-Cal reimbursement, they have a unique advantage in conducting ACEs screenings due to their highly trusted provider status and their emphasis on the two-generation approach. Cosponsors emphasize this is important because ACEs can result in a cycle of intergenerational trauma, where children of parents with ACEs can be at a higher risk themselves. CHWs and Doulas insert their personal experience into their practice, which enhances the quality and cultural competence of their services. Children Now writes in support that conducting ACEs screenings outside of the trusted provider-patient relationship can hinder patients' willingness to share their full history and may be re-traumatizing.

4) **RELATED LEGISLATION.** AB 2250 (Weber) requires a health plan, health insurer, and Medi-Cal to provide coverage for, and provider reimbursement of, SDOH screenings. Requires a health plan or insurer to provide to physicians who provide primary care services with adequate access to peer support specialists, lay health workers, social workers, or CHWs, as defined. Provides for reimbursement of SDOH screenings at the Medi-Cal FFS rate for FQHCs and RHCs. AB 2250 passed the Assembly Health Committee on April 2, 2024, on a vote of 15 to 0.

5) **PREVIOUS LEGISLATION.**

   **a)** AB 85 (Weber), of 2023, was similar to AB 2250 (Weber), above, and required the Department of Health Care Access and Information to convene a working group. AB 85 was vetoed by Governor Newsom, who expressed support for the overall goal of this proposal, but that it is duplicative of existing efforts, such as ACEs screenings and the work DHCS is doing through the CalAIM initiative. The Governor also cited that the bill may be premature given a standardized SDOH screening tool does not yet exist.

   **b)** AB 1110 (Arambula) of 2023 would have required, subject to an appropriation, the DHCS and CA-OSG to develop guidance for culturally and linguistically competent ACEs screenings through improved data collection methods, as specified. AB 1110 was held on the suspense file of the Senate Appropriations Committee.

   **c)** AB 2697 (Aguiar-Curry) Chapter 488, Statutes of 2022, codifies CHW services as a covered Medi-Cal benefit.

   **d)** SB 428 (Hurtado), Chapter 641, Statutes of 2021, requires health plans and insurers that cover pediatric services and preventive care to also cover ACEs screenings.

   **e)** SB 184 (Committee on Budget and Fiscal Review), Chapter 47, Statutes of 2022, authorizes the use of General Fund, in place of funding from Proposition 56 (the California Healthcare, Research and Prevention Tobacco Tax Act of 2016) for

supplemental payments for specified Medi-Cal providers, for, among other services, ACEs screenings.

**f)** ACR 8 (Jones-Sawyer), of 2017, recognized ACEs, also known as post-traumatic "street" disorder in communities of color, as having lasting negative outcomes to both physical and mental health with growing implications for our state.

**g)** ACR 235 (Arambula), of 2018, designated May 22, 2018, as Trauma-Informed Awareness Day in California, in conjunction with National Trauma-Informed Awareness Day, to highlight the impact of trauma and the importance of prevention and community resilience through trauma-informed care.

**h)** AB 74 (Ting), Chapter 23, Statutes of 2019, among other things, appropriates Proposition 56 funding for ACEs screening in Medi-Cal.

**i)** AB 340 (Arambula), Chapter 700, Statutes of 2017, requires screening services provided under the Early and Periodic Screening, Diagnostic and Treatment Program to include screening for trauma, as defined for the purpose of screening. AB 340 requires DHCS, in consultation with DSS, behavioral health experts, child welfare experts, and stakeholders to adopt, employ, and develop tools and protocols for the screening of children for trauma, as specified.

**j)** AB 2691 (Jones-Sawyer) of 2018, would have established within the State Department of Education the Trauma-Informed Schools Initiative to address the impact of ACEs on the educational outcomes of California pupils. AB 2691 was vetoed by Governor Brown. The veto message concurred that schools should be sensitive to the unique and diverse characteristics of all students; however, it noted alarm at the amount of "jargon" the bill would have created and "inevitable labeling" it would have encouraged. The Governor indicated these issues are best handled by local schools.

**6) POLICY COMMENT.** According to state guidance, the use of the ACEs screening tool is only one component of the recommended care and clinical workflow. Conducting the full screen also includes an assessment for clinical manifestations of toxic stress and protective factors, development of treatment plan and follow-up plan, and review an update of the treatment plan at the next visit.

As part of an integrated team-based care setting and under current policy, doulas and CHWs can be involved in screening for ACEs and can also conduct other activities that may be related to results of the screen. In addition, although SDOH screening is not currently reimbursable through a separate billing code, to the extent such a screening is conducted, a CHW or doula can assist with follow-up related to the results of a SDOH screen as part of their existing Medi-Cal services. For instance, a CBO can bill for CHW services of health education and navigation of a family to community-based services, based on ACEs or SDOH screening of a child that identifies that a family needs particular types of support. A doula can also provide linkages to community-based resources to address the HRSN of pregnant and postpartum people as part of their existing services.

However, as discussed above, ACEs screening is distinct from broader SDOH screening, as it is, by definition, more intertwined with clinical manifestations of toxic stress. Informed by an expert advisory group, the state has developed detailed protocols and workflows for ACEs

screening that include clinical components as an inextricable part of the billing code requirements. It does not appear CBO, LHJ, and doula providers that are not integrated with a clinical setting would be able to meet the requirements of the ACEs screening billing code as currently defined.

Ultimately, the policy question raised by this bill is not about the value of CHWs or doulas—there is broad consensus about the value of these personnel and the tremendous benefit of the services they provide to Medi-Cal enrollees in improving health equity and outcomes. CHWs and doulas could and hopefully will play an even greater role in addressing health education, support, and other health-related social needs in the Medi-Cal program as the workforce of CHWs and doulas expands. The policy question is narrow: given the unique features of ACEs screening and the value of incorporating the results into clinical diagnosis, treatment planning, and follow-up, should the state encourage or allow nonclinical providers to independently provide and bill for ACEs screening based on their status as trusted providers, outside of a clinical setting?

The author may wish to engage with DHCS and CA-OSG as well as other experts and stakeholders in this space to discuss approaches to address the mismatch between the CHW/doula training and scope of services, and the requirements of the ACEs screening billing code, as defined by the state. Potential options include allowing a modified billing code for ACEs screening that is appropriate to be conducted by non-licensed personnel, or requiring the ACEs screening be conducted in a team-based clinical environment or otherwise integrated with an enrollee's clinical providers, to avoid fragmentation and duplication in assessing ACEs that can be difficult and traumatic for patients to discuss.

**REGISTERED SUPPORT / OPPOSITION**:

**Support**

ACE Overcomers of Merced County
Alliance for Children's Rights
Beloved Survivors Trauma Recovery Center
Black Wellness & Prosperity Center
California Family Resource Association
Centro LA Familia Advocacy Services
Child Abuse Prevention Center
California Pan - Ethnic Health Network
Children Now
Common Good Solutions LLC
County Health Executives Association of California (CHEAC)
Cultiva LA Salud
Easterseals Central California
First 5 Fresno County
Frontline Perinatal Liberation LLC
Jakara Movement
Jurupa Valley Doulas
Pathways Community Hub Institute
Prevent Child Abuse California
Safe Kids California

State Center Community College District
West Fresno Healthcare Coalition
Western Center on Law & Poverty, Inc.

**Opposition**

None on file.

**Analysis Prepared by**: Lisa Murawski / HEALTH / (916) 319-2097

Date of Hearing: April 9, 2024

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 2129 (Petrie-Norris) – As Introduced February 6, 2024

**SUBJECT**: Immediate postpartum contraception.

**SUMMARY**: Authorizes a health care provider, in a contract between a health plan or insurer, to separately bill for devices, implants, or professional services, or a combination thereof, associated with immediate postpartum contraception (IPPC) if the birth takes place in a licensed hospital or birthing center. Prohibits the provider contract from considering those devices, implants, or services to be part of a payment for a general obstetric procedure. Specifically, **this bill**:

1) Authorizes a health care provider, in a contract between a health plan or insurer, to separately bill for devices, implants, or professional services, or a combination thereof, associated with IPPC if the birth takes place in a licensed hospital or birthing center.

2) Prohibits the provider contract from considering those devices, implants, or services to be part of a payment for a general obstetric procedure.

3) Defines IPPC as the postpartum insertion of intrauterine devices (IUD) or contraceptive implants performed before the enrollee or insured is discharged from the licensed hospital or birthing center and includes the devices or implants.

4) Specifies that this bill does not affect an enrollee or insured's right to directly access women's health care services, including contraceptive services.

**EXISTING LAW**:

1) Establishes the Department of Managed Health Care to regulate health plans and California Department of Insurance to regulate health insurance. [Health and Safety Code (HSC) §1340, *et seq.*; Insurance Code (INS) §106, *et seq.*]

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

3) Requires health plans and health insurers, except for a specialized health plan contract or a specialized health insurance policy, to provide coverage for all of the following services and contraceptive methods for women:

   a) All Food and Drug Administration (FDA) approved contraceptive drugs, devices, and other products for women, including all FDA-approved contraceptive drugs, devices, and products available over the counter, as prescribed by the enrollee's or insured's provider;
   b) Voluntary sterilization procedures;

c) Patient education and counseling on contraception; and,
d) Follow-up services related to the drugs, devices, products, and procedures, including, but not limited to, management of side effects, counseling for continued adherence, and device insertion and removal. [HSC § 1367.25 and INS § 10123.196]

4) Requires health plans to ensure that all services are 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]

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

**COMMENTS**:

**1) PURPOSE OF THIS BILL.** According to the author, since 2016, the Centers for Medicare and Medicaid Services (CMS) encouraged payers to consider "reimbursing for immediate postpartum insertion of long acting reversible contraceptives (LARC) by unbundling payment for LARC from other labor and delivery services." Nearly 40 states have since revised their Medicaid reimbursement policies for IPPC access, allowing the reimbursement of immediate postpartum LARCs separate from the global fee for labor and delivery. Unfortunately, existing payment structures in California for commercial payers do not consistently carve out the payment from the global labor and delivery fee, leading to confusion among patients and providers. The author concludes that this bill will remove barriers for patient access to these devices through the standardization of benefits for LARC and allow providers to receive payment for IPPC when provided in a hospital or a birth center.

**2) BACKGROUND.**

**a) LARCs.** LARCs are highly effective birth control devices inserted into the body. They include IUDs and implants, which can stay in the body for several years and can be removed if an individual wants to become pregnant. Due to the good safety profile and high patient satisfaction, as well as very high efficacy, evidence-based clinical guidelines such as those issued by the American College of Obstetricians and Gynecologists (ACOG) advocate for improving access to and removing barriers to use of LARCs. ACOG recommends that women should be counseled about all forms of postpartum contraception in a context that allows informed decision-making and LARC should be offered as an effective option for postpartum contraception. Obstetric care providers should discuss LARC during the antepartum period and counsel all pregnant women about options for immediate postpartum initiation.

**b) Immediate Postpartum LARC**. According to an ACOG Policy Brief, LARCs can be offered immediately postpartum (the period following childbirth and prior to hospital discharge) as a safe, effective option for postpartum contraception. Postpartum contraception is usually offered and provided during the 6-week postpartum visit. However, approximately 10- 40% of women do not return for this visit and are at risk for subsequent unintended, short-interval pregnancy. For those who do return, nearly 60% may have resumed intercourse and could already be at risk for another pregnancy. Adolescents are at higher risk for a rapid repeat pregnancy, with estimates of 12-49% of

postpartum adolescents experiencing a pregnancy within one year of delivery. Unintended and short-interval pregnancies can result in a higher risk of preterm birth and worsened neonatal outcomes. Immediate postpartum LARC has the potential to reduce unintended and short-interval pregnancy. However, more widespread adoption of immediate postpartum LARC has been hampered by systems barriers, such as the inability to obtain reimbursement for LARC devices and services provided immediately postpartum.

**c) Reimbursement for LARC**. According to information from the author, when insurance policies do not cover the hospital's cost of IPPC LARC placement, providers cannot offer this contraceptive option to their patients since LARC devices are among the most expensive methods of pregnancy prevention (with some priced as high as $1300). Without guaranteed reimbursement from insurers for providing LARCs immediately following childbirth, hospitals are disincentivized to offer the service. Most insurance plans use a standard method of payment called a Diagnosis Related Group (DRG) to reimburse hospitals for a patient's labor and delivery. Also called a "global" or "bundled" payment, the DRG is a single, predetermined, fixed amount that is all-inclusive of most labor and delivery care that's provided. Under many commercial insurance plans, IPPC LARC is assumed to be included in the DRG. But some services, including anesthesiology or tubal ligation performed after a cesarean delivery, are not included and thus can be billed separately from the DRG. This is known as "debundling" payment, and it allows providers and hospitals to bill and be reimbursed for the true cost of these expensive services. In 2016, CMS encouraged payers to consider reimbursing for immediate postpartum insertion LARCs by unbundling payment for LARC from other labor and delivery services and nearly 40 states have revised their Medicaid reimbursement policies for IPPC access.

3) **SUPPORT.** ACOG, the sponsor of this bill, states that studies show that healthy birth spacing helps reduce adverse health outcomes for both parents and babies. Most of the data from observational studies in the United States suggest a modest increase in risk of adverse outcomes associated with intervals of less than 18 months and more significant risk of adverse outcome with intervals of less than six months between birth and the start of the next pregnancy. Despite these risks, short intervals between pregnancies still occur, and at least 70% of pregnancies within one year after delivery were unintended. ACOG believes everyone who desires LARC should have timely access to contraceptive implants and IUDs. Obstetrician– gynecologists and other reproductive health care clinicians can best serve those who want to delay or avoid pregnancy by all medically appropriate contraceptive methods, but they can only do so if it is available. LARC devices should be easily accessible to all people who want them, including adolescents, those who have never given birth, and after spontaneous or induced abortion and childbirth. ACOG has long recommended and supported removing financial barriers to contraception by advocating for coverage and appropriate payment and reimbursement for all contraceptive methods by all payers for all eligible patients.

4) **RELATED LEGISLATION.**

**a)** AB 90 (Petrie-Norris) of 2023 clarifies that the Family Planning, Access, Care, and Treatment (Family PACT administered by the Department of Health Care Services) comprehensive clinical family planning services include inpatient services relating to the

placement or insertion of a contraceptive device. It should be noted that the author states that the Administration modified their regulations to address this issue. AB 90 is pending in Senate Health Committee.

**b)** SB 1053 (Mitchell), Chapter 576, Statutes of 2014, requires a health plan contract or health insurance policy issued, amended, or renewed on or after January 1, 2016, to provide coverage for women for all prescribed and FDA-approved female contraceptive drugs, devices, and products, as well as voluntary sterilization procedures, contraceptive education and counseling, and related follow-up services. Prohibits a nongrandfathered plan contract or health insurance policy from imposing any cost-sharing requirements or other restrictions or delays with respect to this coverage, as specified.

**5) PREVIOUS LEGISLATION.** SB 1234 (Pan) of 2022 would have expanded eligibility for sexually transmitted disease-related services through the Family PACT Program to individuals not at risk for experiencing or causing an unintended pregnancy, and not in need of contraceptive services, and required related reporting. SB 1234 was vetoed based on concerns it expanded Family PACT services beyond the federal definition of family planning and would have put ongoing cost pressure on the General Fund.

**6) AMENDMENTS**. The author wishes to amend this bill as follows:

**a)** Clarify that the provisions apply to general acute care hospital or accredited birthing centers; and,

**b)** Clarify that this bill does not affect informed consent protections in existing law.

**REGISTERED SUPPORT / OPPOSITION**:

**Support**

American College of Obstetricians and Gynecologists (sponsor)
California Medical Association
California Life Sciences
Junior Leagues of California State Public Affairs Committee
Reproductive Freedom for All

**Opposition**

None on file.

**Analysis Prepared by**: Kristene Mapile / HEALTH / (916) 319-2097

Date of Hearing: April 9, 2024

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 2161 (Arambula) – As Amended April 1, 2024

**SUBJECT**: The Early Psychosis Intervention Plus Program.

**SUMMARY**: Requires the Mental Health Services Oversight and Accountability Commission (MHSOAC) to consult with the Department of Health Care Services (DHCS) and related state departments to create a strategic plan on psychosis. Requires DHCS to seek to partner with the University of California (UC) to develop a plan to establish the Center for Mental Health Wellness and Innovations (the Center). Specifically, **this bill**:

1) Requires MHSOAC to consult with the DHCS and related state departments to create a strategic plan on psychosis.

2) Requires the strategic plan to achieve all of the following:

    a) Improve understanding of psychosis, its impacts on California's communities, and the quality of life and outcomes for individuals and families experiencing psychosis;
    b) Document the fiscal impact of unaddressed or inadequately addressed psychosis and related disorders; and,
    c) Recommend opportunities to improve California's response to early psychosis, including, but not limited to, finance, workforce, technical assistance and training, research and evaluation, accountability strategies, public understanding and awareness, outreach, and education.

3) Requires MHSOAC to submit the strategic plan to the Legislature no later than July 1, 2025.

4) Requires DHCS to seek to partner with the UC to develop a plan to establish the Center to promote the widespread availability of evidence-based practices to improve behavioral health services, ensure accountability, and promote recovery-oriented outcomes for consumers and families.

5) Authorizes the center's duties to include, but not be limited to, the following:

    a) Providing training support to increase the competencies of the behavioral health workforce;
    b) Providing implementation support to enhance the adoption of evidence-based treatments and services;
    c) Developing and distributing educational courses, guidelines, manuals, and toolkits; and,
    d) Implementing a research agenda.

6) Requires DHCS, if the Center is established, to submit the plan to the Legislature no later than July 1, 2025.

7) Makes findings and declarations regarding the behavioral health crisis, California's behavioral health response, and the importance of early psychosis intervention.

**EXISTING LAW**:

1) Establishes the Early Psychosis Intervention Plus (EPI Plus) Program to encompass early psychosis and mood disorder detection and intervention. [Welfare and Institutions Code (WIC) §5835]

2) Establishes the Early Psychosis and Mood Disorder (EPMD) Detection and Intervention Fund within the State Treasury. Makes funds available to MHSOAC, upon appropriation by the Legislature, to provide grants to create or expand existing capacity for early psychosis and mood disorder detection and intervention services and supports. [WIC §5385.1]

3) Establishes an advisory committee for which MHSOAC is required to accept nominations and applications for committee membership. Requires members, as defined, to be appointed by the chair of the MHSOAC. Requires the advisory committee to provide advice, guidance, and recommendations, as defined. [WIC §5835.2]

4) States Legislative intent to authorize MHSOAC to administer a competitive selection process to create new, and to expand and improve the fidelity of existing, service capacity for EPMD detection and intervention programs in the state. Requires funds allocated by the MHSOAC to be made available to selected counties, or counties acting jointly. Requires awards made by the MHSOAC to be used to create, or expand existing capacity for, EPMD detection and intervention services and supports. Requires the MHSOAC to ensure awards result in cost-effective and evidence-based services, as specified. [WIC §5835.3]

5) Requires implementation of the EPI Plus program to be contingent upon the deposit into the fund of at least $500,000 in non-state funds for the purpose of funding awards. Permits the advisory committee not to make awards if available funds are insufficient. Prohibits appropriations from the General Fund for EPMD detection and intervention programs. [WIC §5385.5]

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

**COMMENTS**:

1) **PURPOSE OF THIS BILL.** According to the author it is essential that first-episode psychosis (FEP), or early psychosis, be identified before individuals experience harm. The author continues that psychosis may result in impaired judgement, putting individuals at risk of engaging in dangerous behaviors such as self-harm, substance abuse, and suicide. The author argues that through Coordinated Specialty Care (CSC), medical professionals can take steps to develop specialized treatment plans for patients, but unfortunately the current landscape of FEP intervention is fragmented and standards of practice can vary. The author concludes by stating this bill will establish a strategic plan to improve the understanding of psychosis, document the fiscal impact of unaddressed psychosis, while also establishing the Center to promote evidence-based practices to improve behavioral health services.

2) **BACKGROUND.** Early psychosis, or FEP, refers to when a person first shows signs of beginning to lose contact with reality. Psychosis can be a symptom of many different mental and physical disorders such as schizophrenia as well as bipolar disorder and major depressive disorder. Psychosis includes a range of symptoms, but usually involves hallucinations or delusions. According to the National Alliance on Mental Illness (NAMI) nearly 100,000

young people in the United States experience psychosis each year, with an average onset in late-teens to mid-20s. Three in 100 people will have an episode of psychosis at some point in their lives. There is no one cause of psychosis. Experts are still learning how and why psychosis develops, but it's thought to result from a combination of genetic risk, differences in brain development, and exposure to stressors or trauma. Detecting the early signs of psychosis is difficult, especially for younger adults as the warning signs can be similar to typical teen behavior. But the National Institute of Mental Health (NIMH) states that reducing the duration of untreated psychosis is critical as early treatment often means better recovery.

a) **Disparate Impacts.** Disorders that include psychosis are known to disparately impact underserved and marginalized communities. For example, research published by the National Institute of Health found that Black Americans had higher lifetime rates of disorders that included psychotic symptoms (15.3%) compared with Latino (13.6%), white (9.7%), and Asian Americans (9.6%). Black communities are also diagnosed with schizophrenia-spectrum disorders at a rate that is three to four times higher than white communities. While genetics can play a role, researchers theorize that Black individuals have increased vulnerability to these disorders due to experiencing unique environmental stressors, such as alienation, discrimination, and racism. Even more concerning is that when care related to psychosis is not provided early it leads to homelessness, incarceration, educational loss, an increase in hospitalization, and a decrease in the quality of life of the individual.

b) **CSC.** Experts, such as NAMI and NIMH, argue that the most effective treatment for early psychosis is CSC, where a team of medical specialists work with patients to develop an early intervention treatment plan. These plans include components ranging from case management, psychotherapy, medication, and peer support. In California, there are 30 programs throughout 24 of the 58 counties. However, the current landscape is fragmented and standards of practice vary from county to county.

   Through the statutorily created EPI Plus program, MHSOAC has invested in CSC programs in Kern, Lake, San Francisco, Santa Barbara, Sonoma, Santa Clara, Nevada, Colusa, and Mono Counties. These investments represent evidence-based approaches to care delivery, technical assistance and data collection strategy, and the formation of a multi-site learning collaborative. However, despite these significant investments research suggests that less than ten percent of Californians currently access effective care for psychosis.

3) **SUPPORT.** MHSOAC is in support of this bill, stating that it would take the necessary next step to improve California's strategy to expand access to early psychosis interventions and better understand how such a strategy would impact mental health outcomes for individuals, families, and communities, including fiscal impacts borne by the state, local agencies, the private sector and others. MHSOAC additionally argues that this bill would create the infrastructure to standardize and scale evidence-based practices like early psychosis intervention through a public-private partnership with the UC.

4) **PREVIOUS LEGISLATION.**

**a)** SB 1337 (McGuire) of 2022 would have required the California Health and Human Services Agency, in consultation with MHSOAC, to commission a study on untreated psychosis, and its impacts, as specified. Would have required a health care plan, or insurance policy, as specified, to provide coverage for CSC services for the treatment of early psychosis. Would have required treatment modalities and affiliated activities to be billed and reimbursed as a bundle. SB 1337 was held on the Senate Appropriations suspense file.

**b)** AB 1315 (Mullin), Chapter 414, Statutes of 2017, establishes the EPI Plus Program and advisory committee to MHSOAC for the purpose of creating an early psychosis detection and intervention competitive selection process to expand the provision of high-quality, evidence-based early psychosis detection and intervention services by providing funding to counties. Provides that the implementation of the grant program and adoption of regulations be contingent upon the deposit into the Early Psychosis Detection and Intervention Fund of at least $500,000 in non-state funds for the purpose of funding grants.

5) **TECHNICAL AMENDMENT.** In the 2024 statewide primary election, California voters approved Proposition 1 which revises and recasts the MHSA as the Behavioral Health Services Act (BHSA). The act among other things, renames the MHSOAC to the Behavioral Health Services Oversight and Accountability Commission. With Proposition 1 going into effect on January 1, 2025, the committee may wish to amend this bill to ensure that the commission's name change is reflected in the language.

**REGISTERED SUPPORT / OPPOSITION**:

**Support**

Mental Health Services Oversight & Accountability Commission

**Opposition**

None on file.

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

Date of Hearing: April 9, 2024

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 2169 (Bauer-Kahan) – As Amended March 21, 2024

**SUBJECT**: Prescription drug coverage: dose adjustments.

**SUMMARY**: Authorizes a licensed health care professional to request, and to be granted, the authority to adjust the dose or frequency of a drug to meet the specific medical needs of the enrollee or insured without prior authorization or subsequent utilization management under specified conditions. Specifically, **this bill**:

1) Authorizes a licensed health care professional to request, and to be granted, the authority to adjust the dose or frequency of a drug to meet the specific medical needs of the enrollee or insured without prior authorization or subsequent utilization management if the following conditions are met:

    a) The drug previously had been approved for coverage by the plan for an enrollee or insured's chronic medical condition or cancer treatment and the plan or insurer's prescribing provider continues to prescribe the drug for the enrollee's chronic medical condition or cancer treatment;

    b) The drug is not an opioid or a scheduled controlled substance; and,

    c) The dose has not been adjusted more than two times without prior authorization.

2) Prohibits the health plan or insurer from limiting or excluding coverage of that prescription if the enrollee or insured has been continuously using a prescription drug selected by the enrollee or insured's prescribing provider for the medical condition under consideration while covered by their current or previous health coverage.

3) Exempts Medi-Cal managed care plans contracting with the Department of Health Care Services from the provisions of this bill.

**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 California Department of Insurance (CDI) to regulate health insurance. [Health and Safety Code (HSC) §1340, *et seq*., Insurance Code (INS) §106, *et seq*.]

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

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 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]

5) 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, the request to be deemed granted. [HSC §1367.241 and INS §10123.191]

6) 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]

7) Prohibits a health plan contract from limiting or excluding coverage for a drug for an enrollee if the drug previously had been approved for coverage by the plan for a medical condition of the enrollee and the plan's prescribing provider continues to prescribe the drug for the medical condition, provided that the drug is appropriately prescribed and is considered safe and effective for treating the enrollee's condition. Does not preclude the prescriber from prescribing another covered drug that is medically appropriate or a generic substitution, as authorized. Specifies that provisions do not apply to coverage for any drug that is prescribed for a use that is different from the use for which that drug has been approved for marketing by the federal Food and Drug Administration. [HSC §1367.22]

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

**COMMENTS**:

1) **PURPOSE OF THIS BILL.** According to the author, nearly half of all Americans live with a chronic medical condition, and that number is expected to rise by 25% in the next 20 years. According to the California Health Care Foundation, 38% of Californians are living with one or more chronic medical conditions. Many Californians who suffer from chronic disease or illness rely on prescription medications to survive. One example is inflammatory bowel disease (IBD), a lifelong chronic illness that requires access to specific treatment as there is

no "one size fits all" treatment for everyone with IBD. When providers find an effective medication, over time adjustment is often necessary, either by increasing the dose or by decreasing the dosing interval. The author states that a change in dosage is not a different treatment, but insurance policies treat them as such. This creates long pre-approval, denial, and appeal processes that make treatment less effective and more expensive over the long term. The author concludes that this bill authorizes prescribers to adjust, up to two times, the dose or frequency of a drug without prior authorization or subsequent UM, as long as the drug has been approved for coverage by the plan and the plan's prescribing provider continues to prescribe it.

**2) BACKGROUND.**

**a) Prescription drug coverage**. According to the California Health Benefit Review Program, almost all enrollees in plans and policies regulated by DMHC and CDI have pharmacy benefit coverage. Pharmacy benefits cover outpatient prescription drugs by covering prescriptions (scripts) that are generally filled at a retail pharmacy, a mail-order pharmacy, or a specialty pharmacy. Plans and policies that include a pharmacy benefit may apply UM techniques, including prior authorization, step therapy, and formulary requirements. UM techniques are generally applied to new prescriptions, but they may also be applied if there is a change in dose or dosage form (inhaled vs. oral, immediate vs. extended release, etc.) for a recurring prescription. Additionally, they may be applied to recurring prescriptions, should the enrollee's plan or policy alter applicable UM techniques or if an enrollee switches from one plan or policy to another. Prescribers submit medical documentation along with a prior authorization request for an enrollee seeking to fill a script for a drug when UM requirements are present. Plans and insurers regulated by DMHC and CDI must complete UR for a completed prior authorization request within 72 hours (within 24 hours in emergency circumstances) or coverage for the script is required. UR may result in the plan or insurer covering the drug or denying coverage. Should a plan or insurer review a prior authorization request and then deny coverage, an enrollee, with assistance from the prescriber, may appeal the decision to the plan or insurer. Plans and insurers regulated by DMHC and CDI generally must review and respond to completed appeals within 30 days. The plan or insurer may agree to the appeal and cover the drug or may uphold their original denial. Should a plan or insurer review an appeal and uphold their denial, an enrollee, with assistance from the prescriber, may appeal the second denial to the appropriate regulator for state regulated health insurance. The regulator may uphold the denial or may require the plan or insurer to cover the drug.

**b) Continuity Provisions of California Law.** California law with respect to continuity of coverage requires that plans regulated by DMHC or CDI that include a pharmacy benefit not limit or exclude coverage for a drug for an enrollee when: i) the drug previously had been approved for coverage by the plan for a medical condition of the enrollee; ii) the plan's prescribing provider continues to prescribe the drug for the medical condition; and, iii) provided that the drug is appropriately prescribed and is considered safe and effective for treating the enrollee's medical condition. This bill amends existing law to allow a prescriber to adjust the dose or frequency of a drug previously approved for a chronic medical condition or cancer. This authorization does not apply to opioids or a scheduled controlled substance.

3) **SUPPORT.** The Crohn's and Colitis Foundation (CCF), sponsor of this bill, writes that most prescriptions for a dose adjustment that are initially denied are ultimately approved when appealed. For example, in 2021, 87.5% of IBD patients who appealed their insurance medication denials through the DMHC IMR process eventually had their request approved. This means that patients were denied an effective dose of a life preserving medication for an unnecessary period of time. Moreover, many patients do not know this appeal is available to them, and the process can be lengthy, leaving patients without their necessary medication until a final decision is made. According to CCF, when a decision is made, the patient's condition may have deteriorated or they were forced to move to another drug, which then limits future options and may not have the same therapeutic response as the previous drug at the right dose. Limiting access to medically necessary drugs and drug dosage is not adequate and does not represent quality care. CCF concludes that this bill addresses this problem by ensuring patients have appropriate access to the right dose of a life sustaining drug that meets their specific medical needs as determined by their physician.

4) **OPPOSITION.** The California Association of Health Plans (CAHP), the Association of California Life and Health Insurance Companies (ACLHIC), and America's Health Insurance Plans (AHIP), contend that this bill would undermine existing utilization management protocols for prescription drugs by nullifying these processes and allowing a provider to increase the dosage of a drug up to two times without giving a health plan or insurer the ability to ensure clinically appropriate use. CAHP, ACLHIC, AHIP note that clinical research and efficacy are not static and evolve over time. Oftentimes, a health plan may switch an enrollee to a more effective medication or a lower cost brand equivalent to treat a certain condition that is clinically appropriate and already on the health plan or insurer's formulary. This bill ignores these considerations and gives providers a free pass to increase the dose of a particular drug without having to provide the health plan with a reason why the enrollee/insured should remain on the drug at elevated doses. The opposition concludes this bill will increase health care costs in California and will add costs to our healthcare delivery system by encouraging the use of expensive specialty and brand name drugs.

5) **RELATED LEGISLATION.** SB 516 (Skinner) prohibits a health plan or health insurer from requiring a contracted health professional to complete or obtain a prior authorization for any covered health care services if the plan or insurer approved or would have approved not less than 90% of the prior authorization requests they submitted in the most recent completed one-year contracted period. SB 516 is pending in Assembly Appropriations Committee.

6) **PREVIOUS LEGISLATION.**

   **a)** SB 70 (Wiener) of 2023 was similar to this bill and would have additionally prohibit limiting or excluding coverage of a drug, dose of a drug, or dosage form of a drug that is prescribed for off-label use if the drug has been previously covered for a chronic condition or cancer, as specified, regardless of whether or not the drug, dose, or dosage form is on the plan's or insurer's formulary. Would have prohibited a health plan contract or health insurance policy from requiring additional cost sharing not already imposed for a drug that was previously approved for coverage. SB 70 was held in the Assembly Appropriations Committee.

**b)** SB 598 (Skinner) of 2023 was substantially similar to SB 516 (Skinner) and was held in Assembly Appropriations Committee.

**c)** SB 853 (Wiener) of 2022 was similar to SB 70 (Wiener) of 2023. SB 853 was held in the Assembly Appropriations Committee.

**d)** AB 347 (Arambula), Chapter 742, Statutes of 2021, requires a health plan or health insurer to expeditiously grant a step therapy exception if specified criteria are met, including that the health care provider submit necessary justification and supporting clinical documentation supporting the provider's determination that the required prescription drug is inconsistent with good professional practice for provision of medically necessary covered services, as specified.

**REGISTERED SUPPORT / OPPOSITION**:

**Support**

Crohn's & Colitis Foundation (sponsor)
California Chapter American College of Cardiology
California Chronic Care Coalition
California Life Sciences
California Medical Association
California Retired Teachers Association
Children's Specialty Care Coalition
National Multiple Sclerosis Society, MS-CAN
Oncology Nursing Society

**Opposition**

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

**Analysis Prepared by**: Kristene Mapile / HEALTH / (916) 319-2097

Date of Hearing: April 9, 2024

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 2237 (Aguiar-Curry) – As Amended March 18, 2024

**SUBJECT**: Children and youth: transfer of specialty mental health services

**SUMMARY**: Requires a county to continue providing specialty mental health services (SMHS) to high-risk or vulnerable youth who moves to the county and is receiving SMHS; requires the Department of Health Care Services (DHCS) and Department of Social Services (DSS) to create a standardized system to notify counties and providers when such a youth moves from one county to another; requires DSS to establish a care team to support counties in implementation; and, requires DHCS to collect related data.

**EXISTING FEDERAL LAW** defines Early Periodic and Screening Diagnostic, and Treatment Services (EPSDT) as screening services, vision services, dental services, hearing services, and other necessary health care, diagnostic services, treatment and other measures to correct or ameliorate defects and physical and mental illnesses and conditions discovered by the screening services, including SMHS, for Medicaid eligible individuals who are under the age of 21. [42 United States Code §1396d(r)]

**EXISTING STATE LAW**:

1) Establishes a state and local system of child welfare services, including foster care, for children who have been adjudged by the court to be at risk or have been abused or neglected, as specified. [Welfare and Institutions Code (WIC) §202]

2) Requires DHCS to implement mental health managed care through contracts with mental health plans (MHPs). Requires DHCS to contract with a county or counties acting jointly for the delivery of SMHS to each county's eligible Medi-Cal beneficiary population. Authorizes MHP contracts to be awarded exclusively and on a geographic basis. [WIC §14712]

3) States legislative intent to ensure that foster children who are placed outside of their county of original jurisdiction are able to access SMHS in a timely manner, consistent with their individual strengths and needs and the requirements of the federal EPSDT services. [WIC §14717.1]

4) Defines "presumptive transfer" as the requirement that, absent any exceptions as established by current law, responsibility for providing or arranging for SMHS promptly transfer from the county of original jurisdiction to the county in which the foster child resides, under certain conditions, as specified. [WIC §14717.1]

5) Makes it the responsibility of a recipient of aid (CalWORKs, CalFresh, or Medi-Cal) changing residence from one county to another to promptly notify either the county from which he or she moves or the county to which he or she moves of the change of residence. [WIC §10003]

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

**COMMENTS**:

1) **PURPOSE OF THIS BILL.** According to the author, today, over 243,000 young Californians rely on county SMHS. However, the author asserts, when these minors move from county to county, they cannot receive county services in their new area until they re-establish their eligibility for services — a process that can take months. The author explains this results in gaps in mental health care during a major transition, creating a burden for families and risking that minors enter the foster care system. This bill is intended to preserve critical mental health coverage for high-risk and vulnerable minors when they move across county lines by making sure that eligible minors receive services through the transition and the transfer of services is streamlined across county lines.

2) **BACKGROUND.**

   a) **SMHS**. Medi-Cal mental health benefits are delivered through two main delivery systems (county MHPs and Medi-Cal managed care plans), as well as fee-for-service (FFS) Medi-Cal. County MHPs provide a broad range of SMHS to individuals with more severe mental illnesses, while Medi-Cal managed care plans provide a narrower set of non-SMHS (the Medi-Cal managed care plan benefit is sometimes referred to as the "mild to moderate" benefit).

   b) **EPSDT under Medicaid**. A range of children's health care services are required to be provided by federal law, which establishes an entitlement to the EPSDT benefit. The EPSDT benefit provides a comprehensive array of prevention, diagnostic, and treatment services for individuals under the age of 21 who are enrolled in Medi-Cal, including physical and mental health services.

   c) **Recent Medi-Cal Behavioral Health Initiatives.** DHCS has recently undertaken numerous initiatives to improve the Medi-Cal behavioral health system, reduce administrative burden, and streamline access to services. Two key initiatives related to this bill are described below:

      i) **No Wrong Door and Updates to Medical Necessity Criteria**. On July 1, 2022, DHCS implemented the "no wrong door" policy to ensure Medi-Cal beneficiaries receive mental health services regardless of the delivery system where they seek care (via county MHP, Medi-Cal managed care plan, or FFS Medi-Cal). In a related effort, DHCS also updated and clarified the responsibilities of county MHPs, including updates to the medical necessity criteria for access to specialty services, both for adults and members under age 21. These criteria were intended to improve members' access to services and reduce provider administrative burdens.

      ii) **Screening and Transition of Care Tools**. DHCS created standardized screening tools for adults and youth in order to determine the most appropriate Medi-Cal mental health delivery system (e.g., county MHP or Medi-Cal managed care plan) for members seeking services, as well as a transition of care tool for the transition of services between delivery systems, or when adding a service. According to DHCS, the purpose of these tools is to guide referrals of adult and youth beneficiaries to the appropriate Medi-Cal mental health delivery system and ensure that beneficiaries requiring transition between delivery systems receive timely, coordinated care.

**d) Presumptive Transfer.** AB 1299 (Ridley-Thomas), Chapter 603, Statutes of 2016, established presumptive transfer, a process to transfer responsibility for provision of SMHS for foster children and youth. Presumptive transfer guidelines are strict, and only apply within the foster care system.

According to DHCS, presumptive transfer means a prompt transfer of the responsibility for providing or arranging and paying for SMHS from the county of original jurisdiction to the county in which the foster child or youth resides. Presumptive transfer is intended to provide children and youth in foster care who are placed outside their counties of original jurisdiction timely access to SMHS, consistent with their individual strengths and needs, and Medicaid EPSDT requirements.

Effective July 1, 2017, presumptive transfer statute transferred the responsibility for authorization, provision, and payment of SMHS to the MHP in the foster child's **county of residence** for foster children placed in a county other than the county of original jurisdiction, pursuant to the timeframes outlined in statute, unless any exceptions to presumptive transfer apply. More recently, AB 1051 (Bennet), Chapter 402, Statutes of 2022, required the youth's **county of original jurisdiction** to retain responsibility to arrange and provide SMHS if placed out of the county of original jurisdiction in a community treatment facility, group home, or short-term residential therapeutic program, unless specified circumstances exist.

On July 14, 2017, DHCS and DSS issued joint guidance to counties implementing presumptive transfer requirements (All County Letter No. 17-77 Mental Health and Substance Use Disorder Services Information Notice No. 17-032). According to this notice, upon presumptive transfer (unless an exception applies), the MHP in the county in which the foster child resides assumes responsibility for the authorization and provision of SMHS, and the payment for services. To provide timely provision of mental health services, the MHP in the foster child's county of residence is required to accept an assessment, if one exists, of needed SMHS for the foster child from the MHP in the county of original jurisdiction. The notice states nothing should preclude the MHP of residence from updating the assessment or conducting a new assessment if clinically indicated, but these updates or new assessments may not delay the timely provision of SMHS to the child.

Pursuant to the notice, as counties implement procedural steps for presumptive transfer, they should identify a single point of contact or unit and have a dedicated phone number and/or e-mail address at the MHP and each placing agency and post that information to a public website to ensure timely communication. The notice states all parties must comply with the Health Insurance Portability and Accountability Act (HIPAA) of 1996 requirements and all applicable Federal and State regulations promulgated from HIPAA when making presumptive transfers, providing notifications, and requesting information regarding the foster child.

**e) Moving Counties in Medi-Cal (Inter-County Transfer (ICT)).** Current law requires a beneficiary to promptly notify either the county from which they move (sending county) or the county to which they move (receiving county) of the change in residence. The Medi-Cal beneficiary has the option to report a change of residence in person, in writing,

telephonically, or electronically online and individuals must be advised of these options at the time of application, redetermination, and/or certification.

SB 1339 (Monning), Chapter 801, Statutes of 2016, establishes requirements related to ICT. It places responsibility on the county that the beneficiary notifies of the change in residence to initiate an ICT for all the benefits that the beneficiary is receiving. The notified county can be either the sending county or the receiving county. It also requires that within seven business days of notice of a new residence, the notified county to initiate an ICT.

DHCS provides guidance on ICTs in a January 18, 2018, All County Welfare Directors Letter (ACWDL) 18-02. According to the ACWDL:

**i)** Counties are prohibited from requiring the beneficiary changing county residences to reapply for Medi-Cal benefits in the receiving county;

**ii)** Counties must ensure all Medi-Cal cases remain active throughout the ICT period without an interruption in benefits; and,

**iii)** The ICT must be completed no later than the first day of the next available benefit month following the 30 days after the beneficiary's initial notification to either the sending county or receiving county of the change in residence county.

DHCS provides an example: The beneficiary contacts her current county worker (sending county) on Wednesday, January 10, to report that she is moving to a new county. The sending county must initiate the ICT within seven business days or, in this instance, no later than Friday, January 19. To comply with the law, the ICT must be completed by the next available benefit month which falls after the 30th day from the beneficiary's initial notification that he/she has moved. In this scenario, the beneficiary's ICT must be processed and completed by the receiving county, effective March 1.

DHCS notes that to the greatest extent possible, the ICT process shall be simple, client friendly, and minimize workload for county eligibility operations. DHCS also requires case file documents be electronically shared between the prior county of residence and the new county of residence, to the extent possible, and notes this process ensures that beneficiaries do not need to provide documents that were already provided to the prior county.

**f) DHCS Guidance on Transfer of SMHS to a New County, Outside of Foster Care.** On February 8, 2024, DHCS issued Behavioral Health Information Notice (BHIN) No: 24-008 to clarify distinctions between and responsibilities of the County of Residence and County of Responsibility for members who move to another county. This BHIN applies to all Medi-Cal members receiving SMHS, and is not specific to children and youth in foster care.

The BHIN explains, for services where referral, prior authorization or concurrent review is required, if a provider requests an authorization for SMHS service from a county MHP, for a member that has initiated an ICT to another county, the County of Responsibility must notify the provider that an ICT has been initiated, and the provider must then request the authorization from the County of Residence. Once the County of Residence

field is updated in the applicable state data system, called MEDS, the provider may request authorization from the new county MHP listed in the County of Residence field, and the County of Residence shall review the authorization.

The guidance does not list timelines; however, it appears timelines for the ICT process and the SMHS authorization process discussed directly above have the potential to result in significant gaps in care. Appropriately, the state has put in place a number of protections that expedite the delivery of SMHS to foster youth; however, youth outside the foster system may also have significant mental health needs and benefit from a standardized process and smoother transition of services when moving counties.

3) **SUPPORT.** According to the bill's sponsor, California Council of Community Behavioral Health Agencies (CBHA), a coalition of behavioral health providers, this bill preserves counties' ability to conduct appropriate reviews to meet changing mental health needs and conditions, while also ensuring continuity of care for high-risk and vulnerable youth. CBHA also asserts the bill improves communication between counties, helping reduce the burden on families trying to navigate unfamiliar county systems to meet their child's need for mental health services. Sycamores, a mental health provider, illustrates the need for this bill through an example of a youth who moved counties having to "go through the county system to be assessed for eligibility for SMHS which is causing additional administrative barriers and potential delays for youth to receive services."

4) **PREVIOUS LEGISLATION.**

   **a)** AB 1051 made a number of changes to the presumptive transfer process and required DHCS to collect specified data.

   **b)** SB 1339 establishes requirements related to ICT.

   **c)** AB 1299 established presumptive transfer.

   **d)** SB 785 (Steinberg), Chapter 469, Statutes of 2007, facilitates access to mental health services for foster youth who are placed outside of the original county of jurisdiction, including those being adopted or entering into a guardianship with a relative. Required the former Department of Mental Health (now DHCS), following consultation with stakeholders, to require the use of standardized contracts, authorization procedures, and documentation standards and forms.

5) **DOUBLE REFERRAL**. This bill is double referred, upon passage in this Committee, this bill will be re-referred to the Assembly Committee on Human Services.

6) **AMENDMENTS.** Following discussion between the author, Committee, and key stakeholders, the author and Committee have agreed to recast the bill to accomplish the following:

   **a)** Clarify the bill does not address children and youth for whom the transfer of specialty mental health services is governed by other provisions of law, such as for youth subject to the presumptive transfer process;

**b)** To remove requirements on DSS, given the bill is not specific to foster youth and DHCS is the appropriate oversight entity for SMHS;

**c)** Align with federal EPSDT standards that apply to children and youth in Medi-Cal by changing the age from 18 to 21;

**d)** Remove the provision limiting the bill's applicability to children or youth deemed "high risk or coming from a vulnerable population," in order to reduce administrative burden of an additional screening process and ensure all applicable children and youth receiving SMHS can benefit from a streamlined transfer of services;

**e)** Clarify the data DHCS is required to report;

**f)** Require DHCS to issue guidance to meet the objective of coordinating and expediting the transfer process of SMHS from one county to another and reducing the burden on children and youth and their caregivers to reestablish services in the receiving county;

**g)** Instead of requiring care teams to be established to help counties coordinate the process, require a point of contact at DHCS responsible for overseeing the requirements; and,

**h)** Allow DHCS to issue guidance to counties, such as a Behavioral Health Information Notice, to implement the bill's provisions until regulations are adopted.

The amendments strike the current language and instead insert the following language:

***14716.5.***

***(a) When a child or youth younger than 21 years of age who is receiving Medi-Cal specialty mental health services changes residence from one county to another, and the transfer of the child or youth's specialty mental health services from one county to another is not otherwise governed by a process established in statute, the receiving county shall provide specialty mental health services to the child or youth.***

***(b) The department shall collect data on the receipt of specialty mental health services by children and youth who move outside of the county where they received specialty mental health services. These data shall be included in the department's Medi-Cal specialty mental health services performance dashboard, in compliance with all applicable state and federal privacy and confidentiality laws, and shall contain all of the following statewide information:***

***(1) The number of children and youth receiving specialty mental health services who move outside the original county where they received specialty mental health services.***

***(2) The number of children and youth receiving specialty mental health services after they move outside the original county where they originally received specialty mental health services.***

***(3) The outcomes for children and youth receiving specialty mental health services who move across county lines.***

***(c) The department shall issue guidance that defines requirements on a receiving county for continued provision of specialty mental health services, as required by (a), that have the effect of coordinating and expediting the transfer of specialty mental health services from one county to another and reducing the burden on children and youth and their caregivers to reestablish services in the receiving county. Guidance shall also include:***

***1) A point of contact at DHCS, accessible to applicable children and youth and their caregivers, who is responsible for ensuring counties meet the requirements of subdivision (a).***

***2) Standardized notification and information-sharing requirements for county mental health plans and specialty mental health services providers, to facilitate the continued provision of specialty mental health services by a receiving county, pursuant to subdivision (a).***

***(d) Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, the department may implement, interpret, or make specific this article by means of all-county letters, plan letters, plan or provider bulletins, or similar instructions, without taking any further regulatory action, until regulations are adopted.***

7) **POLICY COMMENT.** Committee staff recommends the author and sponsor continue working with stakeholders and seek technical assistance from DHCS to fine-tune the language consistent with the author's intent and the direction of the amendments, paying particular attention to ensuring the new requirements do not inadvertently undermine any existing protections afforded to children and youth in Medi-Cal and considering whether the obligation on receiving counties to provide SMHS to a child or youth who changes residences is the right or optimal framing to ensure streamlined continuity of services and alignment with other initiatives and requirements.

**REGISTERED SUPPORT / OPPOSITION**:

**Support**

California Council of Community Behavioral Health Agencies (sponsor)
California Access Coalition
Children's Institute
Healthright 360
Pathpoint
Sycamores

**Opposition**

None on file.

**Analysis Prepared by**: Lisa Murawski / HEALTH / (916) 319-2097

Date of Hearing: April 9, 2024

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 2258 (Zbur) – As Amended April 1, 2024

**SUBJECT**: Health care coverage: cost sharing.

**SUMMARY**: Prohibits a group or individual nongrandfathered health plan contract or insurance policy from imposing a cost-sharing requirement for items or services integral to the provision of specified preventative care services and screenings. Specifically, **this bill**:

1) Prohibits a health plan contract or insurance policy issued, amended, or renewed on or after January 1, 2025, from imposing any cost-sharing requirement for any items or services that are integral to the provision of an item or service that is required as a preventive care and screening, regardless of whether or not the integral item or service is billed separately from an item or service.

2) Specifies that this bill does not prohibit a health plan or insurer from doing either of the following:
   a) Provide coverage for preventive items or services in addition to those required; or,
   b) Deny coverage for services that are not recommended by the United States Preventive Services Task Force (USPSTF), except as provided.

3) Requires a health plan contract or insurance policy to cover items and services pursuant to this bill, prophylaxis of HIV infection (PEP and PrEP), sexually transmitted infection (STI) screening, home test kits for sexually transmitted diseases (STDs), and colorectal cancer screening consistent with existing law.

4) Authorizes the California Department of Insurance (CDI) to exercise authority, as provided and the Administrative Procedure Act (APA) to implement and enforce this bill and all related law. Allows any hearing that is requested by the insurer to be conducted by an administrative law judge if the CDI Commissioner assesses a civil penalty for a violation. Specifies that this bill does not impair or restrict the CDI's Commissioner's authority pursuant to another provision of law or the APA.

**EXISTING LAW**:

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

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

USPSTF and immunizations that have in effect a recommendation from the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC). [HSC §1367.002 and INS §10112.2]

4) Requires health plans and insurers to provide coverage for home test kits for STDs, 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) 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 to not 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. [HSC §1342.74, INS §10123.1933]

6) Requires a health plan contract or a health insurance policy issued, amended, or renewed on or after January 1, 2022, to provide coverage without cost sharing for a colorectal cancer screening test, and for a colorectal cancer screening examination in specified circumstances, assigned either a grade of "A" or a grade of "B" by the USPSTF. [HSC §1367.668, INS §10123.207]

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

**COMMENTS**:

1) **PURPOSE OF THIS BILL.** According to the author, every Californian deserves access to preventive health care that is comprehensive, inclusive, and affordable. Current California law relating to preventive health care and screenings for STIs contains loopholes that need closing. This bill codifies federal guidance requiring health plans and health insurers to cover services that are integral to the delivery of recommended preventive services without out-of-pocket cost. The author concludes that these services include anesthesia and polyp removal during a colonoscopy; placement, management, and removal of long-acting reversible contraceptives; and ancillary and support services for PrEP, including HIV and other STI screening.

2) **BACKGROUND.** The California Health Benefits Review Program writes that preventive services are services such as screening tests and counseling that aim to prevent illness and disease.

   **a)** Multiple sources make recommendations as to who should use which preventive services when, including:

      **i)** The USPSTF "A" and "B" recommendations: Includes counseling and screening for conditions such as cancer, cardiovascular disease, depression, diabetes, obesity, osteoporosis, and STIs and behaviors related to tobacco, alcohol, and drug use. The USPSTF offers recommendations for screenings of individuals that may be at higher

risk for certain adverse health outcomes due to age, gender, and current health conditions;

**ii)** The Health Resources and Services Administration (HRSA)-supported health plan coverage recommendations for women's preventive services: Includes preventive services that address mental health, sexual health (contraception and STI screening), cancer (breast, cervical), and overall wellness among women in general, and specific services for pregnant (diabetes, mental health, STI screening) and postpartum (breast feeding services and supplies, diabetes screening) people;

**iii)** The HRSA-supported comprehensive recommendations for infants, children, and adolescents which include: The Bright Futures Recommendations for Pediatric Preventive Health Care, and the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children. The Bright Futures recommendations provide recommendations for preventive care screenings and routine visits for newborns through the age of 21 years. The recommendations of the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children focus on the implementation of a uniform screening panel in every newborn screening program, enabling screening for 36 core disorders and secondary disorders. Beyond newborn screening, the committee also provides recommendations regarding medical foods, specific health conditions, and health care reform: and,

**iv)** ACIP recommendations adopted by the CDC: The recommendations include immunizations, immunization schedules, and catch-up immunization schedules for both children and adults. Recommendations also provide guidance in regards to vulnerable populations or emergencies.

Preventive services recommended in any of these four sources are required to be covered without cost-sharing initially required by the ACA and later codified in AB 406 (Pan), Chapter 302, Statutes of 2020. CDI, the sponsor of this bill, provided additional information describing federal guidance on preventive care. Federal guidance specifies that plans and issues subject to the ACA's requirements to cover preventive services must cover, without cost sharing, items and services that are integral to the furnishing of the recommended preventive service, regardless of whether the item or service is billed separately. Examples in this guidance include polyp removal or anesthesia for preventive colonoscopies, administration for immunizations, and specimen collection for diabetes and other recommended screening tests. This bill codifies federal guidance into state law to require coverage of items and services integral to the provision of covered preventative care services and services.

**b) ACA Preventive Care litigation.** On March 30, 2023, a federal court in Texas struck down protections for preventive care benefits under the ACA in *Braidwood Management Inc. v. Becerra*. This court also found that the coverage of PrEP medications for HIV prevention violates plaintiff rights who have religious objections. If *Braidwood* is upheld by the Supreme Court, California law will still require coverage of recommended preventive care benefits (pursuant to AB 406 (Pan), Chapter 302, Statutes of 2020). However, the federal guidance on covering integral services without cost sharing will be unenforceable. Consequently, health plans and insurers could require consumers to pay cost sharing for integral services for PrEP and other preventive care, such as

colonoscopies, birth control, and screening for STI. According to the sponsor, although legal appeals are expected, there will be no question that preventative care and access to life-saving drugs will remain covered without cost sharing under this bill.

3) **SUPPORT.** CDI, cosponsors of this bill, writes that every Californian deserves access to preventive health care that is comprehensive, inclusive, and affordable. Federal guidance under the ACA requires health insurers and health plans to cover both recommended preventive care and health care that is integral to providing recommended preventive care ("integral services") without out-of-pocket costs to the consumer. Although California codified the ACA statute on preventive services, it has not codified the guidance pertaining to integral services. Out-of-pocket cost for preventive care is a barrier to care. For example, a recent study found that as little as $10 in cost sharing for HIV PrEP doubled the rate at which patients abandon their prescriptions, leading to a higher incidence of HIV infection in those patients. CDI states that California can continue to provide fair and equal access to preventive care for all, as potential continued changes by some federal courts may attempt to curtail access to these essential services. Health coverage plays a major role in enabling people to access health care and protecting families from high medical costs. Persons of color have faced longstanding disparities in health coverage that contribute to disparities in health. Persons from racial and ethnic groups are more likely to be uninsured compared to non-Hispanic whites, limiting their access to health care. CDI concludes that other barriers to health care access include lack of transportation and childcare, inability to take time off work, experiences with housing instability or homelessness, communication and language barriers, racism, discrimination, and lack of trust in health care providers.

4) **RELATED LEGISLATION.**

   **a)** SB 437 (Portantino) prohibits cost sharing for PrEP or PEP. SB 437 is pending on the Assembly Floor.

   **b)** AB 3245 (Joe Patterson) prohibits cost sharing for a colorectal cancer screening test by other accredited or certified guideline agencies. AB 3245 is pending in Assembly Health Committee.

5) **PREVIOUS LEGISLATION.**

   **a)** SB 339 (Wiener), Chapter 1, Statutes of 2024, authorizes a pharmacist to furnish up to a 90-day course of PrEP, or PEP beyond a 90-day course, if specified conditions are met.

   **b)** AB 1645 (Zbur) of 2023 was similar to this bill. AB 1645 would have additionally required a plan or insurer to directly reimburse a nonparticipating provider or facility of STI screening that meets specified criteria for screening tests and integral items and services rendered, as specified, and would have prohibited a nonparticipating provider from billing or collecting a cost-sharing amount for a STI screening from an enrollee or insured. AB 1645 was vetoed by Governor Newsom who stated, in part:

   "I appreciate the author's efforts to increase access to preventive health care, including HIV and STI testing, colorectal screening, and other services. However, components of this proposal depart from structures in federal and state law, such as the existing policies for reimbursement to non-contracted providers. Further, because this bill exceeds the cost-sharing provisions under the ACA, it would result in increased costs to health plans

passed on to consumers through premiums. The State must weigh the potential benefits of all new mandates with the comprehensive costs to the entire delivery system."

**c)** SB 306 (Pan), Chapter 486, Statutes of 2021, permits pharmacists to dispense a drug, without the name of an individual for whom the drug is intended, when prescribed for the sexual partner of someone who has been diagnosed with a STD; prohibits health care providers who prescribe, dispense, or furnish such a drug from being subject to, civil, criminal, or administrative penalties, as specified; requires a syphilis blood test, during the third trimester of pregnancy and at delivery, as specified; requires public and commercial health coverage of home STD test kits; and adds rapid STD tests to existing law which permits HIV counselors to perform rapid HIV and hepatitis C tests.

**d)** AB 342 (Gipson), Chapter 436, Statutes of 2021, requires a health plan contract or a health insurance policy, except as specified, that is issued, amended, or renewed on or after January 1, 2022, to provide coverage for a colorectal cancer screening test, and requires the colonoscopy for a positive result on a test or procedure to be provided without cost sharing, unless the underlying test or procedure was a colonoscopy.

**e)** SB 406 codifies existing ACA law into state law that prohibits lifetime or annual limits in health plan and health insurance policies and requires coverage of preventative health services without cost sharing.

**f)** SB 159 (Wiener), Chapter 532, Statutes of 2019, authorizes a pharmacist to initiate and furnish HIV PrEP and PEP, as specified.

**REGISTERED SUPPORT / OPPOSITION**:

**Support**

California Insurance Commissioner Ricardo Lara (cosponsor)
Equality California (cosponsor)
San Francisco AIDS Foundation (cosponsor)
Los Angeles LGBT Center (cosponsor)
APLA Health (cosponsor)
ACLU California Action
AIDS Healthcare Foundation
API Equality-LA
Asian Americans Advancing Justice Southern California
Bienestar Human Services
California Chronic Care Coalition
California Life Sciences
California Retired Teachers Association
California Rural Legal Assistance Foundation, INC.
California State Council of Service Employees International Union (SEIU California)
Central California LGBTQ+ Collaborative
Courage California
End the Epidemics: Californians Mobilizing to End HIV, Viral Hepatitis, STIs, and Overdose
Glide
Health Access California

National Health Law Program
Rainbow Pride Youth Alliance
Reproductive Freedom for All CA
San Francisco AIDS Foundation
Santa Monica Democratic Club
The Source LGBT+ Center
Transgender Health and Wellness Center
Transgender Resource, Advocacy & Network Service
ViiV Healthcare
Youth Leadership Institute

**Opposition**

None on file.

**Analysis Prepared by**: Kristene Mapile / HEALTH / (916) 319-2097

Date of Hearing: April 9, 2024

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 2297 (Friedman) – As Introduced February 12, 2024

**SUBJECT**: Hospital and Emergency Physician Fair Pricing Policies.

**SUMMARY**: Authorizes an emergency physician to grant eligibility for a discount payment policy to patients with incomes over 400% of the federal poverty level (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. Specifically, **this bill**:

1) Prohibits a hospital, in determining eligibility under its discount payment policy, from considering the monetary assets of the patient.

2) Requires, rather than authorizes, eligibility for discounted payments or charity care to be determined at any time the hospitals is in receipt of a patients pay stubs or income tax returns, and prohibits a hospital from imposing time limits for eligibility for charity care or discounted payments.

3) Authorizes a hospital to waive Medi-Cal and Medicare cost-sharing amounts as part of its charity care program or discount payment program.

4) Prohibits a hospital or other assignee that is an affiliate or subsidiary of the hospital, in dealing with patients eligible under the hospitals charity care or discount payment policies, from using wage garnishment or liens on primary residences or any real property as a means of collecting unpaid hospital bills.

5) Prohibits a collection agency, debt buyer, or other assignee that is not a subsidiary or affiliate of the hospital, from conducting a sale of any real property owned, in part or completely, by the patient, or placing liens on any real property.

6) Raises eligibility to apply for discount payment policies for uninsured patients or patients with high medical costs from 350% to 400% of FPL.

7) Requires eligibility for discounted payment to be determined at any time the emergency physician of the patient's pay stubs or income tax returns.

8) Prohibits an emergency physician from imposing time limits for eligibility for discounted payments, and authorizes an emergency physician to waive Medi-Cal and Medicare cost-sharing amounts as part of their discount payment program.

9) Prohibits an emergency physician or other assignee, in dealing with patients eligible under the emergency physician's discount payment policies, from using wage garnishments or liens on any real property as a means of collecting unpaid emergency physician bills.

10) Prohibits a collection agency or other assignee, in dealing with any patient under the emergency physician's discount payment policy, from noticing or conducting a sale of any real property owned, in part or completely, by the patient, or placing liens on any real property.

11) Revises the definition of "high medical costs" to include an expenses for medical care that are not reimbursed by insurance or a health coverage program, such as Medicare copays or Medi-Cal costs sharing.

12) Defines, for purposes of this bill:

    a) "Charity care policy" to mean free care; and,

    b) "Discounted payment policy" or "discount payment policy" to mean any cost of care that is reduced and for which a patient may pay the amount in monthly installments.

**EXISTING LAW**:

1) Establishes the 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) 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. [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 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 the federal poverty level. [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]

**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 debt can have profound consequences that impact not just an individual's financial security, but also their health. In a nationwide survey, 24% of adults stated that they had medical bills that were past due or that they were unable to pay. In nearly 20% of those cases, the burden of the debt has forced individuals to change their living situation, putting them at risk for homelessness. The author states that many also forgo future medical care because of the debt. The author also notes that over one third of Californians report having medical debt. The author contends that in recent years, we've taken steps to better protect patients and ensure that hospitals are accountable for their charity care and financial assistance practices, however, patients can still fall through the gaps in our safety net. The author concludes that this bill will shield a qualifying patient's property from liens during the debt collection process, thereby helping to preserve their housing stability, and better clarify eligibility rules so that we can ensure more consistent compliance among hospitals.

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) Debt collection/medical debt.** According to the 2024 California Health Care Foundation Survey, 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. For every $100 of net income, hospitals in the top-earning quartile gave $11.5 of charity care to uninsured patients and $5.1 to insured patients. In contrast, hospitals in the lower, third quartile of income gave considerably more – $72.3 to the uninsured and $40.9 to the insured. Hospitals in the top 1% of earnings generated 23% of the net income of all nonprofit hospitals and provided 7% (to the uninsured) and 5% (insured) of the charity care at all nonprofit hospitals. The data came from 2017 Medicare cost reports published by the federal Centers for Medicare and Medicaid Services. 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 $1,380 million, an amount large enough to wipe out 581,510 medical debts (or 18% of medical debt in the state). Hospitals also have inconsistent practices in accepting financial assistance applications. While the law requires hospitals to process applications at any time, many hospitals impose arbitrary deadlines. As a result, hospitals disqualify eligible patients from financial assistance to expedite collections. *Kaiser Health News* reported in 2019 that non-profit hospitals in California could have—but did not—provide $135 million in charity care to patients.

**d) Home ownership and wealth.** Homeownership is an effective way to build wealth, especially for low-income households. According to a 2020 Habitat for Humanity evidence brief "Financial benefits of homeownership for low-income households,"

homeownership promotes wealth building by acting as a forced savings mechanism and through home value appreciation. Homeownership is the largest source of wealth among families, with the median value of a primary residence worth about 10 times the median value of financial assets held by families. Housing wealth gains are built up through price appreciation and by paying off the mortgage. Homeownership confers several economic benefits on homeowners, including the ability to accumulate wealth by accessing credit, building equity and reducing housing costs.

3) **SUPPORT.** Bet Tzedek and Western Center on Law and Poverty are cosponsors of this bill and state that it will eliminate practices of collecting medical debt that have disproportionately harmed communities of color and update eligibility criteria for hospital financial assistance with best practices to serve low- and moderate-income patients. The cosponsors also state that this bill also address historic inequities in wealth accumulation. Home ownership is the greatest asset for many Californians, and often the main way that families build generational wealth. Currently, hospitals are prohibited from placing liens on a patient's primary residence, but debt collectors are allowed to place liens on a patient's home to collect unpaid hospital bills. Property liens are regularly used to collect unpaid medical debt. In Los Angeles County, a review of two debt collectors that work exclusively on behalf of healthcare providers found that over 140 property liens were placed in 2023 with similar numbers in previous years. The cosponsors note that this bill would completely prohibit the use of home liens in the collection of unpaid hospital bills from financially qualified patients. The bill would also eliminate asset consideration in financial assistance determinations. This change would align with current Medi-Cal eligibility rules, simplify the financial assistance application process, and bring hospital financial assistance programs more uniformity across the state. Effective January 2024, the Medi-Cal program eliminated asset consideration from its eligibility criteria to reduce poverty among seniors and persons with disabilities, who previously were allowed to maintain only $2,000 to $3,000 in assets to qualify for no-cost Medi-Cal. Assets are not an accurate measure of a person's current level of financial need, since assets are usually meant to cover large, unexpected life expenses.

   The sponsors conclude that this bill would protect Californians' savings from being depleted when seeking hospital care. While retirement plans are protected from eligibility exclusions in charity care determinations, personal savings accounts and other monetary assets are not. Californians need their savings to prevent senior poverty. As of 2019, 7.4 million Californians ages 25 to 64 do not have access to an employer-sponsored retirement plan and nearly half of California's private sector workers have no retirement assets at all. The majority of private sector Latinx workers (seven out of 10) lack access to workplace retirement plans, a marked disparity compared to other races.

4) **OPPOSE UNLESS AMENDED.** The California Hospital Association (CHA) is opposed to this bill unless it is amended. CHA states that it appreciates the author's and sponsors' intent to ease the financial and emotional strain on patients who struggle to pay medical bills, however, CHA has the following concerns with the bill as written:

   **a)** This bill would prohibit hospitals from considering a patient's Health Savings Account (HSA) when determining whether the patient qualifies for charity care or discounted payment. HSAs were created by federal law expressly to pay for medical care, and employers fund them for this purpose. Hospitals should be able to consider HSAs in the charity care eligibility determination process.

**b)** This bill could compel hospitals to be out of compliance with federal laws and guidelines regarding consideration of patients' assets when waiving Medicare and Medi-Cal cost sharing and when providing charity allowances. This bill should be amended to comport with federal law that calls for an assessment of a patient's assets for waivers of Medicare and Medi-Cal cost sharing.

**c)** This bill would prohibit hospitals from establishing a reasonable deadline for patients to apply for charity care or discounted payment. This presents two problems.

**i)** Setting a deadline serves as an incentive for patients to complete the charity care application so they can get the aid they need. For some patients, the first time they pay attention to their bill is when it goes to collections. CHA states that this bill should be amended to permit a hospital to impose a reasonable deadline, which cannot be earlier than six months after a debt is sent to collections.

**ii)** Existing law requires hospitals to refund any amount paid if a patient later completes an application and is found eligible for charity care/discounted payment. Rather than allowing a patient to return years later for a refund, CHA states that this bill should be amended to establish a reasonable deadline — approximately four years after payment is made — after which the account is closed.

The California Association of Collectors (CAC) is opposed to this bill unless it is amended and notes that it will preclude hospitals, or their assignees, from obtaining a lien against any real property, not just the patient's primary residence, in an attempt to collect unpaid hospital debt. This is an unnecessary expansion of existing law that will create a loophole for the wealthy. CAC states that they understand the need to protect low-income individuals from burdensome hospital debt, but this bill will protect the assets of those who can afford to pay their medical debt and it will increase the cost of, and restrict access to medical care as hospitals are faced with doing more with less.

**5) PREVIOUS LEGISLATION.**

**a)** AB 532 (Wood), Chapter 465, Statutes of 2021, requires the notice hospitals provide to patients under current law regarding discounted payments and charity care to include additional information on organizations that will help the patient understand the billing and payment process, and information on health coverage options. Requires the notice to be provided at the time of service whenever possible.

**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.

**c)** AB 774 (Chan), Chapter 755, Statutes of 2006, establishes hospital fair pricing policies, which requires every hospital to offer reduced rates to uninsured and underinsured

patients who may have low or moderate income, and to provide policies that clearly state the qualifications for free care and discounted payments.

6) **DOUBLE REFERRAL**. This bill is double referred, upon passage in this Committee, this bill will be re-referred to the Assembly Committee on Judiciary.

7) **PROPOSED AMENDMENTS.** In order to address concerns raised by CHA, the author is proposing to amend this bill to update the definition of charity care and discount care, and allow a hospital to consider the balance of a health savings account in determining an individuals' qualification for charity care.

**REGISTERED SUPPORT / OPPOSITION**:

**Support**

Bet Tzedek (cosponsor)
Western Center on Law and Poverty (cosponsor)
American Federation of State, County and Municipal Employees (AFL-CIO)
Asian Americans Advancing Justice-southern California
Asian Resources, INC.
Bay Area Legal Aid
California Advocates for Nursing Home Reform
California Retired Teachers Association
California Rural Legal Assistance Foundation, INC.
California State Association of Psychiatrists (CSAP)
California State Council of Service Employees International Union (SEIU California)
Community Health Councils
Community Legal Aid SoCal
Courage California
Disability Rights California
Friends Committee on Legislation of California
Health Access California
Justice in Aging
Latino Coalition for A Healthy California
National Multiple Sclerosis Society
The Leukemia & Lymphoma Society
Voices for Progress
Young Invincibles

**Opposition**

None on file.

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

Date of Hearing: April 9, 2024

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 2356 (Wallis) – As Introduced February 12, 2024

**SUBJECT**: Medi-Cal: monthly maintenance amount: personal and incidental needs.

**SUMMARY**: Increases the personal needs allowance (PNA) amount, which is the amount of money a Medi-Cal beneficiary in a medical institution, nursing facility, or receiving services from a Program of All-Inclusive Care for Elderly (PACE) is allowed to retain, from $35 to $50 per month.

**EXISTING LAW**:

1) Establishes the Medi-Cal program, administered by the Department of Health Care Services (DHCS), under which low-income individuals are eligible for medical coverage. [Welfare and Institutions Code (WIC) §14000, *et seq.*]

2) Requires DHCS to establish the income levels for maintenance need for Medi-Cal beneficiaries residing in a facility at the lowest levels that reasonably permits a medically needy person to meet their basic needs for food, clothing, and shelter, and for which federal financial participation (FFP) will still be provided. [WIC §14005.12]

3) Requires the maintenance need level (MNL) for a person in a medical institution, in a nursing facility, or receiving institutional or noninstitutional services from a PACE to be an amount that considers the following:

    a) Personal and incidental needs of at least $35 per month;
    b) The upkeep and maintenance of the home, referred to as the "home upkeep allowance;"
    c) The support and care of minor children or any disabled relative, if the person does not have a spouse living in the community; and,
    d) The support and care of a spouse living in the community, minor or dependent children, dependent parents, or dependent siblings of either spouse, provided the individuals are residing with the spouse living in the community. [WIC § 14005.12]

4) Allows DHCS, by regulation, to increase the $35 PNA amount as is necessitated by increasing costs of personal and incidental needs. [WIC § 14005.12]

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

**COMMENTS**:

1) **PURPOSE OF THIS BILL.** According to the author, our seniors deserve to live with dignity, and raising the PNA will ensure they can access the essential items they need to live healthy lives. The author asserts this need has gone unaddressed for too long and the current PNA set at just $35 does not account for rampant inflation. The author argues California needs to lead on showing how to care for our seniors and it is simply unacceptable that we have one of the lowest PNAs in the nation.

**2) BACKGROUND.**

**a) PNA in Medicaid**. Individuals who have income slightly higher than the standard Medi-Cal income eligibility thresholds may be eligible for Medi-Cal with a "share of cost" Once eligible for Medicaid, such individuals in institutions, such as nursing homes, generally must contribute most of their monthly income to the cost of their care, with the exception of a small allowance used to pay for personal needs that are not covered by Medicaid, such as clothing, shoes, personal hygiene items, cards for friends and family members, and haircuts or beauty services beyond a basic trim (which the facility is required to provide). In addition to the PNA, individuals are allowed to retain amounts needed to care for children, relatives, or spouses, as well as home upkeep, as applicable. The federal minimum PNA is $30 per month, though states can choose to adopt a higher amount.

**b) PNA in Medi-Cal**. Many Medi-Cal beneficiaries residing in institutions who have income and qualify for Medi-Cal with a share of cost are only eligible to retain the PNA, and the rest of their income goes towards the cost of their care.

For a Medi-Cal beneficiary receiving care in a facility or through a PACE program with a share of cost, the beneficiary's share of cost is calculated by determining the beneficiary's countable income (minus deductions) and subtracting the PNA. For example, a single individual ("Mary" in the example below) in a skilled nursing facility with a countable income of $1,600 per month would be allowed to retain $35 per month for personal needs, as shown in the example below:

Mary enters a SNF. Her income is $1,600 month:

$1,600 =Gross unearned income
-35 =Maintenance Need for long-term-care resident
$1,565 =Mary's share of cost to be paid each month to the nursing home or for medical costs not covered by Medi-Cal.

* The remaining $35 is Mary's PNA.

Medi-Cal pays the remainder ($1,565) of her income for the month up to the Medi-Cal reimbursement rate for that facility.

DHCS is required to establish the PNA at the lowest levels that permit an individual to meet their basic needs for which federal financial participation will be provided. California's PNA of $35 was last increased in 1985 pursuant to AB 2845 (Allen), Chapter 1621, Statutes of 1984. Current law authorizes DHCS, by regulation, to annually increase the PNA amount as necessitated by increasing costs of personal and incidental needs. However, DHCS has never increased the PNA and no increase is pending.

**c) PNAs in Other State Medicaid Programs**. According to a July 2022 Issue Brief issued by the Kaiser Family Foundation entitled "Medicaid Financial Eligibility in Pathways Based on Old Age or Disability in 2022: Findings from a 50-State Survey" the median PNA for an individual residing in an institution is $50 per month. Three states (Alabama, North Carolina, and South Carolina) set their PNA at the federal minimum of $30 per month. California and Nevada are tied for the fourth and fifth lowest PNA in the country

at $35. The state with the highest PNA in the continental U.S. is Florida ($130 per month) and Alaska has a PNA of $200 per month.

California is known as a higher-cost state, even when excluding housing. The Legislative Analyst's Office reports prices have grown about 20% overall since 2020, according to an analysis of the most recent consumer price index data.

According to the U.S. Bureau of Labor Statistics Consumer Price Index Inflation Calculator, $35 in 1985 has the same buying power as $102.95 today.

3) **SUPPORT.** This bill is sponsored by the California Senior Legislature and supported by seniors and groups advocating on behalf of low-income consumers, who argue this bill provides much needed financial support for some of California's most vulnerable. Alzheimer's Los Angeles, Alzheimer's Orange County, and Alzheimer's San Diego write that $35 is inadequate to cover expenses such as cell phones and clothing. Justice in Aging writes in support that this bill takes a modest but necessary step to restoring dignity and personal agency to Medi-Cal recipients who have been deprived of this much-needed increase in personal needs allowances for far too long.

4) **PREVIOUS LEGISLATION.**

**a)** AB 2077 (Calderon) of 2022 would have increased the PNA amount from $35 to $80 per month. AB 2077 was vetoed by Governor Newsom, who expressed sympathy with the author's efforts but noted concern about ongoing General Fund costs that were not accounted for in the budget and the desire to prioritize existing obligations and priorities, including education, health care, public safety and safety-net programs.

**b)** AB 848 (Calderon) of 2021 would have increased the PNA amount from $35 to $80 per month and required DHCS to annually increase the PNA based on the percentage increase in the California consumer price index. AB 848 was held on the Assembly Appropriations Committee suspense file.

**c)** AB 2739 (Weber) of 2020 was identical to AB 848 but was not heard in the Assembly Health Committee due to the shortened Legislative calendar brought on by the COVID-19 pandemic.

**d)** AB 1042 (Wood), of 2019, would have increased the maximum dollar value of the "home upkeep allowance" in the Medi-Cal program, which is money a Medi-Cal beneficiary in a LTC facility is allowed for upkeep and maintenance of the home. AB 1042 was held on the Senate Appropriations Committee suspense file.

**e)** SB 202 (Dodd) of 2017 was substantially similar to AB 2739. SB 202 was held on the Senate Appropriations Committee suspense file.

**f)** AB 1655 (Dodd) of 2016 was identical to SB 202. AB 1655 was held on the Assembly Appropriations Committee suspense file.

**g)** AB 1235 (Gipson) of 2015 would have required the home upkeep allowance for eligible Medi-Cal beneficiaries in LTC facilities to be based on the actual minimum cost of maintaining the resident's home. AB 1235 would have allowed a LTC facility resident

who does not have a home to establish a transitional personal needs fund of up to $7,500, to be set aside from the income that otherwise would be applied toward the resident's Medi-Cal share of cost for residing in the LTC facility. AB 1235 was held on the Senate Appropriations Committee suspense file.

**h)** AB 1319 (Dababneh) of 2015 would have increased the PNA deduction for Medi-Cal beneficiaries residing in a licensed community care facility from $20 to $50. AB 1319 was held on the Senate Appropriations Committee suspense file.

**i)** AB 789 (Campbell) of 1999 would have increased the PNA to not less than $40 per month. AB 789 was vetoed by Governor Davis. In his veto message, Governor Davis stated that, while well intentioned, this bill would result in estimated new annual General Fund costs in excess of $2 million that was not included in the 1999-2000 budget, and that any increase in the personal and incidental needs allowance should be considered as part of the annual budget deliberations.

**REGISTERED SUPPORT / OPPOSITION**:

**Support**

California Senior Legislature (sponsor)
Alzheimer's Greater Los Angeles
Alzheimer's Orange County
Alzheimer's San Diego
Association of Regional Center Agencies
California Advocates for Nursing Home Reform
California Long Term Care Ombudsman Association
California Retired Teachers Association
Justice in Aging
LeadingAge California

**Opposition**

None on file.

**Analysis Prepared by**: Lisa Murawski / HEALTH / (916) 319-2097

Date of Hearing: April 9, 2024

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 2365 (Haney) – As Amended March 18, 2024

**SUBJECT**: Public health: kratom.

**SUMMARY**: Adds kratom products to the Sherman Food, Drug, and Cosmetic Law (Sherman Law). **Specifically,** this bill:

1) Prohibits a kratom product sold or offered for sale, if consisting of or containing kratom leaf extract, from exceeding the amount specified for pharmaceutical products in guidance offered by the federal Food and Drug Administration (FDA) of any residual solvent used in manufacturing of the extract.

2) Requires a kratom product sold or offered for sale to have a label that clearly and conspicuously provides all of the following information on each retail package:
   a) A recommendation against the use by individuals who are under 18 years of age, who are pregnant, or who are breastfeeding;
   b) A recommendation to consult a health care professional prior to use;
   c) An advisement that kratom may be habit forming;
   d) The following statement: "This product has not been evaluated by the United States Food and Drug Administration and is not intended to diagnose, treat, cure, or prevent any disease;"
   e) The name and place of business of the manufacturer, packer, or distributor; and,
   f) Directions for use that include all of the following:
      i) A recommended amount of the kratom product per serving;
      ii) A recommended number of servings that can be safely consumed in a 24-hour period; and,
      iii) Quantitative declarations of the amount per serving of each of the following:
         (1) Total kratom alkaloids;
         (2) Mitragynine; and,
         (3) 7-hydroxymitragynine.

3) Requires a kratom product to be packaged in a retail container that meets all of the following requirements:
   a) Clearly marks the number of servings in the container;
   b) Contains no more than three servings. This subdivision applies only to products that meet all of the following conditions:
      i) The kratom product is in liquid form;
      ii) The kratom product is sold in a container that is less than eight fluid ounces; and,
      iii) The kratom product does not include a calibrated measuring device.
   c) Requires the container to have clear serving size markings if the kratom product is in liquid form; and,
   d) Requires the package to include a calibrated measuring device if the kratom product is in powdered form.

4) Requires a processor to register pursuant to the Sherman Act and to annually register each kratom product it manufactures, packs, distributes, or labels.

5) Requires annual registration of a kratom product to include a certificate of analysis from an independent laboratory. Requires the laboratory be accredited under the standards of the International Organization for Standardization 17025:2017 accreditation from an accreditation body that is a signatory to the International Laboratory Accreditation Cooperation Mutual Recognition Arrangement.

6) Requires the certificate of analysis to confirm that the product complies with the requirements for a kratom product.

7) Authorizes the Department of Public Health (DPH), upon a reasonable basis, to require an independent third-party test of a registered kratom product by a laboratory of the DPH's choice, and requires the processor to submit payment for the test and equitable administrative fee within a reasonable timeframe.

8) Requires DPH to revoke registration for a kratom product if the processor does not tender payment to the DPH within 30 days of receipt of the invoice for the testing and administrative fee.

9) Prohibits an individual from selling kratom leaf or a kratom product to a person under 18 years of age.

10) Defines a kratom leaf as the leaf of the kratom plant, also known as mitragyna speciosa, in fresh or dehydrated form, and subjected to no postharvest processing except for drying or size reduction, by cutting, milling, or similar procedure, and to cleaning or sterilization through application of heat, steam, pressurization, irradiation, or other standard treatments applied to food ingredients.

11) Prohibits the total alkaloid content of kratom leaf material used in a kratom product from exceeding 3.5 % on a dried weight basis.

12) Defines "kratom leaf extract" means the material obtained by extraction of kratom leaves with a solvent consisting of water, ethanol, or food grade carbon dioxide, or any other solvent authorized by regulation to be used in manufacturing a food ingredient and that meets all of the following requirements:
    a) Contains an amount of residual solvent not to exceed the amount specified by FDA guidance;
    b) Contains mitragynine as the most abundant alkaloid on a weight-by-weight basis and at a level that is equal to or more than twofold that of any other alkaloid present; and,
    c) Makes the ratio of mitragynine to other alkaloids is the same or greater than that of the starting material.

13) Defines a "kratom product" as a food or dietary supplement that meets all of the following requirements:
    a) Consists of or contains kratom leaf or kratom leaf extract;
    b) Does not contain any synthesized kratom alkaloids or other kratom constituents, or synthesized metabolites of any kratom constituent; and,

c) The level of 7-hydroxymitragynine on a percent weight basis is not greater than 1% of the amount of total kratom alkaloids confirmed with a high-pressure liquid chromatography testing method.

14) Defines "synthesized" as produced using directed synthetic or biosynthetic chemistry rather than traditional food preparation techniques, such as heating or extracting.

15) Defines "processor" as the party responsible for manufacturing, packaging, labeling, or distributing kratom products, or the party that advertises, represents, or holds itself out as manufacturing, preparing, packaging, or labeling kratom products.

16) Defines "total kratom alkaloids" as the sum of mitragynine, speciociliatine, speciogynine, paynantheine, and 7-hydroxymitragynine in a kratom product.

**EXISTING LAW**:

1) Provides, through the Sherman Law, for the regulation of various subjects relating to the processing, labeling, advertising, and sale of food, drugs, and cosmetics, including enriched food, under the administration and enforcement of DPH. [Health and Safety Code (HSC) § 109875-111929.4]

2) Defines the following under the Sherman Law:

   a) A label to mean a display of written, printed, or graphic matter upon a food, drug, device, or cosmetic or upon its immediate container. [HSC §109955]

   b) Manufacture to mean the preparation, compounding, propagation, processing, or fabrication of any food, drug, device, or cosmetic. The term "manufacture" includes repackaging or otherwise changing the container, wrapper, or labeling of any food, drug, device, or cosmetic in furtherance of the distribution of the food, drug, device, or cosmetic. The term "manufacture" does not include repackaging from a bulk container by a retailer at the time of sale to its ultimate consumer. [HSC §109970]

3) Requires all labels of foods, drugs, devices, or cosmetics to conform to with the requirements of the net quality of contents of the federal Fair Packaging and Labeling Act (Act) and the regulations pursuant to this Act. [HSC §110340]

4) Provides that all food additive and food labeling regulations and any amendments to those regulations adopted pursuant to federal law are the regulations of this state, and authorizes DPH to prescribe conditions under which a food additive is allowed to be used in this state whether or not these conditions are in accordance with the regulations adopted pursuant to the federal law and to adopt additional food labeling regulations. [HSC § 110085]

5) Prohibits the sale or distribution of any dietary supplement product that contains ephedrine group alkaloids unless the product contains a specified label. Permits the sale of any dietary supplement containing ephedrine if the product label clearly and conspicuously contains specified warnings, including the following:

   a) "WARNING: NOT FOR USE BY INDIVIDUALS UNDER THE AGE OF 18 YEARS. DO NOT USE IF PREGNANT OR NURSING. Consult a physician or licensed qualified

health care professional before using this product if you have, or have a family history of, heart disease, thyroid disease, diabetes, high blood pressure, depression or other psychiatric condition, glaucoma, difficulty in urinating, prostate enlargement, or seizure disorder, or if you are using a monoamine oxidase inhibitor or any other dietary supplement, prescription drug, or over-the-counter drug containing ephedrine, pseudoephedrine, or phenylpropanolamine (ingredients found in certain allergy, asthma, cough or cold, and weight control products)."

b) "Do not exceed recommended serving. Exceeding recommended serving may cause serious adverse health effects, including heart attack and stroke."

c) "Discontinue use and call a physician or licensed qualified health care professional immediately if you experience rapid heartbeat, dizziness, severe headache, shortness of breath, or other similar symptoms."

d) "Individuals who are sensitive to the effects of caffeine should consult a licensed health care professional before consuming this product."

e) "KEEP OUT OF REACH OF CHILDREN." [HSC § 110423(a)]

6) Prohibits the sale or distribution of dietary supplements containing steroid hormone precursors unless the product label for these dietary supplements clearly and conspicuously contains the following warning:

"WARNING: NOT FOR USE BY INDIVIDUALS UNDER THE AGE OF 18 YEARS. DO NOT USE IF PREGNANT OR NURSING. Consult a physician or licensed qualified health care professional before using this product if you have, or have a family history of, prostate cancer, prostate enlargement, heart disease, low "good" cholesterol, or if you are using any other dietary supplement, prescription drug, or OTC drug. Do not exceed recommended serving. Exceeding recommended serving may cause serious adverse health effects. Possible side effects include acne, hair loss, hair growth on the face (in women), aggressiveness, irritability, and increased levels of estrogen. Discontinue use and call a physician or licensed qualified health care professional immediately if you experience rapid heartbeat, dizziness, blurred vision, or other similar symptoms. KEEP OUT OF REACH OF CHILDREN." [HSC § 110423(b)]

7) Requires the product label for any dietary supplement product containing ephedrine group alkaloids or steroid hormone precursors to clearly and conspicuously display the following statement: "To report any adverse events call 1-800-332-1088" [MedWatch program]. [HSC § 110423(c)]

8) Establishes the California Unfair Practices which prohibits unfair competition and any unlawful, unfair or fraudulent business act or practice and unfair, deceptive, untrue or misleading advertising. [Business and Professions Code (BPC) § 17500]

9) Requires the product label for any dietary supplement product containing ephedrine group alkaloids or steroid hormone precursors to clearly and conspicuously display the following statement: "To report any adverse events call 1-800-332-1088" [MedWatch program]. [HSC § 110423(c)]

10) Makes it a misdemeanor to sell, furnish, give, or cause to be sold, furnished, or given away, any alcoholic beverage to any person under the age of 21 years. Makes it a misdemeanor for any person under the age of 21 years to purchase any alcoholic beverage, or to consume any alcoholic beverage, as specified. [BPC § 25658]

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

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

**COMMENTS**:

1) **PURPOSE OF THIS BILL.** According to the author, kratom is widely available throughout California. Some estimates show that nearly 25% of all kratom sales in the US are in California alone. With the increase in demand for kratom, some manufacturers have irresponsibly created more potent and dangerous products. Without any kratom regulations, consumers can easily access products that can cause serious illness or harm. The author concludes that this bill will follow the lead of other states and ban high potency kratom, while making sure that safe kratom is accessible for consumers.

2) **BACKGROUND.**

   a) **What is kratom?** Kratom (Mitragyna speciosa) is a tree in the coffee family, found in Thailand and neighboring countries. These leaves are crushed and then smoked, brewed with tea, or placed into gel capsules. Kratom has a long history of use in Southeast Asia, where it is commonly known as thang, kakuam, thom, ketum, and biak. Traditionally, in Southeast Asia, people have chewed its leaves or made them into a tea that is used to fight fatigue and improve work productivity. Kratom has also traditionally been used during religious ceremonies and to treat symptoms such as pain and diarrhea, sometimes as a substitute for opium. In this bill, kratom leaf refers to the leaf of a kratom plant, in either fresh or dehydrated form, that has not been processed except for drying or size reduction and cleaning or sterilization. The alkaloid content refers to the various alkaloids that are present in the leaf material that contribute the effect of the plant, including mitragynine, paynantheine, speciogynine and speciociliatine.

   b) **Effects of kratom usage**. Kratom leaves contain two major psychoactive ingredients, mitragynine and 7-hydroxymitragynine, interact with opioid receptors in the brain. People who use kratom have reported both stimulant-like effects (increased energy, alertness, rapid heart rate) and effects like those of opioids and sedatives (relaxation, pain relief, confusion). Per the US Drug Enforcement Administration (DEA), consumption of kratom tree leaves produces a stimulant effect in low doses, and a sedative effect in high doses. Consumption of kratom in high doses can also lead to psychotic symptoms, and psychological and physiological dependence.

      According to the National Center for Complementary and Integrative Health, people may use kratom to try to overcome opioid addiction, kratom itself may have the potential to be addictive. People have reported using kratom to manage opioid withdrawal symptoms and cravings, and researchers are studying whether kratom is helpful for this purpose. However, kratom has not been shown to be safe and effective for this or any other

medical use. Regular kratom users may experience withdrawal symptoms if they stop using it. A variety of side effects of kratom have been reported. They include mild effects, such as nausea, constipation, dizziness, and drowsiness, and rare but serious effects such as seizures, high blood pressure, and liver problems. Fatal overdoses from kratom alone appear to be extremely rare. The use of kratom in combination with other drugs has been linked to deaths and severe adverse effects such as liver problems. More research is needed on drug interactions involving kratom. The long-term effects of kratom use are not well understood. There have been reports that long-term use of large doses of kratom may cause serious liver problems in some people. Harmful contaminants such as heavy metals and disease-causing bacteria have been found in some kratom products.

According to the DEA, the abuse of kratom has increased markedly in recent years. Several cases of psychosis resulting from use of kratom have been reported, where individuals addicted to kratom exhibited psychotic symptoms, including hallucinations, delusion, and confusion.

c) **Research on kratom use.** According to a study published in the *National Library of Medicine* in 2019 on perspectives of the impact of kratom use, the national poison center reporting database documented 1,807 calls related to kratom exposure from 2011 to 2017. The Centers for Disease Control and Prevention analyzed data on unintentional and undetermined opioid overdose deaths from the State Unintentional Drug Overdose Reporting System. Kratom was detected on postmortem toxicology testing in 152 cases of 27,338 overdose deaths from data collected from 11 states during July 2016-June 2017 and 27 states during July–December 2017. Kratom was identified as the cause of death by a medical examiner in 91 of the 152 kratom-positive deaths, but was the only identified substance in just seven of these cases. Presence of additional substances in these seven kratom-only cases cannot be ruled out. The co-occurring substances in the 91 cases where kratom was identified as the cause of death include fentanyl (including analogs), heroin, benzodiazepines, prescription opioids, cocaine, and alcohol. Multi-substance exposures involving kratom, predominantly in combination with opioids, are associated with a greater odds ratio of admittance to a health care facility and occurrence of a serious medical outcome when compared to kratom-only exposure. These data highlight that kratom use is associated with a complex population of poly-drug users and especially with opioid use disorder. These data further suggest that a deeper investigation into the toxicity of kratom is needed, especially focusing on drug–herb interactions.

d) **Legal Status of Kratom.**
   i) **National level.** Kratom is currently legal and accessible online and in stores in many areas of the United States. In 2016, DEA published notice of its intent to place mitragynine and 7-hydroxymitragynine in Schedule I on an emergency basis, which would have criminalized possession of kratom and made distribution a felony. However, after receiving numerous comments from some Members of Congress, advocacy groups, and others, DEA withdrew that notice. DEA has listed kratom as a Drug and Chemical of Concern but to date has not exercised its authority to schedule kratom or its active compounds under the federal Controlled Substances Act. Even though the DEA has listed kratom as a "drug of concern," but kratom and kratom compounds are not listed in the U.S. schedule of controlled substances. The FDA has not approved kratom as safe and effective for any medical purpose. Under the Federal

Food, Drug, and Cosmetic Act, kratom is considered a new dietary ingredient since it was not marketed as a dietary ingredient in the United States before October 15, 1994; evidence of safety is required for new dietary ingredients. FDA has issued a series of import alerts, most recently in July 2023, authorizing FDA personnel to seize imported kratom products from specified firms without physical inspection. FDA has also seized kratom products manufactured in the United States, including an April 2023 seizure of kratom products worth approximately $3 million from an Oklahoma company. In October 2023, Members introduced essentially identical bills in both the House and the Senate to "protect access to kratom." Members introduced similar bills in the House and the Senate in the 117th Congress. These bills would neither ban kratom nor impose new regulations on kratom. Instead, the bills would direct the Secretary of Health and Human Services (the Secretary) to gather information about kratom and would limit the Secretary's authority to impose regulations on kratom. The bills would require the Secretary to hold at least one public hearing to discuss the safety of kratom products. That hearing would have to cover several specified topics, including any potential benefits of kratom usage and any adverse health impacts of a kratom ban. The bills would also require the Secretary to establish a task force to coordinate and report on federally funded kratom-related research. Before promulgating any new rule regulating kratom, the Secretary would have to follow procedures for formal rulemaking and to have public, in-person hearings. The bills would prohibit the Secretary from: imposing requirements on kratom that are more restrictive than those for foods, dietary supplements, or dietary ingredients under the Federal Food, Drug, and Cosmetic Act; requiring kratom to follow the notification requirements for new dietary ingredients; using certain specified grounds to treat kratom as an adulterated dietary supplement; or enforcing any import alert for kratom products absent evidence that the particular product is adulterated. Each bill contains a nonpreemption provision, which would leave existing state laws—whether banning kratom or regulating it—in place.

**ii) Other States.**

**(1) Kratom bans**: Alabama, Arkansas, Indiana, Rhode Island, Vermont, and Wisconsin currently ban mitragynine and hydroxymitragynine or 7-hydroxymitragynine (kratom's active alkaloids). Legislators in Indiana, Rhode Island, Wisconsin, and Vermont have introduced bills to replace existing bans with regulations that would permit the sale of kratom products.

**(2) Age restriction**: Age restriction: Arizona, Georgia, Illinois, Minnesota, Nevada, Oklahoma, Texas, and Utah ban sales to persons under 18 years of age.

**(3) Strength**: Arizona, Oklahoma, Texas, and Utah prohibit sale of products in which 7-hydroxymitragynine is greater than 2% of the total alkaloid content.

**(4) Labeling**: Nine of the 16 states with laws regulating kratom sales require labels on kratom products, but the content required varies by state. Texas, Nevada, Georgia, and Oklahoma require that kratom products include labels with directions for safe or suggested use. Utah and Virginia require that labels bear a warning that the product may be harmful; has not been evaluated by the FDA; and is not intended to diagnose, treat, cure, or prevent any disease. West Virginia requires the commissioner of agriculture to develop labeling standards, which

must include warnings to keep the product out of reach of children and to consult a physician before use if pregnant or taking medication. Colorado (effective July 1, 2024), Georgia, and Oklahoma require that labels state the identity and address of the product's manufacturer or distributor. Arizona, Georgia, Oklahoma, and Utah require that labels state the amount of mitragynine and 7-hydroxymitragynine in the product. Colorado (effective July 1, 2024), Nevada, and Virginia require labels listing all ingredients. Georgia and Oklahoma require a list of ingredients that includes common names. Oklahoma law requires kratom vendors to provide, upon request of the Oklahoma Department of Health, test results from a "United States-based testing facility" confirming the items on the label. Oregon requires third-party testing for microbiological contaminants, pesticides, solvents, heavy metals, and mycotoxins. Utah requires a certificate of analysis from a certified third-party laboratory indicating the results of testing for alkaloid content and levels of pathogens and specified heavy metals. The state periodically tests kratom products to confirm those certificates of analysis and may test for pesticides, fentanyl derivatives, cannabinoids, cocaine, and benzodiazepines. Oregon and Utah require kratom sellers to register with state agencies. West Virginia requires kratom sellers to obtain state permits.

**(5) Local authority**: Colorado and Louisiana explicitly allow localities to adopt stricter controls on kratom or to ban kratom completely but do not allow localities to permit sales to persons under 21 years of age.

**e) Kratom in California.** Some estimates show that nearly 25% of all kratom sales in the United States are in California. In March 2024, the city of Newport Beach approved an ordinance to prohibit the sale and distribution of kratom. The City of San Diego and Oceanside banned the use and sale of kratom in 2016. It has been reported that some manufacturers have created stronger and more potent kratom concentrates to put into their products. This bill seeks to regulate kratom. This bill states that the total alkaloid content of kratom leaf material used in a kratom leaf product shall not exceed 3.5 % on a dried weight basis. The Global Kratom Coalition, who supports this bill, states that this number is based on studies in which the alkaloid content of kratom leaf material in a kratom product did not go above 2.5%. The Global Kratom Coalition contends that putting in a limit of the total alkaloid content of kratom leaf material used in a kratom product based on what has been seen natural will ensure that the leaf material is not altered post harvest to make it more potent, as alteration may make the product unsafe. This bill states that the level of 7-hydroxymitragynine on a percent weight basis is not greater than 1% of the amount of total kratom alkaloids confirmed with a high pressure. According to research provided by the sponsors published by the National Library of Medicine, older reports have shown the level of 7-hydroxymitragynine in the total alkaloid content in a kratom product can reach up to 2%, but water or ethanolic extracts and dried leaf material contain 7-hydroxymitragynine at no more than 1% of the total alkaloid content in the product. The coalition contends that limiting the amount of 7-hydroxymitragynine to 1% will ensure that kratom users are unlikely to experience adverse events at commonly reported serving levels.

**3) SUPPORT.** According to the Global Kratom Coalition (GKC), a coalition of kratom distributors, manufacturers, processors, and industry leaders, this bill is a crucial step toward protecting Californians by establishing essential guidelines and regulations that promote

transparency, quality, and safety within the kratom market. The GKC continues that this bill addresses the lack of regulation and universal standards in the kratom industry issue in the kratom industry, providing peace of mind to kratom users by assuring them that the products they buy meet stringent safety standards. The GKC believes that this bill's framework, among other things, will improve the market for our industry by setting widely accepted and well-tread manufacturing standards as the floor for kratom processing practices in California.

**4) RELATED LEGISLATION.**

**a)** AB 2217 (Weber) prohibits, commencing January 1, 2027, a person or entity from manufacturing, selling, delivering, distributing, holding, or offering for sale, in commerce a food product for human consumption that contains tianeptine. AB 2217 makes it a violation of these provisions punishable by a civil penalty not to exceed $5,000 for a first violation and not to exceed $10,000 for each subsequent violation, upon an action brought by the Attorney General, a city attorney, a county counsel, or a district attorney. AB 2217 is pending a hearing in the Assembly Committee on Health. Should this bill pass out of this committee, it will be referred to the Assembly Committee on Judiciary.

**b)** AB 1830 (Arambula) requires a manufacturer of corn masa flour (CMF) to add folic acid at a level not to exceed 0.7 milligrams of folic acid per pound of CMF and to include a declaration of folic acid on the nutrition label in accordance with applicable federal law. AB 1830 is pending a hearing in the Assembly Committee on Appropriations.

**c)** AB 2223 (Aguiar-Curry) of 2024 would state that the Medicinal and Adult-Use Cannabis Regulation and Safety Act (MAUCRSA) does not prohibit a licensee from manufacturing, processing, distributing, or selling products that contain industrial hemp or cannabinoids, extracts, or derivatives from industrial hemp if the product complies with all applicable state laws and regulations. AB 2223 is pending a hearing in Assembly Business and Professions Committee.

**d)** AB 82 (Weber) of 2023 prohibits a retail establishment from selling, transferring, or otherwise furnishing dietary supplements for weight loss or over-the-counter diet pills, as defined, to any person under 18 years of age without a prescription. AB 82 has been referred to the Senate Committee on Rules.

**5) PREVIOUS LEGISLATION.**

**a)** AB 418 (Gabriel), Chapter 328, Statutes of 2023, prohibits a person or entity, commencing January 1, 2027, from manufacturing, selling, delivering, distributing, holding, or offering for sale, in commerce a food product for human consumption that contains any of the following substances: Brominated vegetable oil; Potassium bromate; Propylparaben; or Red dye 3. AB 418 makes a violation of its provisions punishable by a civil penalty not to exceed $5,000 for a first violation and not to exceed $10,000 for each subsequent violation, upon an action brought by the Attorney General, a city attorney, a county counsel, or a district attorney.

**b)** AB 420 (Aguiar-Curry) of 2023 would have specified that MAUCRSA does not prohibit a cannabis licensee from manufacturing, distributing, or selling industrial hemp products if the product complies with applicable laws and regulations governing industrial hemp.

AB 420 was held on the Senate Appropriations suspense file.

6) **DOUBLE REFERRAL.** This bill is double-referred, upon passage of this committee, it will be referred to the Assembly Committee on Environmental Safety and Toxic Materials.

7) **POLICY COMMENT.** As this bill moves through the process, the author may wish to consider working with DPH and other stakeholders to determine the appropriate total alkaloid content of kratom leaf material used in a kratom product, and the appropriate level of mitragynine and 7-hydroxymitragynine on a percent weight basis within a kratom product.

**REGISTERED SUPPORT / OPPOSITION**:

**Support**

Arcadia Police Officers' Association
Burbank Police Officers' Association
California Coalition of School Safety Professionals
California District Attorneys Association
California Narcotic Officers' Association
California Reserve Peace Officers Association
Claremont Police Officers Association
Corona Police Officers Association
Culver City Police Officers' Association
Deputy Sheriffs' Association of Monterey County
Fullerton Police Officers' Association
Global Kratom Coalition
Los Angeles School Police Management Association
Los Angeles School Police Officers Association
Murrieta Police Officers' Association
Newport Beach Police Association
Novato Police Officers Association
Palos Verdes Police Officers Association
Placer County Deputy Sheriffs' Association
Planted in Science Consulting, LLC
Pomona Police Officers' Association
Riverside Police Officers Association
Riverside Sheriffs' Association
Santa Ana Police Officers Association
Upland Police Officers Association

**Opposition**

None on file.

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

Date of Hearing: April 9, 2024

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 2390 (Arambula) – As Amended March 21, 2024

**SUBJECT**: Social Media Harm Reduction Pilot Program.

**SUMMARY**: Establishes the Social Media Harm Reduction Pilot Program. Specifically, **this bill**:

1) Establishes the Social Media Harm Reduction Pilot Program (program). Requires the California Health and Human Services Agency to designate a nonprofit organization to undertake the responsibilities of the program.

2) Requires the program to:

    a) Develop model educational materials and methods to leverage existing peer-to-peer support programs to inform pupils about the harms of social media, foster the development of healthy social media habits among pupils, and create a supportive environment in which they may do so;
    b) Evaluate the impact of those educational materials and methods and the peer-to-peer support program through the establishment of statewide learning communities;
    c) Recommend statewide standards for the use of online social networks by kindergarten and grades one to 12 pupils, inclusive; and,
    d) Define best practices for expansion of the program.

3) Requires the program to coordinate with existing laws regulating social media platforms to ensure consistency and avoid duplication of effort.

4) Sunsets the program on December 31, 2029.

**EXISTING LAW**:

1) Establishes the Federal Children's Online Privacy Protection Act providing parents tools to control what information is collected from their children online. Requires the Federal Trade Commission to develop regulations requiring operators of commercial websites and online services directed to children under 13 or knowingly collecting personal information from children under 13 to: notify parents of their information practices; obtain verifiable parental consent for the collection, use, or disclosure of children's personal information; let parents prevent further maintenance or use of, or future collection of their child's personal information; provide parents access to their child's personal information; not require a child to provide more personal information that is reasonably necessary to participate in activities; and, maintain reasonable procedures to protect the confidentiality, security and integrity of the personal information. [15 United States Code §6501-6506]

2) Establishes the California Age-Appropriate Design Code Act requiring a business that provides an online service, product, or feature likely to be accessed by children to comply with specified requirements, including a requirement to configure all default privacy settings offered by the online service, product, or feature to the settings that offer a high level of

privacy, unless the business can demonstrate a compelling reason that a different setting is in the best interests of children, and to provide privacy information, terms of service, policies, and community standards concisely, prominently, and using clear language suited to the age of children likely to access that online service, product, or feature. [Civil Code (CIV) §1798.99.28, *et seq.*]

3) Requires a business that provides an online service, product, or feature likely to be accessed by children to complete a Data Protection Impact Assessment for any new, publicly offered, online service, product, or feature likely to be accessed by children and maintain documentation of this assessment as long as the online service, product, or feature is likely to be accessed by children. Requires a business to biennially review all Data Protection Impact Assessments. [CIV §1798.99.31]

4) Requires the business' Data Protection Impact Assessment to identify the purpose of the online service, product, or feature, how it uses children's personal information, and the risks of material detriment to children that arise from the data management practices of the business, including:
   a) Whether the design of the online product, service, or feature could harm children, including by exposing children to harmful, or potentially harmful, content on the online product, service, or feature;
   b) Whether the design of the online product, service, or feature could lead to children experiencing or being targeted by harmful, or potentially harmful, contacts on the online product, service, or feature;
   c) Whether the design of the online product, service, or feature could permit children to witness, participate in, or be subject to harmful, or potentially harmful, conduct on the online product, service, or feature;
   d) Whether the design of the online product, service, or feature could allow children to be party to or exploited by a harmful, or potentially harmful, contact on the online product, service, or feature;
   e) Whether algorithms used by the online product, service, or feature could harm children;
   f) Whether targeted advertising systems used by the online product, service, or feature could harm children;
   g) Whether and how the online product, service, or feature uses system design features to increase, sustain, or extend use of the online product, service, or feature by children, including the automatic playing of media, rewards for time spent, and notifications; and,
   h) Whether, how, and for what purpose the online product, service, or feature collects or processes sensitive personal information of children. [CIV §1798.99.31]

5) Establishes the California Children's Data Protection Working Group, as specified, which is required to deliver a report every two years to the Legislature with recommendations on, at minimum, the following:
   a) Identifying online services, products, or features likely to be accessed by children;
   b) Evaluating and prioritizing the best interests of children with respect to their privacy, physical health, and mental health and well-being and evaluating how those interests may be furthered by the design, development, and implementation of an online service, product, or feature;
   c) Ensuring that age assurance methods used by businesses that provide online services, products, or features likely to be accessed by children are proportionate to the risks that

arise from the data management practices of the business, privacy protective, and minimally invasive;
d) Assessing and mitigating risks to children that arise from the use of an online service, product, or feature;
e) Publishing privacy information, policies, and standards in concise, clear language suited for the age of children likely to access an online service, product, or feature; and,
f) How the working group and the Department of Justice may leverage the substantial and growing expertise of the California Privacy Protection Agency in the long-term development of data privacy policies that affect the privacy, rights, and safety of children online. [CIV §1798.99.32]

6) Establishes the California Consumer Privacy Act of 2018, which grants to a consumer various rights with respect to personal information, as defined, that is collected by a business, as defined, including the right to request that a business delete personal information about the consumer that the business has collected from the consumer. Authorizes a minor to disaffirm a contract before majority or within a reasonable time afterwards or, in case of the minor's death within that period, by the minor's heirs or personal representative. [CIV § 1798.199.10]

7) Establishes the Privacy Rights for California Minors in the Digital World which prohibits an operator of an internet website, online service, online application, or mobile application from the following:
a) Marketing or advertising specified products or services, such as firearms, cigarettes, and alcoholic beverages, on its internet website, online service, online application, or mobile application that is directed to minors;
b) Marketing or advertising such products or services to minors who the operator has actual knowledge are using its site, service, or application online and is a minor, if the marketing or advertising is specifically directed to that minor based upon the personal information of the minor; and,
c) Knowingly using, disclosing, compiling, or allowing a third party to use, disclose, or compile, the personal information of a minor with actual knowledge that the use, disclosure, or compilation is for the purpose of marketing or advertising such products or services to that minor, where the website, service, or application is directed to minors or there is actual knowledge that a minor is using the website, service, or application. [Business & Professions Code §22580]

**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 promise of social media was to build virtual communities that would bring people together to share information and ideas. The author argues that in many ways, this promise has been fulfilled as some platforms have billions of users and act as a digital thread connecting friends and families. The author continues that unfortunately, social media companies have abused their position by prioritizing screen time and profits over the mental health of their users through their addictive design that exacerbates compulsive and obsessive behaviors detracting from real-world in-person engagement and contributing to social isolation The author continues that teens and adolescents who use social media should be safe from harm. The author concludes

that this bill will address the mental health impacts resulting from the intentionally addictive design of social media platforms by establishing a pilot program to develop methods to mitigate the harm to youth and adolescents caused by modern social media platform design.

2) **BACKGROUND.** According to the United States Surgeon General, mental health challenges are the leading cause of disability and poor life outcomes in young people. Research indicates that half of all mental health conditions begin by the age of 14 and more than 75% of mental health challenges develop before a person reaches the age of 24.

   a) **US Centers for Disease Control and Prevention (CDC)'s Youth Risk Behavior Survey Data Summary & Trends Report 2011-2021 (YRBS**): According to the YRBS, in 2021, 16% of high school students were electronically bullied, including through texting, Instagram, Facebook, or other social media, during the past year. Female students were more likely than male students to be electronically bullied. American Indian or Alaska Native and white students were more likely than students from most other racial and ethnic groups to be electronically bullied. LGBTQ+ students and students who had any same-sex partners were more likely than their peers to be electronically bullied. The percentage of male students who were electronically bullied increased from 2011 to 2021. The YRBS also reported that in 2021, 42% of high school students felt so sad or hopeless almost every day for at least two weeks in a row that they stopped doing their usual activities. Female students were more likely than male students to experience persistent feelings of sadness or hopelessness. Hispanic and multiracial students were more likely than Asian, Black, and white students to experience persistent feelings of sadness or hopelessness. LGBTQ+ students and students who had any same-sex partners were also more likely than their peers to experience persistent feelings of sadness or hopelessness. Additionally, the survey found that 29% of high school students experienced poor mental health during the past 30 days. Female students were more likely than male students to experience poor mental health. Asian and Black students were less likely than Hispanic and multiracial students to experience poor mental health. Asian students were also less likely than white students to experience poor mental health. LGBTQ+ students and students who had any same-sex partners were more likely than their peers to experience poor mental health. Finally, the survey found that, in 2021, 22% of high school students seriously considered attempting suicide during the past year, 18% of high school students made a suicide plan during the past year, and 10% of high school students attempted suicide one or more times during the past year.

   b) **Impact on Young Girls.** In reporting out the YRBS, the CDC stated that teen girls specifically are "engulfed in a growing wave of violence and trauma" experiencing record high levels of violence, sadness, and suicide risk amid significant and "heartbreaking" declines in youth health and wellbeing overall. Overall, the number of psychiatric-related hospital visits among young people increased 31% last year. For young women this number was far more grievous. Suspected suicide attempts in girls increased 50.6% compared to a 3.7% increase in young men. An August 2016 report in the *Harvard Health Publication* reported that between 1999 and 2014 deaths as a result of suicide rose by 200% among girls age 10 to 14 rising most sharply from 2006 on. According to a researcher with the CDC, "There is no question from this data young people are telling us that they are in crisis. There is this growing wave of violence and trauma that's affecting young people, especially teen girls and LGBTQ+ youth. Social media plays a major role stating that for girls and their social networks, even when

they're socializing, they are not socializing in person, they are socializing through their phone or through some type of device rather than in-person." Social media also exposes girls to all kinds of negative social pressures. Body type expectations and the images that they're shown with the flood of information that we have available to us has detrimental effects and they are being exposed to them earlier and earlier in their lives when their brains are not prepared to deal with this information and know what to do with it.

c) **Prevalence and Effect of Cyberbullying on Children and Young People: A Scoping Review of Social Media Studies.** A literature review of existing publications that examine the health-related effects of cyberbullying via social media among children and adolescents was conducted in 2015. Eleven electronic databases were searched with studies screened by two independent reviewers. The findings included 36 studies in 34 publications. Most were conducted in the United States and sampled middle and high school populations and included adolescents who were 12 to 18 years of age. The review concluded that there is a consistent relationship across studies between cyberbullying and depression among children and adolescents; however the evidence further reflected the effect of cyberbully on other mental health conditions is inconsistent.

d) **Why Social Media Addiction is a Real Thing and the Dangers Associated with it.** A June 10, 2022, publication from Excelsior University reported that the majority of the dangers associated with social media stem from the idea that social media, like recreational drugs, sugar, etc., can be addicting.

   i) **Attachment Styles.** Social media allows humans to interact and form relationships on a grander level than ever before possible, connecting users across the globe in real-time. Relationships, whether in person or parasocial, (a one-sided relationship that a media user engages in with a media persona) are based on an individual's attachment style. Attachment theory is a psychological theory that was developed in the 1950s and hypothesizes that the "affectional tie that individuals develop between themselves and another specific person is not based solely on food, safety, and other survival needs. Humans and other social animals need more—mainly love, affection, and acceptance." There have been numerous studies that suggest that how people use social media and how much information they make publicly available relates to their attachment style in relationships. If an individual is in healthy and secure relationships, they use social media very differently from those who are in more unhealthy circumstances. Those who have toxic attachment styles use social media in vastly different ways even from each other. If someone has high attachment anxiety, they struggle with abandonment, are overwhelmed by emotion, tend to pursue someone emotionally unavailable, and will likely be over sharers on social media and try to compensate for what they do not find in in-person relationships. Those who have high attachment avoidance, who avoid intimacy, who push others away, and tend to not trust, are not typically active social media users. Both types of attachment anxiety have shown a significant positive association between the attachment and a dysfunctional use of the internet and social media sites. Based on attachment styles, it is fair to assume that those who do not have healthy interpersonal relationships seek them out on the internet, and thus are more susceptible to the dangers that can be associated with parasocial relationships.

ii) **Social Media Addiction and Cyberbullying.** The same studies that look at attachment theory as it relates to social media use can also be used to predict social media addiction. Those who are deeply preoccupied about relationships tend to use social media as a therapy tool, a place where they can find the emotional support lacking in their day-to-day lives. When this many people who are like-minded use a platform such as TikTok, where they crave the immediate response and attention you can get uniquely from social media. The age group at risk for social media addiction is young adults and preteens, and given the increased access to technology and social media that this age group has, social media also creates a bigger risk for cyberbullying and mental health concerns. Prior to the rise of social media, cyberbullying existed but was not as widespread. Social media amplifies the effect of cyberbullying. Interestingly, a study by the University of Georgia, published in March of 2021 entitled, "Social Media Addiction Linked to Cyberbullying" suggests that increased hours spent online, and on social media platforms, results in higher social media addiction scores (at least in males), significantly predicting perpetration of cyberbullying.

iii) **Social Media Culture for Youth.** Social media is an entirely different culture for many, particularly youth. There is a separate set of societal norms associated with interacting with their peers on social media as opposed to in person. With the anonymity of social media and the ability to avoid retaliation, perpetrators feel less remorse for their actions and are held less accountable with consequences for their behavior. Many feel rewarded from the likes, comments, and shares that their actions on social media receive, even if they are aggressive or bullying in nature, which in turn will cause them to want to continue the behavioral pattern, and this can border on an addiction. In addition, individuals who have certain psychiatric conditions may be more susceptible to internet addiction, and in particular, social media addiction. Individuals with conditions such as obsessive compulsive disorder (OCD), attention hyperactivity deficit disorder (ADHD), or other mood disorders are more likely to report excessive use of social media than their neurotypical peers. A study conducted in Norway suggests that those with ADHD are more likely to engage in excessive social networking as a form of self-medication, similar to those with anxious attachment styles. Whereas, those with OCD are driven to addictive social media use due to a "constant urge to check their networks for updates or fear of missing out.

e) **School Districts Sue Social Media Companies.** *Education Week* reported on January 31, 2024 that over 200 school districts have sued more than a dozen social media companies over the youth mental health crisis. In California, the San Mateo County School Board was the first of many California school boards and districts to file suit against the tech companies that run Facebook, Instagram, TikTok, Snapchat, WhatsApp, YouTube, and Google. According to a *Calmatters* report, the plaintiffs argue these platforms – and the algorithms designed to keep kids hooked – have caused unprecedented levels of anxiety, depression, bullying, eating disorders and suicidal ideation. The litigation points to research that has found a host of poor health, behavioral, and emotional outcomes associated with heavy social media use, such as depression, low self-esteem, cyberbullying, eating disorders, sleep deprivation, and more. The social media companies, in response to *The San Diego Union-Tribune* said they have taken many steps to regulate content for the sake of safety and well-being of their users. This is not the first issue over which school districts have engaged in mass litigation against

corporate giants, alleging harm against their students. Hundreds of school districts nationwide had previously sued Juul Labs for its role in the youth vaping epidemic. Juul agreed to a nearly half-billion dollar settlement with six states, including California.

**f) California's Children and Youth Behavioral Health Initiative (CYBHI).** The CYBHI is a five-year, $4.6 billion initiative intended to transform the way California meets the behavioral health needs of children, youth and families. Launched in 2021, this five-year initiative is core to Governor Newsom's Master Plan for Kids' Mental Health. CYBHI is moving initiatives across four core strategies: Workforce Training and Capacity, Behavioral Health Ecosystem Infrastructure, Coverage, and Public Awareness**.**

In 2022, CYBHI executed a contract with The Children's Partnership, who convened an advisory board to inform the design of the peer-to-peer youth mental health pilot program. Requests for applications to identify high schools for the demonstration pilot, an $8 million effort to support eight sites across the state, closed on March 24, 2024. The Children's Partnership stated their commitment to a collaborative partnership with the eight high school grantees, desiring to identify best practices for peer-to-peer programs that can be implemented statewide and serve as a model for national effort. The author has stated that this bill is intended to model this recent effort and the proven successful peer-to-peer models.

**3) RELATED LEGISLATION.**

**a)** AB 1282 (Lowenthal) requires the Mental Health Services Oversight and Accountability Commission on or before July 1, 2026 to report to the relevant policy committees of the Legislature a statewide strategy to understand, communicate, and mitigate mental health risks associated with the use of social media by children and youth. AB 1282 is currently pending on the Senate Inactive File.

**b)** AB 2657 (Arambula) establishes the Social Media Commission for the purpose of bringing together a diverse group of experts and invested stakeholders to provide a comprehensive report with formal recommendations for regulation of social media as it relates to child and adolescent mental health and well-being. AB 2657 is currently pending in Assembly Health Committee.

**c)** SB 764 (Padilla) provides protections to children performing in "vlogs," monetized content appearing on online platforms, as specified. This includes the establishment of trust accounts for the benefit of those minors and specified accounting practices. SB 764 is pending referral in the Assembly Rules Committee.

**4) PREVIOUS LEGISLATION.**

**a)** AB 1394 (Wicks), Chapter 579, Statutes of 2023, requires social media platforms to provide a mechanism for users to report child sexual abuse material in which they are depicted; provides platforms 30 to 60 days after receiving a report to verify the content of the material and block it from reappearing. Also provides victims of commercial sexual exploitation the right to sue social media platforms for having deployed features that were a substantial factor in causing their exploitation.

**b)** SB 287 (Skinner) of 2023 would have subjected social media platforms to civil liability for damages caused by their designs, algorithms, or features, as provided. This bill would have provided a safe harbor where certain auditing practices are carried out. SB 287 was held on the Senate Floor.

**c)** AB 2273 (Wicks), Chapter 320, Statutes of 2022, establishes the California Age-Appropriate Design Code Act which generally requires businesses that provide online services, products, or features likely to be accessed by children to comply with specified standards.

**d)** AB 2408 (Cunningham) of 2022 would have created the Social Media Platform Duty to Children Act prohibiting a social media platform, as defined from using a design, feature, or affordance that the platform knew, or by the exercise of reasonable care should have known, causes a child user, as defined, to become addicted to the platform. AB 2408 was held on the Senate Appropriations suspense file.

**e)** AB 1628 (Ramos), Chapter 432, Statutes of 2022, requires until January 1, 2028, and subject to specified exceptions, a social media platform, as defined, that operates in the state to create and publicly post a policy statement that includes, among other things, the platform's policy on the use of the platform to illegally distribute a controlled substance, as defined, and a link to the platform's reporting mechanism for illegal or harmful content or behavior if one exists.

**f)** AB 2879 (Low), Chapter 700, Statutes of 2022, requires a social media platform to disclose all cyberbullying reporting procedures in the platform's terms of service, and would require a platform to establish a mechanism within its internet-based service that allows an individual, whether or not that individual has a profile on the internet-based service, to report cyberbullying or any content that violates the existing terms of service, as specified.

**5) DOUBLE REFERRAL.** This bill is double referred, upon passage of this Committee it will be referred to the Assembly Committee on Privacy and Consumer Protection.

**6) POLICY COMMENT.** This bill has overlapping goals with other proposals that this author has before the Committee. In order to streamline efforts, the author may wish to combine these proposals to ensure the Legislature is taking a coordinated and intentional approach to this important issue.

**REGISTERED SUPPORT / OPPOSITION**:

**Support**

None on file.

**Opposition**

None on file.

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

Date of Hearing: April 9, 2024

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 2411 (Wendy Carrillo) – As Amended April 1, 2024

**SUBJECT**: Local Youth Mental Health Boards.

**SUMMARY**: Requires each community mental health (MH) service to have a local youth mental health board (board), as specified, consisting of members between 15 and 23 years of age. Specifically, **this bill**:

1) Requires each community MH service to have a board consisting of eight or more members, as determined by the governing body, and appointed by the governing body. Permits boards in counties with a population of fewer than 80,000 to have a minimum of five members.

2) Requires board membership to include county residents between 15 and 23 years of age, inclusive. Requires membership to reflect the diversity of the population in the county, including race, ethnicity, sexual orientation, and gender identity, to the extent possible.

3) Establishes the board to inform decisions by the governing body, school districts, the county office of education, and other governmental and nongovernmental bodies involved with the community MH service, as determined by the board.

4) Requires the board to serve in an advisory role to the governing body, governing bodies of school districts within the county, the county office of education, and other public entities and officials within the county, as determined by the board.

5) Requires, to the extent possible, one-half or more of the board membership to be MH consumers who are receiving, or have received, MH services, or siblings or close family members of MH consumers, as determined by the governing board.

6) Requires, to the extent possible, one-half or more of the board members to be enrolled in school in the county.

7) Requires, in counties with a population of fewer than 80,000, at least two members to be consumers who are receiving, or who have received, MH services.

8) Permits the board, at its discretion, to meet concurrently with and advise the community MH board established pursuant to Section 5604 of the Welfare and Institutions Code (WIC) on matters pertaining to meeting the MH needs of youth.

9) Requires the board to review and evaluate the local public MH system and advise the county and school district governing bodies on MH services related to youth that are delivered by the local MH agency or local behavioral health agency, school districts, or others, as applicable.

10) Requires the term of each member of the board to be for no less than two years and no more than three years. Requires the governing body to equitably stagger appointments so that an equal number of appointments, to the extent possible, expire in each year.

11) Requires, if two or more local agencies jointly establish a community MH service, the board for the community MH service to consist of an additional five members for each additional agency, with equal representation from each local agency to the extent possible.

12) Prohibits a member of the board or the member's spouse, parent, or sibling to be a full-time or part-time employee of a county MH service, an employee of the State Department of Health Care Services, or an employee or a member of the governing body of a MH contract agency doing business in the local jurisdiction.

13) Prohibits members of the board from voting on any issue in which the member has a financial interest.

14) Permits the board to be established as an advisory board or a commission, depending on the preference of the county.

15) Permits a board to do all of the following:

    a) Review and evaluate the community's youth MH needs, services, and related challenges and opportunities, as determined by the board;
    b) Review county agreements affecting youth. Authorizes the board to make recommendations to the governing body regarding concerns identified within these agreements;
    c) Advise the governing body and the local MH director as to any aspect of the local MH program relating to youth. Authorizes the board to request assistance from the local patients' rights advocates, local agencies, the grand jury, and others when reviewing and advising on MH evaluations or services provided in facilities with limited access;
    d) Review and advise on the procedures used to ensure youth involvement at all stages of the MH planning process;
    e) Submit an annual report to the county governing body, school districts, and other local governing bodies, where relevant, on the needs and performance of the county's MH system as it relates to the needs of youth, with recommendations for improvement as needed;
    f) Review and comment on the county's performance outcome data as it relates to youth and communicate its findings to the California Behavioral Health Planning Council and the Behavioral Health Services Oversight and Accountability Commission (BHSOAC); and,
    g) Perform any other duties transferred by the governing body.

16) Requires the BHSOAC to, on or before December 30, 2027, and once every five years thereafter, assess the extent to which boards have been established consistent with the intent of this enactment and make recommendations on ways to strengthen the youth voice to support appropriate behavioral health services.

17) Requires the governing body to assign staff to support the board and pay, from any available funds, the actual and necessary expenses of the members of the board incurred incident to the

performance of their official duties and functions, including travel, lodging, childcare, and meals for the members of a board while on official business, as approved by the director of the local MH program.

18) Requires the governing body to include the board in the county planning process. Requires the governing body to provide a budget for the board that is sufficient to facilitate the purposes, duties, and responsibilities of the board.

19) Requires the board to develop bylaws to be approved by the governing body that do all of the following:
    a) Establish the specific number of members on the board;
    b) Ensure that the composition of the board represents and reflects the diversity and demographics of the county as a whole, to the extent feasible;
    c) Establish that a quorum be one person more than one-half of the appointed members; and,
    d) Establish that the chairperson of the board be in consultation with the local MH director.

**EXISTING LAW**:

1) Establishes the Bronzan-McCorquodale Act to organize and finance community MH services for those with MH disorders in every county through locally administered and controlled community MH programs. [WIC §5600]

2) Specifies that community MH services should be organized to provide an array of treatment options in the following areas, to the extent resources are available: pre-crisis and crisis services; comprehensive evaluation and assessment; individual service plans; medication education and management; case management; 24-hour treatment services; rehabilitation and support services; vocational rehabilitation; residential services; services for the homeless; and, group services. [WIC §5600.4]

3) Requires each community MH service to have a mental health board (MHB) consisting of 10 to 15 members, depending on the preference of the county, appointed by the governing board, with added requirements for counties depending on the size of its population and the size of its board of supervisors. Requires each MHB member to serve for a term of three years. Permits a MHB to be established as an advisory board or a commission, depending on the preference of the county. [WIC §5604]

4) Requires a local MHB to do the following:
    a) Review and evaluate the community's MH needs, services, facilities, and special problems;
    b) Review any county agreements, as specified;
    c) Advise the governing body and local MH director as to any aspect of the local MH program;
    d) Review and approve procedures used to ensure citizen and professional involvement in all stages of the planning process;
    e) Submit an annual report to the governing body on the needs and performance of the county's MH system;

f) Review and make recommendations on applicants for the appointment of a local director of MH services, and be included in the selection process prior to the vote of the governing body;
g) Review and comment on the county's performance outcome data and communicate its findings to the California Behavioral Health Planning Council; and,
h) Perform any other duties transferred by the governing body. [WIC §5604.2]

5) Establishes the Mental Health Services Act (MHSA), enacted by voters in 2004 as Proposition 63, to provide funds to counties to expand MH services, develop innovative programs, and integrate service plans for mentally ill children, adults, and seniors through a 1% income tax on personal income above $1 million. [WIC §5890, et seq.]

6) Establishes the Mental Health Services Oversight and Accountability Commission (MHSOAC) to oversee the implementation of MHSA, made up of 16 members appointed by the Governor, and the Legislature, as specified. [WIC §5845 and §5846]

7) Requires each county MH program to prepare and submit a three-year plan to the Department of Health Care Services (DHCS) that must be updated each year and approved by DHCS after review and comment by the MHSOAC. Requires development of the three-year plans to include a community stakeholder process and include a list of all programs for which MHSA funding is being requested and that identifies how the funds will be spent and which populations will be served. [WIC §5847 and §5848]

8) Requires a MHB to conduct a public hearing on the draft MHSA three-year plan and annual updates at the close of the 30-day comment period, as specified. Requires each adopted three-year plan and update to include any substantive written recommendations for revision, and a summary and analysis of the recommended revisions. Requires the MHB to review the adopted plan or update, and to make recommendations to the county MH department for revisions. [WIC §5848]

9) Requires a local mental or behavioral health agency to provide a report of written explanations to the local governing body and DHCS for any substantive recommendations made by the MHB that are not included in the final three-year plan or annual report. [WIC §5848]

10) Requires specified MHSA allocations to counties to include funding for annual planning costs, including funds for county MH programs to pay for various costs of consumers, family members, and other stakeholders to participate in the planning process and for the planning and implementation required for private provider contracts to be significantly expanded to provide additional services. [WIC §5892]

**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 represents an opportunity to engage youth in the community planning process for youth specific MH services. The author continues that the MH of youth has always been a major public health concern that became an even more pressing during the COVID-19 pandemic. The author argues that by requiring

each community MH service to have a local youth advisory board, young people will have a platform to better advocate for quality and effective MH programs. The author concludes that youth should be able to seek help and speak freely without feeling insecure or overshadowed and in order to better comprehend their experiences and tribulations, youth should and must be included in these conversations.

2) **BACKGROUND.** According to the United States Surgeon General, MH challenges are the leading cause of disability and poor life outcomes in young people. Research indicates that half of all MH conditions begin by the age of 14 and more than 75% of MH challenges develop before a person reaches the age of 24.

   a) **MH Services and Boards.** In 1992-93, California passed the Bronzan-McCorquodale Act, which significantly changed mental services with more of the focus and responsibility passing to the counties including requiring each community MH service to have a MHB. MHBs remain the primary vehicle for citizens to have oversight of the administration and provision of the services funded by their tax dollars. The composition of MHBs are required to represent, proportionately, the populations and stakeholders interested in MH services. The creation of MHBs was intended to provide community input into the development and adoption of community MH services plans, and to act as a check and balance to plans that are developed by the local mental/behavioral health departments and approved by the county boards of supervisors.

      In 2004, California voters enacted the MHSA to provide funds to counties to expand MH services, develop innovative programs, and integrated service plans for mentally ill children, adults, and seniors through a 1% income tax on personal income above $1 million. The MHSA also established the MHSOAC to oversee the implementation of MHSA.

   b) **Proposition 1.** In the 2024 statewide primary election, California voters approved Proposition 1 which revises and recasts the MHSA as the Behavioral Health Services Act (BHSA). The act among other things, modifies local and state spending priorities under the BHSA and renames the MHSOAC to the Behavioral Health Services Oversight and Accountability Commission and changes the duties of the commission to include promoting transformational change in California's behavioral health system. Proposition 1 goes into effect on January 1, 2025.

   c) **MHSOAC Youth Innovation Project (YIP).** MHSOAC formed a Youth Innovation Committee in February of 2019 in order to identify unmet MH needs of California youth and to identify opportunities for innovation. The committee was made up of 14 members, ages 15-25, from 12 different counties. The committee worked with the Youth Leadership Institute, the Born This Way Foundation, California Youth Connection, The Children's Trust, and others to gather research, host focus groups and to conduct a statewide survey in order to understand opportunities to improve mental wellness of young people. The Committee took those initial learnings and then hosted three idea labs with youth from across the state from 2019 to 2020.

      As part of the YIP effort, the Born This Way Foundation and MHSOAC through the Beneson Strategy Group, conducted 485 online interviews with 13-24 year olds in California. While MH is a priority for nearly all (90%) young people surveyed,

alarmingly, one-in-three say they do not have reliable access to MH resources. The disconnect is not for lack of will or want: eight-in-ten young people are looking to learn coping skills to help them deal with the stresses of everyday life. It is clear that there are significant barriers to resources for many young people in California.

Broad awareness of resources does not exist: almost half (48%) of all young people do not know where to turn to get MH support. Where awareness exists, the funds to pay for these resources do not: 36% of young people say even if they did know where to look for help with their MH, the cost of these services puts them out of reach. While not the primary barriers to resource access, MH stigmatization and a lack of trust in existing resources stand in the way of many young people getting the MH care help they need.

Young people are ready to fight the stigma surrounding MH, but acknowledge they cannot do it without the help of their schools and communities. They want their schools to make MH a priority by implementing MH trainings for their counselors, teachers, and peers and believe funding should go to those trainings as well as MH programs, clubs, and classes in school that encourage students to talk about their feelings. Participants also long for their schools and communities to be more connected in their resources, which young people say, should be reliable, long lasting, and affordable, even for those without health insurance.

3) **SUPPORT.** MHSOAC is sponsoring this bill, stating that youth are experts in the systems that serve them; how well they are working and where they are not. MHSOAC argues that youth are vitally important in transforming behavioral health, but they must be engaged based on active participation and decision making rather than "decoration" and "tokenism." MHSOAC continues that the boards established in this bill would support young people by initiating programs and sharing decision-making with adults through youth-led activism and youth-adult partnerships. MHSOAC concludes that this bill would amplify the voices of youth and give them the power of choice in creating ways to overcome the challenges they face in pursuit of emotional wellbeing.

4) **PREVIOUS LEGISLATION.**

   **a)** SB 326 (Eggman), Chapter 790, Statutes of 2023, recasts the MHSA as the BHSA and modifies local and state spending priorities under the BHSA, including requiring 30% of all local BHSA funds to be spent on housing interventions, as specified; eliminating allocations for local MH prevention-based programs and recasting other local spending categories; and, adding a state-level population-based prevention and stigma reduction program and statewide workforce program. Allows BHSA funding to be used to provide services to individuals with substance use disorders regardless of whether they have additional MH diagnoses or needs. Makes most changes subject to voter approval on the March 5, 2024, primary election ballot (combined with AB 531 (Irwin), Chapter 798, Statutes of 2023, the Behavioral Health Infrastructure Bond Act.

   **b)** AB 289 (Holden), Chapter 518, Statutes of 2023, expands the list of local stakeholders with which a county MH program is required to develop and update the three-year program and expenditure plan pursuant to the MHSA to include youth or youth MH organizations.

**c)** AB 573 (Carrillo) of 2021 would have established the California Youth Mental Health Board within the California Health and Human Services Agency to advise the Governor and Legislature on the challenges facing youth with MH needs and determine opportunities for improvement. Would have required each community MH service to have a board to advise the county MH programs, school districts, and other entities on issues relating to youth MH. AB 573 was held in the Assembly Appropriations Committee.

**d)** AB 552 (Quirk Silva) of 2021 would have authorized local educational agencies and county behavioral health agencies to enter into partnerships to provide school-based behavioral health and substance abuse disorder services on school sites; and would have authorized the billing of private insurance providers for these services under specified conditions. AB 552 was vetoed by the Governor.

**e)** AB 1352 (Waldron), Chapter 460, Statutes of 2019, requires MHBs to report directly to the county governing body and grants the MHBs autonomy to act, review, and report independently from the county MH departments or county behavioral health departments.

**f)** AB 1689 (McCarty) of 2019 would have required the MHSOAC , subject to appropriation by the Legislature, to create a grant program for public community colleges, colleges, and universities for the purpose of improving access to MH services on those campuses, as specified. Would have required campuses awarded grants to report annually on the use of those grant funds and to post that information on their internet websites. AB 1689 was held in the Assembly Appropriations Committee.

**g)** SB 12 (Beall) of 2019 would have required the MHSOAC, subject to an appropriation, to administer an Integrated Youth Mental Health Program for purposes of establishing local centers to provide integrated youth MH services, as specified. SB 12 was held in the Assembly Appropriations Committee.

**REGISTERED SUPPORT / OPPOSITION**:

**Support**

Mental Health Services Oversight and Accountability Commission (sponsor)

**Opposition**

None on file.

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

Date of Hearing: April 9, 2024

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 2428 (Calderon) – As Introduced February 13, 2024

**SUBJECT**: Medi-Cal: Community-Based Adult Services.

**SUMMARY**: Requires Medi-Cal managed care plans to pay a minimum fee to Community-Based Adult Services (CBAS) providers for CBAS services, retroactive to July 1, 2019, and prohibits this requirement from being construed to require the Department of Health Care Services (DHCS) to retroactively recalculate the plans' capitation rates.

**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) Notwithstanding any other law, commencing January 1, 2012, makes CBAS a Medi-Cal benefit covered under every managed care health plan contract, and commencing January 1, 2022, requires CBAS to continue to be available as a Medi-Cal benefit only through managed care health plans. [WIC § 14186.3]

3) Requires each Medi-Cal managed care plan (MCP) to reimburse a network provider furnishing CBAS to a Medi-Cal beneficiary enrolled in that plan. [WIC § 14184.201]

4) Requires each network provider of CBAS to accept the payment amount the network provider of CBAS would be paid for the service in the Medi-Cal fee-for-service (FFS) delivery system, unless the MCP and network provider mutually agree to reimbursement in a different amount. [*Ibid.*]

5) Increases Medi-Cal FFS rates for a targeted list of services and providers (not including CBAS), and requires MCPs to reimburse those same targeted network providers at least the FFS rate for the listed services. [WIC § 14105.201]

**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 requires Medi-Cal managed care plans to reimburse CBAS providers at a rate equal to or greater than the amount paid for the service by the Medi-Cal FFS delivery system. The author states CBAS is a community-based health program that provides daytime services to more than 35,000 low-income, multicultural and ethnically diverse, seniors living with chronic medical, cognitive, mental health conditions or disabilities. The author points out, with the elderly population in California expected to grow more than three times as fast as the total population, this bill ensures CBAS will continue playing a vital role in enabling seniors to age gracefully. California Association for Adult Day Services (CAADS) is the bill's sponsor.

**2) BACKGROUND.**

**a) Home and Community Based Services (HCBS), and CBAS**. Access to HCBS is essential to allowing many older, frail, and disabled individuals to maintain physical and mental health and independence, as well as to prevent or delay unnecessary or premature institutionalization. CBAS (formerly Adult Day Health Center (ADHC) services) is a community-based health program that provides daytime services to older persons and adults with chronic medical, cognitive, mental health conditions, and/or disabilities who are at risk of needing institutional care. These services often delay or prevent institutionalization and maintain individuals in their homes for as long as possible. CBAS services are center-based, and include an individual assessment; professional nursing services; physical, occupational and speech therapies; mental health services; therapeutic activities; social services; personal care; a meal; nutritional counseling; and, transportation to and from the participant's residence and the CBAS center.

**b) Recent History and Oversight of CBAS in California.** On March 31, 2012, the ADHC benefit ended as an optional benefit under California's Medicaid State Plan. ADHC continues as a licensed health facility category under California law, licensed by the Department of Public Health (DPH). Former ADHC participants who met more stringent CBAS eligibility standards began receiving CBAS services in approved centers on April 1, 2012. There are approximately 259 CBAS centers statewide. In addition to meeting Medi-Cal program and waiver requirements, CBAS providers must maintain an ADHC license.

Under an interagency agreement, the CBAS Program is administered among the DHCS, the DPH, and the California Department of Aging (CDA). CDA certifies licensed ADHC centers as Medi-Cal CBAS providers.

**c) Demand for CBAS**. CDA contracted with the University of California, Los Angeles Center for Health Policy Research to conduct a needs assessment for CBAS and another HCBS program called Multipurpose Senior Services Program. According to these projections, more than 240,000 people who are potentially eligible for CBAS statewide in 2020 were not receiving these services. This is more than six times the number (38,373) of those who were actually served by CBAS in that year. A comparison of users versus estimated eligible users of CBAS suggests untapped opportunities to serve a younger population (18 to 49 years of age), more Black or African American individuals, and more people who identify as biracial or multiracial. Only 4% of Black or African American individuals who qualified received CBAS services.

**d) Fiscal Condition of CBAS Centers**. CAADS, this bill's sponsor and the entity representing CBAS centers, indicates a survey conducted this year shows 76% of CBAS centers are operating at a deficit and 22% are at high risk of closure, compared to nine percent in 2023. CAADS notes Medi-Cal reimbursement rates have not increased in the last 15 years, despite the rate of inflation for these services increasing by 61%. Based on data from CDA, CAADS reports from 2020 to 2023, 18 centers have closed, or six percent of current CBAS centers.

**e) Medi-Cal Managed Care and Capitation Rate-Setting**. Existing law requires that CBAS continue to be available as a capitated benefit for qualified Medi-Cal beneficiaries

with an applicable Medi-Cal managed care plan. DHCS contracts with Medi-Cal managed care plans to deliver services to the overwhelming majority of Medi-Cal enrollees.

According to MacPAC, a federal entity that tracks and advises on Medicaid policy, state Medicaid programs pay plans to cover a defined package of benefits for an enrolled population through fixed periodic payments, also referred to as capitation payments. Capitation payment rates are typically established prospectively and remain in effect for the duration of the 12-month rating period, per federal regulations, regardless of changes in health care costs or use of services. The rates are based on actuarial estimates of the amounts necessary to cover the anticipated health care costs of covered enrollees as well as plan administration, reserves, and profit.

MacPAC notes the federal standard for payment adequacy in managed care is the actuarial soundness rule, a standard established in statute and defined in regulations that require a qualified actuary to certify that the capitation rates should cover anticipated costs and appropriately balance profit and risk.

A number of factors are considered in rate development, including base rates and various types of adjustments.

**f) Ten Percent Budget Cut and "AB 97 Buyback."** In 2011, the health-related budget trailer bill, AB 97 (Committee on Budget), Chapter 3, Statutes of 2011, enacted a series of Medi-Cal cost reduction measures, including a 10% provider payment reduction to CBAS. Once the 10% rate cut was were restored, DHCS subsequently adjusted managed care capitation rates in order to "buy back" the cost of restoring the 10% rate cuts for many providers. According to the DHCS 2021 Rate Certification Report produced by Mercer, DHCS's contracted actuarial firm, effective July 1, 2019, the restoration of the CBAS facility payment rates to levels in effect prior to the AB 97 10% rate reduction was expected to produce corresponding pricing pressures in managed care. As a result, an adjustment was applied in developing the rates.

Based on the review of CBAS data, if it was observed that a plan was paying a CBAS rate less than $76.27 (the state fee schedule CBAS daily rate without the AB 97 10% reduction applied), an adjustment was made in these instances to raise the unit cost to $76.27. If a plan was paying CBAS daily rates in excess of this amount, no adjustment was made. In other words, the increased cost associated with restoring the rate to $76.27 was "baked in" to the capitation rates paid to the plans, on the assumption the plans would in turn pay these increased rates to the centers. However, passing the rate increase onto CBAS centers was not mandatory for the plans, as plans generally have the ability to negotiate payment rates with providers. The Legislature and Administration made a good-faith assumption that the dollars allocated specifically to restore rates for CBAS providers would reach those providers, and most plans did pass on the rates to CBAS providers; however, CAADS indicates on behalf of CBAS providers that several did not.

**g) Directed Payments**. One exception to the flexibility of plans to negotiate payment rates with providers relates to federal rules on "directed payments." Under federal regulations (42 Code of Federal Regulations 438.6), states cannot direct managed care plans to make payments to particular providers; however, states can establish minimum fee schedules

for managed care providers. For instance, last year's health trailer bill, AB 118 (Committee on Budget), Chapter 42, Statutes of 2023, sets certain Medi-Cal FFS rates at 87.5% of the Medicare rate for the service, and requires each managed care plan to reimburse their network providers "at least the amount the network provider would be paid for those services in the Medi-Cal FFS delivery system." CAADS notes that given the application of a minimum fee schedule in AB 118, a similar construct included in this bill would not set a precedent in Medi-Cal. However, directed payments reduce flexibility for plans, increase complexity of program administration, and require federal approval. In any case, the unique situation addressed by this bill may not form a solid basis to establish precedent for other directed payment proposals.

**h) Retroactivity.** As noted, on a practical basis, plans have been made whole for the costs of restoring the 10% cut to CBAS rates, effective July 1, 2019. However, the requirement for retroactivity, coupled with the prohibition on further rate adjustment to account for the costs of the rate adjustment, appears fairly novel and it is unclear whether federal rules would allow this. Technical assistance from DHCS and potentially the Centers for Medicare & Medicaid Services would be required to understand whether the retroactivity portion of the bill is federally allowable in this particular case.

**3) SUPPORT.** CAADS, aging advocacy organizations, and a large cadre of ADHCs/CBAS providers support this bill. CAADS argues that although funding was restored, four MCPs-HealthNet, Blue Shield, Molina, and Kaiser— did not immediately restore rates for CBAS providers in their network. CAADS argues that since 2019, CBAS providers that contract with these Managed Care Organizations (MCOs) have been reimbursed at the reduced rate of $68.60 per day per recipient instead of the restored rate of $76.27. CAADS notes there is an inherent imbalance of negotiating power between CBAS centers and plans because of their reliance on Medi-Cal, often resulting in CBAS providers being underpaid from "take it or leave it" contracts. CAADS concludes that reimbursement rates are not based on the actual cost of doing business, which is part of why CBAS centers are closing around the state. AARP writes in strong support that CBAS provides essential services that keep older Californians in their homes and communities, helps to reduce isolation, engages participants in a variety of enrichment and educational activities, and provides family caregivers with much-needed respite.

**4) PREVIOUS LEGISLATION.**

**a)** AB 118 applies a minimum fee schedule for targeted services and providers, to be funded initially via a tax on Medi-Cal managed care plans (the MCO Tax).

**b)** AB 133 (Committee on Budget), Chapter 143, Statutes of 2021, reauthorized CBAS as a managed care benefit under the California Advancing and Innovating Medi-Cal initiative.

**c)** AB 97 imposed 10% rate cuts on a number of Medi-Cal FFS rates.

**REGISTERED SUPPORT / OPPOSITION**:

**Support**

California Association for Adult Day Services (sponsor)
AARP

Alzheimer's Association State Policy Office
Alzheimer's Greater Los Angeles
Alzheimer's Orange County
Alzheimer's San Diego
ARCA, Inc.
Arcadia Adult Day Health Care Center
Association of Regional Center Agencies
Beverly Adult Day Health Care Center
C&C Carson Adult Day Health Care Center
California Coalition on Family Caregiving
Circle of Friends Adult Day Health Care
Commonwealth Adult Day Health Care Center
Daylight Adult Day Health Care Center
E&V Adult Day Health Care Center
El Monte Adult Day Health Care Center
Family Bridges
Family Caregiver Alliance
GetTogether Adult Day Health Care Center
Golden Castle ADHC Center
Hearts & Minds Activity Center
Hollywood Adult Day Health Care Center
HomeAvenue, INC. Dba Home Avenue Adult Day Health Care Center
Justice in Aging
Laguna Adult Day Health Center
LeadingAge California
On Lok Senior Health Services
ONEgeneration
Placer Independent Resource Services
Poway Adult Day Health Care Center
Reimagine
Reimagine Network
Senior Services Coalition of Alameda County
Steppingstone Health
Sunny Adult Day Health Care Center
Sunny Cal ADHC
SunnyDay Adult Day Health Care
The Neighborhood House Association
Yolo Adult Day Health Center
Yolo Healthy Aging Alliance

**Opposition**

None on file.

**Analysis Prepared by**: Lisa Murawski / HEALTH / (916) 319-2097

Date of Hearing: April 9, 2024

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 2549 (Gallagher) – As Amended April 1, 2024

**SUBJECT**: Patient visitation.

**SUMMARY**: Establishes the Patients' Visitation Rights Act, which requires the Department of Public Health (DPH), not later than January 1, 2026, to provide specific clinical guidance related to safe visitation during a pandemic event for hospitals, as defined. Specifically, **this bill**:

1) Establishes the Patient Visitation Rights Act which, requires DPH, no later than January 1, 2026, to provide specific clinical guidance related to safe visitation during a pandemic event for hospitals, as defined.

2) Requires the guidance provided pursuant to 1) above to include provisions encouraging flexible visitation policies for families, especially those with young children.

3) Requires the guidance to comply with the requirements of existing law requiring health facilities, as defined in 1) of existing law below, to allow a patient's spouse or domestic partner, children, parents, grandchildren, grandparents, and others to visit unless specified conditions are met.

4) Adds a requirement to the provisions described in 3) above to prohibit infants under one year of age from being counted against the total number of visitors if a facility imposes a restriction on the number of visitors allowed at the same time.

5) Specifies that the provisions described above do not create any new civil or criminal liability, including, but not limited to, liability for any illness, infection, or injury experienced by a patient or visitor on the part of a facility that complies with those provisions.

6) Defines "hospitals" for purposes 1) above, to include general acute care hospitals (GACHs), acute psychiatric hospitals, and special hospitals.

**EXISTING LAW**:

1) Establishes DPH which, among other functions, licenses and regulates health facilities. Defines "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) 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) Requires a health facility to allow a patient's domestic partner, the children of the patient's domestic partner, and the domestic partner of the patient's parent or child to visit, unless one of the following is met:

   a) No visitors are allowed;
   b) The facility reasonably determines that the presence of a particular visitor would endanger the health or safety of a patient, member of the health facility staff, or other visitor to the health facility, or would significantly disrupt the operations of a facility; or,
   c) The patient has indicated to health facility staff that the patient does not want this person to visit. [HSC §1261]

3) Prohibits the provisions of 2) above from being construed to prohibit a health facility from otherwise establishing reasonable restrictions upon visitation, including restrictions upon the hours of visitation and number of visitors. [*Ibid.*]

4) Establishes the "California Residential Care Facilities for the Elderly (RCFE) Act" to provide for the licensure and regulation of RCFEs as a separate category within the existing licensing structure of the Department of Social Services (DSS). [HSC §1569 *et seq.*]

5) Defines "RCFE" to mean a housing arrangement chosen voluntarily by individuals ages 60 and older, or their authorized representative, where varying levels and intensities of care and supervision, protective supervision, personal care, or health-related services are provided, based upon their varying needs, as determined in order to be admitted and to remain in the facility. [HSC §1569.2(p)(1)]

6) Defines "residential facility" to mean any family home, group care facility, or similar facility determined by DSS, for 24-hour nonmedical care of persons in need of personal services, supervision, or assistance essential for sustaining the activities of daily living or for the protection of the individual. [HSC §1502(a)(1)]

7) Defines "adult residential facility" to mean any facility of any capacity that provides 24-hour-a-day nonmedical care and supervision to persons 18 years of age through 59 years of age. [Title 22 California Code of Regulations 80001(a)(5)]

8) Establishes the California Emergency Services Act, which provides the Governor with the authority to proclaim a state of emergency, and provides the Governor, during a state of emergency, with complete authority over all agencies of the state government and the right to exercise within the area all police power vested in the state by the Constitution and laws of California, and in exercising these powers, gives the Governor the authority to promulgate, issue, and enforce such orders and regulations as he deems necessary. Permits the Governor 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 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. [Government Code (GOV) §8625, §8627, and §8571]

9) Defines three conditions of emergency for purposes of the Emergency Services Act, including a "state of war emergency," a "local emergency" that is within the territorial limits of a city or county, and a "state of emergency," which could be caused by air pollution, fire, flood, storm, epidemic, riot, drought, cyberterrorism, sudden and severe energy shortage, plant or animal infestation or disease, or an earthquake or other conditions, which are likely to be beyond the control of the services, personnel, equipment, and facilities of any single county or city and require the combined forces of a mutual aid region or regions to combat. [GOV §8558]

10) Gives the State Public Health Officer (PHO), as the Director of DPH, broad authority to detect, monitor, and prevent the spread of communicable disease in the state, including to adopt and enforce regulations requiring strict or modified isolation, or quarantine, for any of the contagious, infectious, or communicable diseases, if in the opinion of DPH, the action is necessary for the protection of the public health. [HSC §120130, *et seq*.]

11) Permits the PHO or a local health officer (LHO), appointed by a county, to declare a health emergency or a local health emergency, respectively, whenever there is a hazardous waste spill or whenever there is an imminent and proximate threat of the introduction of any contagious, infectious, or communicable disease, chemical agent, non-communicable biologic agent, toxin, or radioactive agent. Permits the PHO or the LHO to take specified actions during a health emergency or a local health emergency. [HSC §101080]

12) Requires LHOs knowing or having reason to believe that any case of reportable diseases, or any other contagious, infectious or communicable disease exists, or has recently existed, within the territory under his or her jurisdiction, to take measures as may be necessary to prevent the spread of the disease or occurrence of additional cases. [HSC §120175]

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

**COMMENTS**:

1) **PURPOSE OF THIS BILL.** According to the author, prior to the COVID-19 pandemic, the importance of visitation in patient recovery, comfort, and healing was widely recognized. Flexible visiting hours reduce patient anxiety and delirium, while visitors and care partners play a vital role in patient care by assisting with decision-making and discharge planning. However, during the pandemic, many facilities imposed strict limitations on in-person visitation, isolating patients from their loved ones during critical moments. The author states that research suggests that patients suffered as a result, with long-term care (LTC) facility residents experiencing declines in their physical and mental health. This bill seeks to avoid similar situations by recognizing the importance of visitation while maintaining patient safety. The author concludes that this bill codifies the essential rights of patients and their families, ensuring visitation rights so Californians can stay connected with their loved ones during a health crisis.

2) **BACKGROUND.** On January 30, 2020, the World Health Organization (WHO) declared the COVID-19 pandemic a Public Health Emergency of International Concern, its highest level

of alarm. The pandemic forced health care systems worldwide to introduce mitigating measures to reduce the impact of the disease. One of the WHO recommendations was that "numbers of visitors and visiting periods should be highly restricted." Following this recommendation and similar guidance, visitor restrictions at hospitals and nursing homes were introduced in many countries. During the COVID-19 pandemic, different visiting restrictions were applied in different countries and regions, ranging from an absolute ban on all visits in all kinds of care facilities to comparatively liberal visiting policies, allowing visitors during certain circumstances or with mitigating procedures. These restrictions and policies also changed over time as the pandemic developed and the knowledge of spread-reducing strategies increased.

a) **California health facility visitor access during COVID.** On August 26, 2021 the State PHO issued an order requiring GACHs, SNFs, ICFs, and Adult and Senior RCFEs to verify that visitors were fully vaccinated, or, for unvaccinated or incompletely vaccinated visitors, to verify documentation of a negative SARS-CoV-2 test. Unvaccinated or incompletely vaccinated visitors were eligible for indoor visits only if they could show documentation of a negative SARS-CoV-2 test where the specimen collection occurred within one day of visitation for antigen tests, and within two days of visitation for polymerase chain reaction tests and for which the test results were available at the time of entry to the facility. In SNFs, ICFs and Adult and Senior RCFEs, if a resident was not able to leave their room or otherwise meet with visitors outdoors, the visitation was allowed take place indoors, even for visitors who could not provide vaccine verification or a negative test; however, these visits could not take place in common areas, or in the resident's room if the roommate was present.

b) **California LTC facility access during COVID.** Throughout the course of the COVID-19 pandemic, federal, state, and local guidance on visitation to LTC facilities evolved in response to changing conditions. In September 2020, the Centers for Medicare and Medicaid Services (CMS) allowed limited compassionate care visits to nursing homes. Vaccination clinics began for LTC residents in December 2020, followed by a sharp decline in COVID-19 cases and deaths. CMS lifted restrictions on visitors to nursing homes on March 10, 2021, allowing for responsible indoor visitation at all times and for all residents, with certain exceptions for facilities in counties with high positivity rates and low vaccination rates. As of February 2022, DPH guidance required visitors to show proof of vaccination or a negative test for indoor visitation. DSS also required proof of vaccination or negative test result for indoor visitation to RCFEs.

c) **Working group on LTC Facility Access.** AB 178 (Ting), Chapter 45, Statutes of 2022, was a Budget bill that, among other provisions, commissioned a workgroup to "develop recommendations regarding best policies and practices for LTC facilities during public health emergencies, including, but not limited to, visitation policies. During their discussions, workgroup members weighed the following concepts:

    i) **Balance,** referring to the relationship between the need for public health protection and the physical health, mental health, and advocacy needs of residents, their families, their friends, and others during emergencies, including their individual rights and autonomy;
    ii) **Parity**, referring to similarities or differences in visitation requirements that a facility requires for visitors, outside professional staff, and facility staff;

**iii) Regionalism**, referring to differences among regions of California; and,
**iv) Equity**, referring to the imperative to ensure equity in visitation access, with consideration for ageism, ableism, and barriers for historically marginalized communities.

The working group made several recommendations, including that in a state of emergency in which a local or state order curtails visitation due to a legitimate public health or safety risk, that a "Resident-Designated Support Person" (RDSP) be able to conduct in-person visits with LTC-facility residents subject to the same safety protocols as LTC-facility staff. Many of the recommendations of the LTC Workgroup are included in AB 2075 (Alvarez), which is currently pending in the Assembly Aging and Long-term Care Committee.

**d) Budget ask.** The author of this bill has submitted letter the Assembly Budget Subcommittee No 1, on Health and Human Services, requesting a $450,000 General Fund allocation to DPH to provide funding to develop and implement visitation guidelines for health facilities, particularly in the context of pandemic events, in consultation with DSS.

**e) Federal Law.** The Patient Bill of Rights, established as part of the Patient Protection and Affordable Care Act, requires a hospital to have written policies and procedures regarding the visitation rights of patients, including those setting forth any clinically necessary or reasonable restriction or limitation that the hospital may need to place on such rights and the reasons for the clinical restriction or limitation. A hospital must meet the following requirements:
**i)** Inform each patient (or support person, where appropriate) of their visitation rights, including any clinical restriction or limitation on such rights;
**ii)** Inform each patient (or support person, where appropriate) of the right, subject their consent, to receive the visitors whom they designate, including, but not limited to, a spouse, a domestic partner (including a same-sex domestic partner), another family member, or a friend, and their right to withdraw or deny such consent at any time;
**iii)** Not restrict, limit, or otherwise deny visitation privileges on the basis of race, color, national origin, religion, sex, gender identity, sexual orientation, or disability; and,
**iv)** Ensure that all visitors enjoy full and equal visitation privileges consistent with patient preferences.

This bill requires DPH to provide clinical guidelines regarding visitation policies for specified hospitals.

**3) SUPPORT.** Alzheimer's Los Angeles, Alzheimer's Orange County, and Alzheimer's San Diego support this bill and state that the COVID-19 pandemic has been extremely difficult for people with Alzheimer's and their families. It increased social isolation, anxiety, and stress. For many who live in LTC facilities, visiting family and friends are their main lifeline, providing emotional, moral, and physical support. For those in hospital settings, the presence of a family caregiver can help calm agitation and ensure timely care for emergent issues. In a variety of health care settings, caregivers may be providing food, helping with activities of daily living, helping with medication, or providing social interaction. The supporters conclude, that due to the disease's impact comprehension and communication, phone or

virtual interactions may not be possible. As a result, an in-person visit from a trusted loved one may be that person's lifeline.

4) **RELATED LEGISLATION.** AB 2075 (Alvarez) grants a resident of a LTC facility the right to in-person, onsite access to a designated support person and health care and social services provider during any public health emergency in which visitation rights of residents are curtailed by a state or local order. AB 2075 is pending a hearing in the Assembly Committee on Aging and Long-Term Care.

5) **PREVIOUS LEGISLATION.**

   **a)** AB 1855 (Nazarian), Chapter 583, Statutes of 2022, prohibits a SNF or a RCFE, under any circumstances and notwithstanding any other law, from denying entry to a long term care ombudsman, unless the Governor has declared a state of emergency related to an infectious disease and the ombudsman is positive for, or showing symptoms of, the disease that is the reason for the state of emergency.

   **b)** AB 2546 (Nazarian) would have enacted the RDSP Act, granting residents of LTC facilities the right to in-person, onsite access to a minimum of two designated support person during any public health emergency, as defined, in which the residents' visitation rights are curtailed by a state or local order. AB 2546 was subsequently amended to address a different subject matter.

6) **DOUBLE REFERRAL.** This bill is double referred, upon passage of this Committee, it will be referred to the Assembly Committee on Human Services.

7) **POLICY COMMENT.** As discussed above, federal law currently requires a hospital to have written policies and procedures regarding the visitation rights of patients, including those setting forth any clinically necessary or reasonable restriction or limitation that the hospital may need to place on such rights and the reasons for the clinical restriction or limitation. Moving forward, the author may wish to consult with DPH to determine whether or not existing clinical guidelines are sufficient.

**REGISTERED SUPPORT / OPPOSITION**:

**Support**

A Voice for Choice Advocacy
Alzheimer's Greater Los Angeles
Alzheimer's Orange County
Alzheimer's San Diego

**Opposition**

None on file.

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

Date of Hearing: April 9, 2024

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 2550 (Gabriel) – As Amended March 11, 2024

**SUBJECT**: Business establishments: building standards: retail food safety.

**SUMMARY**: Requires the Building Standards Commission, as a part of the next triennial update of the California Building Standards Code (Title 24 of the California Code of Regulations (CCR)) that occurs on or after January 1, 2025, to adopt various building standards. Specifically, **this bill**:

1) Authorizes a business establishment with less than 150 square feet of seating area or that is takeout only to operate without providing customer restrooms.

2) Authorizes a business establishment, regardless of whether the business establishment sells alcohol, with a maximum occupancy of 49 persons to provide restrooms without urinals.

3) Authorizes a business establishment to install up to 1,000 square feet of patio seating without providing additional restrooms.

4) Authorizes a business establishment that serves alcohol to satisfy a requirement to provide restrooms by exclusively providing restrooms for use by all genders.

5) Authorizes a business establishment with a maximum occupancy of 100 occupants to operate without drinking fountains.

6) Authorizes a business establishment to operate cooking equipment, for the purpose of baking, that does not produce cooking odors, smoke, grease, or vapor without installing a Type 1 hood, as described in Section 508.0 of the California Mechanical Code (Part 4 of Title 24 of CCR), over the cooking equipment.

7) Authorizes a business establishment to operate an under-the-counter dishwasher without installing a mechanical exhaust system over the dishwasher.

8) For the purposes of this section, defines “alcohol” as means ethyl alcohol, hydrated oxide of ethyl, or spirits of wine, from whatever source or by whatever process produced.

9) Prohibits a food facility from locating a grease trap or grease interceptor in a food preparation area, and exempts an aboveground grease trap installed under a 3-compartment sink from this prohibition.

10) Increases the size of a passthrough window service opening to 432 square inches.

11) Exempts walls and ceilings of any areas in which beverages are prepared, or sold or served directly to the consumers, except wall areas adjacent to sinks and areas where food is prepared, from the requirement that a food facility’s walls must be durable, smooth, nonabsorbent, and easily cleanable.

12) Exempts a temporary food facility that is approved for limited food preparation from the existing requirement that temporary food facilities be equipped with overhead protection for all food preparation, food storage, and warewashing areas if environmental factors that could contaminate the food are absent due to the location of the facility or other limiting conditions.

**EXISTING LAW**:

1) Establishes the California Retail Food Code (CRFC) to provide for the regulation of retail food facilities. Establishes health and sanitation standards at the state level through the CRFC, while enforcement is charged to local agencies, carried out by the 58 county environmental health departments and four city environmental health departments (Berkeley, Long Beach, Pasadena, and Vernon). [Health & Safety Code (HSC) § 113700, *et.seq*.]

2) Defines a "food facility" as an operation that stores, prepares, packages, serves, vends, or otherwise provides food for human consumption at the retail level. Excludes various entities from the definition of a "food facility," including a cottage food operation, and a church, private club, or other nonprofit association that gives or sells food to its members and guests, and not to the general public, at an event that occurs no more than three days in any 90 day period. [HSC §113789]

3) Establishes requirements for satellite food services, including requiring satellite food service only be operated by a fully enclosed permanent food facility that meets the requirements for food preparation and service and that is responsible for servicing the satellite food service operation; that the permitholder of the permanent food facility submit to the enforcement agency written standard operating procedures prior to conducting the service, as specified; that all food preparation be conducted within a food compartment or fully enclosed facility; and, that service areas have overhead protection that extends over all food handling areas. [HSC §114067]

4) Prohibits a grease trap or grease interceptor from being located in a food or utensil handling area unless specifically approved by the enforcement agency. [HSC §114201]

5) Requires grease traps and grease interceptors to be easily accessible for servicing. [HSC §114201]

6) Requires a food facility at all times to be constructed, equipped, maintained, and operated as to prevent the entrance and harborage of animals, birds, and vermin, including, but not limited to, rodents and insects.

7) Requires the premises of each food facility to be kept free of vermin. [HSC §114259.1]

8) Requires passthrough window service openings to be limited to 216 square inches each. Prohibits service openings being closer together than 18 inches. Requires each opening to be provided with a solid or screened window, equipped with a self-closing device. Requires screening to be at least 16 mesh per square inch. Authorizes passthrough windows of up to 432 square inches be approved if equipped with an air curtain device. Requires counter surface of the service openings to be smooth and easily cleanable. [HSC §114259.2]

9) Requires the walls and ceilings of all rooms to be of a durable, smooth, nonabsorbent, and easily cleanable surface, except for:

   a) Walls and ceilings of bar areas in which alcoholic beverages are sold or served directly to the consumers, except wall areas adjacent to bar sinks and areas where food is prepared;

   b) Areas where food is stored only in unopened bottles, cans, cartons, sacks, or other original shipping containers;

   c) Dining and sales areas;

   d) Offices;

   e) Restrooms that are used exclusively by the consumers, except that the walls and ceilings in the restrooms shall be of a nonabsorbent and washable surface; and,

   f) Dressing rooms, dressing areas, or locker areas. [HSC §114271]

10) Requires the Department of Alcoholic Beverage Control (ABC) to administer the provisions of the Alcoholic Beverage Control Act, including the licensing of individuals and businesses in the manufacture, importation, and sale of alcoholic beverages. [Business & Professions Code §23000 *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, as small restaurants across California struggle to survive, state action is needed to help facilitate more outdoor dining and small business opportunities, in a manner consistent with public health guidance. The author states that neighborhood restaurants are the backbone of communities across California, but too many are barely hanging on by a thread. The author continues that supporting their start up efforts and operational needs offers a lifeline that can help keep these establishments afloat, and we must do all we can to assist them during these challenging times. The author concludes that this bill ensures that restaurants are fully supported as they continue to innovate their business practices and safely operate.

**2) BACKGROUND.**

   **a) The CRFC.** The CRFC is modeled after the federal Food and Drug Administration's (FDA) Model Food Code (Food Code), which is updated every four years to enhance food safety laws based on the best available science. Between each four-year period, the FDA makes available a Food Code Supplement that updates, modifies, or clarifies certain provisions. The Food Code assists food control jurisdictions at all levels of government by providing them with a scientifically sound technical and legal basis for regulating the retail and food service segment of the industry, such as restaurants, grocery stores, and institutions like nursing homes. Forty-eight states and territories have adopted food codes patterned after the Food Code, representing 80% of the US population.

**b) Impact of COVID-19 on Small Businesses.** On March 4, 2020, Governor Newsom declared the COVID-19 pandemic, and asked all restaurants statewide to suspend dine-in service and only allow takeout or delivery food service. Subsequently, there was also an immediate shutdown of indoor tasting rooms, breweries, and bars across the entire state. According to information provided by the author's office, the COVID-19 pandemic has devastated small businesses in California, with the restaurant industry facing a wave of temporary and permanent closures. As of December 2020, the National Restaurant Association reports that over 110,000 establishments have closed their doors, with 89% of full-service restaurants reporting below normal staffing levels and anticipating additional layoffs. Notably, the restaurant industry employs one of the most diverse workforces in the state, and six out of 10 restaurants in California are owned by people of color.

**3) SUPPORT.** According to the Independent Hospitality Coalition (IHC), the sponsor of this bill, the COVID-19 pandemic has devastated small businesses in California, for restaurants that survived the pandemic, inflation has been the next devastating hurdle. IHC states that certain outdated building codes and regulations in state and local law create significant barriers for small businesses. IHC states that this bill will provide relief to California's small businesses by updating regulations that have yet to account for changes in technology, or that are unclear and do not increase worker or customer safety.

**4) PREVIOUS LEGISLATION.**

**a)** AB 1217 (Gabriel), Chapter 569, Statutes of 2023 extends until July 1, 2026, the authority of the ABC to permit licensees to exercise license privileges in an expanded license area authorized pursuant to a COVID-19 Temporary Catering Authorization approved in accordance with the Fourth Notice of Regulatory Relief issued by ABC on May 15, 2020. A COVID-19 Temporary Catering Authorization authorizes the on-sale consumption of those alcoholic beverages for which the licensee has on-sale privileges on property adjacent to the licensed premises, under the control of the licensee.

**b)** SB 1194 (Allen), Chapter 839, Statutes of 2022, authorizes a local government to require that multiuser public toilet facilities within its jurisdiction be designed, constructed, and identified for use by all genders.

**c)** AB 1632 (Weber), Chapter 893, statutes of 2022, requires a place of business open to the general public for the sale of goods that has a toilet facility for its employees to allow any individual who is lawfully on the premises of that place of business to use the employee toilet facility during normal business hours, if certain conditions are met.

**d)** AB 61 (Gabriel), Chapter 653, Statutes of 2021, authorized ABC, for 365 days from the date the COVID-19 pandemic state of emergency proclaimed by the Governor was lifted, to allow licensees to continue to exercise license privileges in an expanded licensed area authorized pursuant to a COVID-19 Temporary Catering Authorization, as provided. AB 61 authorizes a permitted food facility to prepare and serve food as a temporary satellite food service without obtaining a separate permit for up to one year after the end of the state of emergency declared in response to the COVID-19 pandemic or until January 1, 2024, whichever came first.

**e)** AB 1732 (Ting), Chapter 818, Statutes of 2016, requires businesses, places of public accommodation, or state or local government agencies that offer a single-user toilet facility to be designated as an all-gender toilet facility, as specified, and authorizes an inspector, as specified to inspect for compliance.

**5) DOUBLE REFERRAL**. This bill is double referred, upon passage in this Committee, this bill will be re-referred to the Assembly Committee on Business and Professions.

**REGISTERED SUPPORT / OPPOSITION**:

**Support**

California Restaurant Association
Central City Association
Civil Coffee
Council of Infill Builders
Golden Gate Restaurant Association (GGRA)
Inclusive Action for The City
Independent Hospitality Coalition
Kitchen Culture Recruiting
Last Word Hospitality
Little Tokyo Service Center
Los Angeles County Business Federation (BIZ-FED)
Main Street Business Improvement Association
Public Counsel
Ronan
Santa Monica Chamber of Commerce
Simi Valley Chamber of Commerce
Smorgasburg Ventures LLC
Superfine
West Hollywood Chamber of Commerce

**Opposition**

None on file.

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

Date of Hearing: April 9, 2024

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 2657 (Arambula) – As Amended March 21, 2024

**SUBJECT**: Social Media Commission.

**SUMMARY**: Establishes the Social Media Commission (commission) for the purpose of bringing together a diverse group of experts and invested stakeholders to provide a comprehensive report with formal recommendations for regulation of social media as it relates to child and adolescent mental health and well-being. Specifically, **this bill**:

1) Establishes the commission for the purpose of bringing together a diverse group of experts and invested stakeholders to provide a comprehensive report with formal recommendations for regulation of social media as it relates to child and adolescent mental health and well-being.

2) Requires the commission to be composed of seven subcommittees, each with five total members, including one subcommittee chair. Requires each subcommittee chair to be responsible for leading meetings and writing the subcommittee recommendation reports.

3) Requires the subcommittee chairs to consist of the following:
   a) The Secretary of California Health and Human Services, or the secretary's designee, who shall serve as the chairperson and as subcommittee chair of one of the subcommittees.
   b) Two subcommittee chair members, appointed by the Governor.
   c) Two subcommittee chair members, appointed by the Senate Committee on Rules.
   d) Two subcommittee chair members, appointed by the Speaker of the Assembly.
   e) Requires all appointees to have appropriate knowledge and experience regarding social media, or other relevant expertise.

4) Requires subcommittees to consist of the following:
   a) A subcommittee of parents, divided into two groups:
      i) Requires the first group to consist of parents of children eight to 12 years of age, inclusive; and,
      ii) Requires the second group to consist of parents of children 13 to 17 years of age, inclusive.
   b) A subcommittee of adolescents 13 to 17 years of age, inclusive;
   c) A subcommittee of educators, divided into two groups:
      i) Educators of pupils in second grade to fifth grade, inclusive; and,
      ii) Educators of pupils in sixth grade to twelfth grade, inclusive.
   d) A subcommittee of researchers with expertise that collectively covers the following subject areas:
      i) Communication;
      ii) Human development;
      iii) Psychology;
      iv) Neuroscience;
      v) Pediatrics;
      vi) A subcommittee of media and technology experts in the following subject areas:

vii) Computer science;
viii) Data privacy; and,
ix) User experience researchers;

e) A subcommittee of policy experts in the following subject areas:
   i) Communication law;
   ii) Policy research; and,
   iii) Economics;
f) A subcommittee of mental health professionals, consisting of the following:
   i) Therapists;
   ii) Psychiatrists; and,
   iii) Addiction specialists.

5) Requires the commission to meet for the first time on or before March 30, 2025, and to convene meetings at least quarterly at locations that are easily accessible to the public.

6) Requests the University of California to send, prior to the initial subcommittee meeting, an informational briefing to each committee's members for review that contains a summary document containing all of the following:
   a) A list and description of proposed, enacted, and failed legislation by each state relating to social media and child or adolescent well-being;
   b) A review of other countries' existing legislation relating to social media and child or adolescent well-being;
   c) A review of research on the outcomes of enacted legislation on adolescent social media use and mental health;
   d) A description of the goals and processes of the commission; and,
   e) A description of the legislative process with respect to the commission's purpose.

7) Requires subcommittees to meet a minimum of two times prior to the first commission-wide chairs' meeting.

8) Requires, during the first commission-wide chairs' meeting, each subcommittee chair to share the thoughts of their respective committee and receive feedback from the group.

9) Requires a final subcommittee meeting to occur following the commission-wide chairs' meeting to discuss any new information or recommendations from other committees. Requires, at this final subcommittee meeting, subcommittees to draft their official recommendation report.

10) Requires, at a final commission-wide chairs' meeting, subcommittee chairs to create a summary of recommendations that will be sent to commission leaders to draft a final report.

11) Permits the commission to establish advisory committees that include members of the public with relevant knowledge and experience that support stakeholder engagement and an analytical process by which key design options are developed.

12) Requires the commission and each advisory committee to keep official records of all of their proceedings.

13) Requires, on or before April 1, 2026, the commission to submit a report to the Legislature and the Governor that includes both of the following:
    a) A summary and analysis of the robust, multidisciplinary research and current regulatory practices regarding child and adolescent social media use and mental health with special consideration for parental, youth, and industry perspectives; and,
    b) A formal set of policy recommendations for legislators on how to effectively regulate social media to enhance youth safety and well-being. Authorizes the recommendations to include identifying areas where further investigation is needed to provide ongoing governance recommendations, particularly as technology and research in adolescent well-being co-evolve.

**EXISTING LAW**:

1) Establishes the Federal Children's Online Privacy Protection Act providing parents tools to control what information is collected from their children online. Requires the Federal Trade Commission to develop regulations requiring operators of commercial websites and online services directed to children under 13 or knowingly collecting personal information from children under 13 to: notify parents of their information practices; obtain verifiable parental consent for the collection, use, or disclosure of children's personal information; let parents prevent further maintenance or use of, or future collection of their child's personal information; provide parents access to their child's personal information; not require a child to provide more personal information that is reasonably necessary to participate in activities; and, maintain reasonable procedures to protect the confidentiality, security and integrity of the personal information. [15 United States Code §6501-6506]

2) Establishes the California Age-Appropriate Design Code Act requiring a business that provides an online service, product, or feature likely to be accessed by children to comply with specified requirements, including a requirement to configure all default privacy settings offered by the online service, product, or feature to the settings that offer a high level of privacy, unless the business can demonstrate a compelling reason that a different setting is in the best interests of children, and to provide privacy information, terms of service, policies, and community standards concisely, prominently, and using clear language suited to the age of children likely to access that online service, product, or feature. [Civil Code (CIV) §1798.99.28, *et seq.*]

3) Requires a business that provides an online service, product, or feature likely to be accessed by children to complete a Data Protection Impact Assessment for any new, publicly offered, online service, product, or feature likely to be accessed by children and maintain documentation of this assessment as long as the online service, product, or feature is likely to be accessed by children. Requires a business to biennially review all Data Protection Impact Assessments. [CIV §1798.99.31]

4) Requires the business' Data Protection Impact Assessment to identify the purpose of the online service, product, or feature, how it uses children's personal information, and the risks of material detriment to children that arise from the data management practices of the business, including:
    a) Whether the design of the online product, service, or feature could harm children, including by exposing children to harmful, or potentially harmful, content on the online product, service, or feature;

b) Whether the design of the online product, service, or feature could lead to children experiencing or being targeted by harmful, or potentially harmful, contacts on the online product, service, or feature;
c) Whether the design of the online product, service, or feature could permit children to witness, participate in, or be subject to harmful, or potentially harmful, conduct on the online product, service, or feature;
d) Whether the design of the online product, service, or feature could allow children to be party to or exploited by a harmful, or potentially harmful, contact on the online product, service, or feature;
e) Whether algorithms used by the online product, service, or feature could harm children;
f) Whether targeted advertising systems used by the online product, service, or feature could harm children;
g) Whether and how the online product, service, or feature uses system design features to increase, sustain, or extend use of the online product, service, or feature by children, including the automatic playing of media, rewards for time spent, and notifications; and,
h) Whether, how, and for what purpose the online product, service, or feature collects or processes sensitive personal information of children. [CIV §1798.99.31]

5) Establishes the California Children's Data Protection Working Group, as specified, which is required to deliver a report every two years to the Legislature with recommendations on, at minimum, the following:
   a) Identifying online services, products, or features likely to be accessed by children;
   b) Evaluating and prioritizing the best interests of children with respect to their privacy, physical health, and mental health and well-being and evaluating how those interests may be furthered by the design, development, and implementation of an online service, product, or feature;
   c) Ensuring that age assurance methods used by businesses that provide online services, products, or features likely to be accessed by children are proportionate to the risks that arise from the data management practices of the business, privacy protective, and minimally invasive;
   d) Assessing and mitigating risks to children that arise from the use of an online service, product, or feature;
   e) Publishing privacy information, policies, and standards in concise, clear language suited for the age of children likely to access an online service, product, or feature; and,
   f) How the working group and the Department of Justice may leverage the substantial and growing expertise of the California Privacy Protection Agency in the long-term development of data privacy policies that affect the privacy, rights, and safety of children online. [CIV §1798.99.32]

6) Establishes the California Consumer Privacy Act of 2018, which grants to a consumer various rights with respect to personal information, as defined, that is collected by a business, as defined, including the right to request that a business delete personal information about the consumer that the business has collected from the consumer. Authorizes a minor to disaffirm a contract before majority or within a reasonable time afterwards or, in case of the minor's death within that period, by the minor's heirs or personal representative. [CIV §1798.199.10]

7) Establishes the Privacy Rights for California Minors in the Digital World which prohibits an operator of an internet website, online service, online application, or mobile application from the following:

a) Marketing or advertising specified products or services, such as firearms, cigarettes, and alcoholic beverages, on its internet website, online service, online application, or mobile application that is directed to minors;
b) Marketing or advertising such products or services to minors who the operator has actual knowledge are using its site, service, or application online and is a minor, if the marketing or advertising is specifically directed to that minor based upon the personal information of the minor; and,
c) Knowingly using, disclosing, compiling, or allowing a third party to use, disclose, or compile, the personal information of a minor with actual knowledge that the use, disclosure, or compilation is for the purpose of marketing or advertising such products or services to that minor, where the website, service, or application is directed to minors or there is actual knowledge that a minor is using the website, service, or application. [Business & Professions Code §22580]

**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 promise of social media was to build virtual communities that would bring people together to share information and ideas. The author argues that in many ways, this promise has been fulfilled as some platforms have billions of users and act as a digital thread connecting friends and families. The author continues that unfortunately, social media companies have abused their position by prioritizing screen time and profits over the mental health of their users through their addictive design that exacerbates compulsive and obsessive behaviors detracting from real-world in-person engagement and contributing to social isolation. The author continues that teens and adolescents who use social media should be safe from harm. The author concludes that this bill will identify ways to counteract the addictive design of social media platforms by establishing a commission to investigate methods used by companies and recommend how to prevent future impacts on the mental health of children and adolescents.

2) **BACKGROUND.** According to the United States Surgeon General, mental health challenges are the leading cause of disability and poor life outcomes in young people. Research indicates that half of all mental health conditions begin by the age of 14 and more than 75% of mental health challenges develop before a person reaches the age of 24.
   a) **US Centers for Disease Control and Prevention (CDC)'s Youth Risk Behavior Survey Data Summary & Trends Report 2011-2021 (YRBS**): According to the YRBS, in 2021, 16% of high school students were electronically bullied, including through texting, Instagram, Facebook, or other social media, during the past year. Female students were more likely than male students to be electronically bullied. American Indian or Alaska Native and white students were more likely than students from most other racial and ethnic groups to be electronically bullied. LGBTQ+ students and students who had any same-sex partners were more likely than their peers to be electronically bullied. The percentage of male students who were electronically bullied increased from 2011 to 2021. The YRBS also reported that in 2021, 42% of high school students felt so sad or hopeless almost every day for at least two weeks in a row that they stopped doing their usual activities. Female students were more likely than male students to experience persistent feelings of sadness or hopelessness. Hispanic and multiracial students were more likely than Asian, Black, and white students to experience persistent feelings of

sadness or hopelessness. LGBTQ+ students and students who had any same-sex partners were also more likely than their peers to experience persistent feelings of sadness or hopelessness. Additionally, the survey found that 29% of high school students experienced poor mental health during the past 30 days. Female students were more likely than male students to experience poor mental health. Asian and Black students were less likely than Hispanic and multiracial students to experience poor mental health. Asian students were also less likely than white students to experience poor mental health. LGBTQ+ students and students who had any same-sex partners were more likely than their peers to experience poor mental health. Finally, the survey found that, in 2021, 22% of high school students seriously considered attempting suicide during the past year, 18% of high school students made a suicide plan during the past year, and 10% of high school students attempted suicide one or more times during the past year.

**b) Impact on Young Girls.** In reporting out the YRBS, the CDC stated that teen girls specifically are "engulfed in a growing wave of violence and trauma" experiencing record high levels of violence, sadness, and suicide risk amid significant and "heartbreaking" declines in youth health and wellbeing overall. Overall, the number of psychiatric-related hospital visits among young people increased 31% last year. For young women this number was far more grievous. Suspected suicide attempts in girls increased 50.6% compared to a 3.7% increase in young men. An August 2016 report in the *Harvard Health Publication* reported that between 1999 and 2014 deaths as a result of suicide rose by 200% among girls age 10 to 14 rising most sharply from 2006 on. According to a researcher with the CDC, "There is no question from this data young people are telling us that they are in crisis. There is this growing wave of violence and trauma that's affecting young people, especially teen girls and LGBTQ+ youth. Social media plays a major role stating that for girls and their social networks, even when they're socializing, they are not socializing in person, they are socializing through their phone or through some type of device rather than in-person." Social media also exposes girls to all kinds of negative social pressures. Body type expectations and the images that they're shown with the flood of information that we have available to us has detrimental effects and they are being exposed to them earlier and earlier in their lives when their brains are not prepared to deal with this information and know what to do with it.

**c) Prevalence and Effect of Cyberbullying on Children and Young People: A Scoping Review of Social Media Studies.** A literature review of existing publications that examine the health-related effects of cyberbullying via social media among children and adolescents was conducted in 2015. Eleven electronic databases were searched with studies screened by two independent reviewers. The findings included 36 studies in 34 publications. Most were conducted in the United States and sampled middle and high school populations and included adolescents who were 12 to 18 years of age. The review concluded that there is a consistent relationship across studies between cyberbullying and depression among children and adolescents; however the evidence further reflected the effect of cyberbully on other mental health conditions is inconsistent.

**d) Why Social Media Addiction is a Real Thing and the Dangers Associated with it.** A June 10, 2022, publication from Excelsior University reported that the majority of the dangers associated with social media stem from the idea that social media, like recreational drugs, sugar, etc., can be addicting.

- **i) Attachment Styles.** Social media allows humans to interact and form relationships on a grander level than ever before possible, connecting users across the globe in real-time. Relationships, whether in person or parasocial, (a one-sided relationship that a media user engages in with a media persona) are based on an individual's attachment

style. Attachment theory is a psychological theory that was developed in the 1950s and hypothesizes that the "affectional tie that individuals develop between themselves and another specific person is not based solely on food, safety, and other survival needs. Humans and other social animals need more—mainly love, affection, and acceptance." There have been numerous studies that suggest that how people use social media and how much information they make publicly available relates to their attachment style in relationships. If an individual is in healthy and secure relationships, they use social media very differently from those who are in more unhealthy circumstances. Those who have toxic attachment styles use social media in vastly different ways even from each other. If someone has high attachment anxiety, they struggle with abandonment, are overwhelmed by emotion, tend to pursue someone emotionally unavailable, and will likely be over sharers on social media and try to compensate for what they do not find in in-person relationships. Those who have high attachment avoidance, who avoid intimacy, who push others away, and tend to not trust, are not typically active social media users. Both types of attachment anxiety have shown a significant positive association between the attachment and a dysfunctional use of the internet and social media sites. Based on attachment styles, it is fair to assume that those who do not have healthy interpersonal relationships seek them out on the internet, and thus are more susceptible to the dangers that can be associated with parasocial relationships.

ii) **Social Media Addiction and Cyberbullying.** The same studies that look at attachment theory as it relates to social media use can also be used to predict social media addiction. Those who are deeply preoccupied about relationships tend to use social media as a therapy tool, a place where they can find the emotional support lacking in their day-to-day lives. When this many people who are like-minded use a platform such as TikTok, where they crave the immediate response and attention you can get uniquely from social media. The age group at risk for social media addiction is young adults and preteens, and given the increased access to technology and social media that this age group has, social media also creates a bigger risk for cyberbullying and mental health concerns. Prior to the rise of social media, cyberbullying existed but was not as widespread. Social media amplifies the effect of cyberbullying. Interestingly, a study by the University of Georgia, published in March of 2021 entitled, "Social Media Addiction Linked to Cyberbullying" suggests that increased hours spent online, and on social media platforms, results in higher social media addiction scores (at least in males), significantly predicting perpetration of cyberbullying.

iii) **Social Media Culture for Youth.** Social media is an entirely different culture for many, particularly youth. There is a separate set of societal norms associated with interacting with their peers on social media as opposed to in person. With the anonymity of social media and the ability to avoid retaliation, perpetrators feel less remorse for their actions and are held less accountable with consequences for their behavior. Many feel rewarded from the likes, comments, and shares that their actions on social media receive, even if they are aggressive or bullying in nature, which in turn will cause them to want to continue the behavioral pattern, and this can border on an addiction. In addition, individuals who have certain psychiatric conditions may be more susceptible to internet addiction, and in particular, social media addiction. Individuals with conditions such as obsessive compulsive disorder (OCD), attention hyperactivity deficit disorder (ADHD), or other mood disorders are more likely to report excessive use of social media than their neurotypical peers. A study conducted

in Norway suggests that those with ADHD are more likely to engage in excessive social networking as a form of self-medication, similar to those with anxious attachment styles. Whereas, those with OCD are driven to addictive social media use due to a "constant urge to check their networks for updates or fear of missing out.

**e)** **School Districts Sue Social Media Companies.** *Education Week* reported on January 31, 2024 that over 200 school districts have sued more than a dozen social media companies over the youth mental health crisis. In California, the San Mateo County School Board was the first of many California school boards and districts to file suit against the tech companies that run Facebook, Instagram, TikTok, Snapchat, WhatsApp, YouTube, and Google. According to a *Calmatters* report, the plaintiffs argue these platforms – and the algorithms designed to keep kids hooked – have caused unprecedented levels of anxiety, depression, bullying, eating disorders and suicidal ideation. The litigation points to research that has found a host of poor health, behavioral, and emotional outcomes associated with heavy social media use, such as depression, low self-esteem, cyberbullying, eating disorders, sleep deprivation, and more. The social media companies, in response to *The San Diego Union-Tribune* said they have taken many steps to regulate content for the sake of safety and well-being of their users. This is not the first issue over which school districts have engaged in mass litigation against corporate giants, alleging harm against their students. Hundreds of school districts nationwide had previously sued Juul Labs for its role in the youth vaping epidemic. Juul agreed to a nearly half-billion dollar settlement with six states, including California.

**3) RELATED LEGISLATION.**

**a)** AB 1282 (Lowenthal) requires the Mental Health Services Oversight and Accountability Commission on or before July 1, 2026 to report to the relevant policy committees of the Legislature a statewide strategy to understand, communicate, and mitigate mental health risks associated with the use of social media by children and youth. AB 1282 is currently pending on the Senate Inactive File.

**b)** AB 2390 (Arambula) establishes the Social Media Harm Reduction Pilot Program. AB 2390 is currently pending in Assembly Health Committee.

**c)** SB 764 (Padilla) provides protections to children performing in "vlogs," monetized content appearing on online platforms, as specified. This includes the establishment of trust accounts for the benefit of those minors and specified accounting practices. SB 764 is pending referral in the Assembly Rules Committee.

**4) PREVIOUS LEGISLATION.**

**a)** AB 1394 (Wicks), Chapter 579, Statutes of 2023, requires social media platforms to provide a mechanism for users to report child sexual abuse material in which they are depicted; provides platforms 30 to 60 days after receiving a report to verify the content of the material and block it from reappearing. Also provides victims of commercial sexual exploitation the right to sue social media platforms for having deployed features that were a substantial factor in causing their exploitation.

**b)** SB 287 (Skinner) of 2023 would have subjected social media platforms to civil liability for damages caused by their designs, algorithms, or features, as provided. SB 287 would

have provided a safe harbor where certain auditing practices are carried out. SB 287 was held on the Senate Floor.

**c)** AB 2273 (Wicks), Chapter 320, Statutes of 2022, establishes the California Age-Appropriate Design Code Act which generally requires businesses that provide online services, products, or features likely to be accessed by children to comply with specified standards.

**d)** AB 2408 (Cunningham) of 2022 would have created the Social Media Platform Duty to Children Act prohibiting a social media platform, as defined from using a design, feature, or affordance that the platform knew, or by the exercise of reasonable care should have known, causes a child user, as defined, to become addicted to the platform. AB 2408 was held on the Senate Appropriations suspense file.

**e)** AB 1628 (Ramos), Chapter 432, Statutes of 2022, requires until January 1, 2028, and subject to specified exceptions, a social media platform, as defined, that operates in the state to create and publicly post a policy statement that includes, among other things, the platform's policy on the use of the platform to illegally distribute a controlled substance, as defined, and a link to the platform's reporting mechanism for illegal or harmful content or behavior if one exists.

**f)** AB 2879 (Low), Chapter 700, Statutes of 2022, requires a social media platform to disclose all cyberbullying reporting procedures in the platform's terms of service, and would require a platform to establish a mechanism within its internet-based service that allows an individual, whether or not that individual has a profile on the internet-based service, to report cyberbullying or any content that violates the existing terms of service.

5) **DOUBLE REFERRAL.** This bill is double referred, upon passage of this Committee it will be referred to the Assembly Committee on Privacy and Consumer Protection.

6) **POLICY COMMENT.** This bill has significant overlap with other proposals that this committee has and is considering this legislative session. In order to avoid duplication of efforts, the author may wish to coordinate with other authors to ensure the Legislature is taking a collaborative and intentional approach to this important issue.

**REGISTERED SUPPORT / OPPOSITION**:

**Support**

None on file.

**Opposition**

None on file.

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

Date of Hearing: April 9, 2024

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 2700 (Gabriel) – As Amended April 1, 2024

**SUBJECT**: Emergency medical services: alternate destinations.

**SUMMARY**: Requires the state to survey and analyze the facilities in each county that could serve as an alternate destination facility. Requires the Emergency Medical Services Authority (EMSA) to publish a report that provides each local emergency services agency (LEMSA) with the current number, capacity and type of alternate destination facilities. Requires a LEMSA, in consultation with the county, to develop an alternate destination facility plan with protocols for transporting an individual to an alternate destination facility instead of an emergency department (ED). Specifically, **this bill**:

1) Requires the state to survey and analyze the facilities in each county that can serve as an alternate destination facility. Requires EMSA to publish a report on its internet website that provides each LEMSA with the current number, capacity, and type of alternate destination facilities, as well as the needed number, capacity, and type of alternate destination facilities necessary to meet current demand for services.

2) Requires a LEMSA, in consultation with the county department or departments relevant to behavioral health within its jurisdiction, to develop an alternate destination facility plan with protocols for transporting an individual to an alternate destination facility instead of an ED.

3) Requires the plan developed pursuant to 2) above, to do both of the following:
   a) Ensure that transportation to an ED is no longer the default protocol for an individual in need of mental or behavioral health care services; and,
   b) Utilize existing facilities identified in the report published pursuant to 1) above.

2) Defines the following for purposes of this bill:
   a) "Alternate destination facility" means a treatment location that serves as an alternative to an ED, including a mental health facility or sobering center;
   b) "EMS" means emergency medical services;
   c) "Mental health facility" means a facility that is licensed or certified as a mental health treatment facility or a hospital, and can include a licensed psychiatric hospital, a licensed psychiatric health facility, or a certified crisis stabilization unit. Specifies that an authorized mental health facility can also be a psychiatric health facility licensed by the State Department of Health Care Services (DHCS).
   d) "Sobering center" means a noncorrectional facility that is staffed at all times with at least one registered nurse, that provides a safe, supportive environment for intoxicated individuals to become sober, and that meets any of the following requirements:
      i) The facility is a federally qualified health center, including a clinic exempt from licensure by the Department of Public Health (DPH);
      ii) The facility is certified by DHCS Substance Use Disorder Compliance Division to provide outpatient, nonresidential detoxification services; or,
      iii) The facility meets the National Sobering Collaborative standard of care.

**EXISTING LAW**:

1) Establishes EMSA, which is responsible for the coordination and integration of all state activities concerning EMS), including the establishment of minimum standards, policies, and procedures. [Health and Safety Code (HSC) §1797.100, *et seq*.]

2) Authorizes counties to develop an EMS program and designate a LEMSA responsible for planning and implementing an EMS system, which includes day-to-day EMS system operations. [HSC §1797.200, et seq.]

3) Defines "Emergency Medical Technician-Paramedic," "EMT-P," "paramedic" or "mobile intensive care paramedic" as an individual whose scope of practice includes the ability to provide advanced life support, as specified, including administering specified medications. EMT-Ps are licensed and regulated at the state level through EMSA. [HSC §1797.84]

4) Establishes the Health Workforce Pilot Projects (HWPP) in the Department of Health Care Access and Information (HCAI) which states legislative findings that experimentation with new kinds and combinations of health care delivery systems is desirable and that for purposes of this experimentation, a select number of publicly evaluated HWPPs should be exempt from the healing arts practices acts. [HSC §128125, *et seq*.]

5) Permits HCAI to designate HWPPs as approved projects where the projects are sponsored by community hospitals or clinics, nonprofit educational institutions, or governmental agencies engaged in health or education activities. Permits a trainee (defined as a person being taught health care skills) in an approved project to perform health care services under the supervision of a supervisor (someone who is already licensed to provide the health care services) where the general scope of the services has been approved by HCAI. [HSC §128135 and §128140]

6) Establishes the Community Paramedicine or Triage to Alternate Destination Act of 2020. Defines “community paramedicine program” as consisting of one of two specialties: providing directly observed therapy to persons with tuberculosis in collaboration with a public health agency; and, providing case management services to frequent EMS users in collaboration with, and by providing referral to, existing appropriate community resources. Defines “triage to alternate destination” as consisting of three specialties: providing care and comfort services to hospice patients in their homes in response to 911 calls; providing patients with advanced life support triage and assessment by a triage paramedic and transportation to an alternate destination facility, which can include an authorized mental health facility or an authorized sobering center; and, providing transport services for patients who identify as veterans and desire transport to a local veterans administration ED for treatment. [HSC §1800 et seq.]

7) Requires EMSA to develop regulations that establish minimum standards for the development of a community paramedicine or triage to alternate destination program, and requires the Commission on EMS to review and approve the regulations. Requires the regulations to be based upon, and informed by, the Community Paramedicine Pilot Program under HWPP #173, and the protocols and operation of the pilot projects approved under HWPP #173. [HSC §1830]

8) Requires hospital EDs, under the federal Emergency Medical Treatment and Active Labor Act (EMTALA) and also under similar provisions of state law (state EMTALA), to provide emergency screening and stabilization services without regard to the patient's insurance status or ability to pay. Federal EMTALA imposes this requirement on any hospital that participates in Medicare. State EMTALA imposes this requirement on any hospital that operates an ED. [HSC §1317, *et seq*.]

9) Establishes the Lanterman-Petris-Short (LPS) Act and declares the intent of the Legislature to end the inappropriate, indefinite, and involuntary commitment of persons with mental health disorders, developmental disabilities, and chronic alcoholism, as well as to safeguard a person's rights, provide prompt evaluation and treatment, and provide services in the least restrictive setting appropriate to the needs of each person. [Welfare and Institutions Code (WIC) §5000, *et seq*.]

10) Authorizes, under Section 5150 of the WIC, a peace officer, member of the attending staff of a designated facility, member of the attending staff of a designated facility, or other professional person designated by the county, upon probable cause, to take a person with a mental disorder who is a danger to self or others, or is gravely disabled, into custody (a "5150" hold) and place him or her in a designated facility. [WIC §5150]

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

**COMMENTS**:

**1) PURPOSE OF THIS BILL.** According to the author, California is facing a behavioral health crisis and we have a responsibility to use all appropriate and effective tools to address it. This bill ensures that local governments are prepared to provide these critical services to people in need. The author concludes that by planning ahead for the potential use of alternative destination sites, like crisis stabilization units and sobering centers, we will ensure we strike a balance to keep patients safe and healthy

**2) BACKGROUND.**

**a) The Community Paramedicine or Triage to Alternate Destination Act**. In November of 2014, the Office of Statewide Health Planning and Development (which has since been merged into HCAI) approved an application from EMSA to establish HWPP #173, to test different concepts of community paramedicine. Initially, HWPP #173 encompassed 13 sites testing six concepts, with more sites added over the ensuring years, including a seventh concept testing transporting patients to a sobering center. HWPP #173 was extended multiple times, and over the years, some sites were added while other pilot project sites were shut down. The following are the concepts that were tested by this pilot project:

**i)** Post-Discharge Short-Term Follow-Up, intended to provide home-based follow up care to people recently discharged from a hospital due to a chronic condition;

**ii)** Frequent EMS Users, intended to provide case management to frequent 911 callers and frequent visitors to EDs by connecting them with primary care, behavioral health, housing, and social services;

**iii)** Directly Observed Therapy for Tuberculosis, where the paramedic dispensed medication and observed patients taking them to assure effective treatment;

**iv)** Hospice, where paramedics, in response to 911 calls, collaborated with hospice agency nurses, patients, and family members to treat patients in their homes, according to their wishes, instead of transporting to an ED;

**v)** Alternate Destination – Behavioral Health, where paramedics, in response to 911 calls, offer to transport people who have behavioral health needs but no emergency medical needs to a mental health crisis center instead of an ED;

**vi)** Alternate Destination – Urgent Care, where paramedics, responding to 911 calls, offer people with low-acuity medical conditions transport to an urgent care center instead of an ED; and,

**vii)** Alternate Destination – Sobering Center, where paramedics, in response to 911 calls, offer people who are acutely intoxicated but do not have acute medical or mental health needs transport directly to a sobering center for monitoring instead of an ED.

After several legislative attempts to authorize these concepts in statute to make them permanent, AB 1544 (Gipson), Chapter 138, Statutes of 2020, was signed into law in 2020, creating the Community Paramedicine or Triage to Alternate Destination Act. Of the seven concepts, all were included in AB 1544 except for two: Alternate Destination – Urgent Care, which was not included because all project sites testing this concept had closed down; and Post-Discharge, Short-Term Follow-up, which had mixed results in early test sites, described in more detail in 3) below. While Post-Discharge, Short-Term Follow-up was not included as part of the Community Paramedicine or Triage to Alternate Destination Act, AB 1544 did include a provision permitting the two remaining pilot project sites in that specialty at the time, Solano County and the City of Alameda (since closed down), to continue operating until January 1, 2024.

AB 1544 required EMSA to adopt regulations implementing the bill, and included a provision that permitted the existing pilot programs to continue operating while the regulations were being developed until up to one year after EMSA adopted the regulations. Once the regulations were adopted, EMSA could approve additional community paramedic or alternative destination programs that were developed by LEMSAs, and the existing pilot programs would have to be approved to continue after the initial year. However, regulations were not finalized until October 31, 2022, and because the entire program was scheduled to sunset in January of 2024, no new programs were added, and some pilot project sites are no longer operating. AB 1544 extended the sunset on these pilot programs to January 1, 2031.

**b) Paramedic training and scope of practice.** Under regulations adopted by EMSA, paramedic training consists of a minimum of 1090 hours. These training hours are divided into: 450 hours of didactic instruction and skills laboratories; 160 hours of hospital clinical training; and, a field internship of 480 hours. During the field internship, the paramedic student is required to have a minimum of 40 advanced life support patient contacts, which is defined as the student performance of one or more of advanced life support skills. Following the training program, paramedic applicants are required to pass both a written and practical examination. In addition to state licensure by EMSA, paramedics are required to have "local accreditation" by a LEMSA in order to practice as a paramedic within that jurisdiction. Under their scope of practice, a paramedic is authorized to perform specified advanced life support procedures and administer specified medications while at the scene of a medical emergency or during transport or during interfacility transfer, or while working in a small and rural hospital, as specified.

Procedures that paramedics are authorized to perform include utilizing and monitoring electrocardiograms, defibrillation, adult endotracheal intubation, instituting intravenous catheters or other IV lines in peripheral veins, and monitoring and administering medications through pre-existing vascular access. Regulations specify a list of 25 medications that a paramedic is authorized to administer.

**c) Status of Community Paramedicine and Triage to alternate Destination Projects.** According to the final report by the independent evaluation team at UC San Francisco, with data through September of 2022, the alternate destination for mental health patients have reduced the number of persons in EDs who only need mental health services.

**Alternate Destination – Mental Health**. The four projects enrolled 8,332 persons between September 2015 and September 2022; 2,757 were enrolled after AB 1544 implementation. Across the four Alternate Destination –Mental Health projects, large percentages of patients screened were transported to the mental health crisis center rather than an ED:

**i)** Stanislaus' project transported 28% of the 1,997 patients screened to a mental health crisis center between September 2015 and its closure in July 2022.

**ii)** Fresno's project transported 33% of the 23,152 patients screened between July 2018 and September 2022 to a mental health crisis center.

**iii)** Gilroy's project transported 40% of the 287 patients screened between November 2018 through September 2022 to a mental health crisis center.

**iv)** Los Angeles' project transported 27% of the 302 patients screened between June 2019 and June 2020 to a mental health crisis center. Some patients who were eligible for transport to a mental health crisis center were taken to an ED instead because the crisis center was at capacity.

Transport of patients directly to a mental health crisis center has reduced the number of persons in EDs who only need mental health services, which may help reduce ED overcrowding. Only 2% of patients enrolled in the three Alternate Destination– Mental Health projects (n = 160) were transferred from the mental health crisis center to an ED within six hours of admission. None of the transfers involved a life-threatening condition, and only 20 of the patients transferred to an ED were admitted for inpatient medical care. Ambulance patient offload times at mental health crisis centers are substantially shorter than at EDs in the same communities, which enables 911 response crews who transport patients to the crisis centers to return to the field to respond to other 911 calls more quickly. Law enforcement officers report that having community paramedics available enhances their ability to respond effectively to persons with mental health needs.

**Alternate Destination – Sobering Center**. The three Alternate Destination– Sobering Center projects enrolled 3,906 persons from February 2017 through September 2022; 847 of those patients were enrolled after AB 1544 implementation. Most patients (3,810) were enrolled in San Francisco's Alternate Destination– Sobering Center project. Los Angeles' Alternate Destination– Sobering Center project has enrolled 96 people since it launched in late June of 2019, however no new

patients have enrolled since early 2020. The Santa Clara County EMS Agency and the Gilroy Fire Department's Alternate Destination – Sobering Center project closed in May 2022. Ninety-eight point three percent of patients enrolled in San Francisco's Alternate Destination – Sobering Center project were treated safely and effectively at the sobering center. Only 64 patients (1.6%) were transferred to an ED within six hours of admission to the sobering center, and only three (0.1%) were rerouted from the sobering center to an ED because registered nurses at the sobering center declined to accept them. Only 12 patients were admitted to a hospital for inpatient medical care. None of the patients enrolled in Los Angeles' Alternate Destination – Sobering Center project were transferred to an ED within six hours of admission. The 90th percentile ambulance patient offload time at San Francisco's sobering center is 17 minutes, whereas the 90th percentile ambulance patient offload time for patients transported to all EDs in San Francisco is 34 minutes. This enables 911 response crews who transport patients to the crisis centers to return to the field to respond to other 911 calls more quickly. Data were not available for Los Angele's Alternate Destination – Sobering Center project

3) **SUPPORT.** The Steinberg Institute (SI) is the sponsor of this bill and states that California is increasingly focusing on delivering compassionate care to individuals in behavioral health crises. In 2022, California passed AB 988 (Bauer-Kahan), Chapter 747, Statutes of 2022, to set up an alternative crisis response system to 911. SI notes that we have invested billions into behavioral health crisis facilities infrastructure through the Behavioral Health Continuum Infrastructure Program, with billions more potentially on the horizon with Proposition 1, and through CalAIM, we have added sobering centers as an optional new benefit and added Medi-Cal coverage for these vital services. SI states that at the same time, over the last six years, California has been piloting programs to transport individuals in behavioral health crises to destinations such as crisis stabilization units and sobering centers as appropriate. An independent University of California, San Francisco evaluation found these pilots to be safe and effective means to improve the health and safety of the public. The evaluation found that 98% of patients transported to a mental health crisis center were effectively treated for their behavioral health needs. The evaluation also found that ambulance patient offload times were considerably lower for transports to mental health crisis and sobering centers, meaning ambulance crews can respond more quickly to other 911 calls. In order to maximize California's substantial investments in addressing the behavioral health crisis care, expanding access to these services is critical. Now is the time to expand access to alternative destinations. A key aspect to the expansion of these services is having an assessment of the available behavioral health facilities, and their needs along with a plan to transport people in need of care to these facilities.

4) **OPPOSITION.** The California Nurses Association (CNA) is opposed to this bill and states that the proposed new triage to alternate destination program for patients with behavioral health needs would dangerously eliminate access to emergency medical care for patients with behavioral health needs. In other words, under this bill, people who call 911 but have or appear to have any mental or behavioral health need will no longer by default be provided with emergency care at an ED. CNA contends that this bill requires that LEMSAs develop triage to alternate destination plans that "[e]nsure that transportation to an ED is no longer the default protocol for an individual in need of mental or behavioral health care services." (emphasis added).

5) **OPPOSE UNLESS AMENDED.** The California Chapter of the American College of Emergency Physicians (CalACEP) is opposed to this bill unless it is amended and notes that when the successful pilots were taken to scale statewide, it was important to ensure that they operate under the same training and conditions. CalACEP states that in 2020, they took what they learned from those pilots and used them to inform their co-sponsorship of AB 1544 which was signed into law and, among other things, allowed LEMSAs to create programs to transport 911 callers to mental health facilities rather than EDs. Last year they co-sponsored AB 767 (Gipson), Chapter 270, Statutes of 2023, to extend the sunset on that law. CalACEP notes that the framework established by those bills and enacted in HSC Sections 1800-1857 created statewide standards for training of EMS personnel – including required hours and curriculum content, patient safety protocols, minimum standards, anti-discrimination protections, and reporting and data collection provisions. However, as currently written, this bill proposes to transport 911 callers to mental health facilities entirely outside of that existing patient safety framework. CalACEP also contends that the bill specifically directs LEMSAs to "ensure that transportation to an ED is no longer the default protocol for an individual in need of mental or behavioral health care service," and that this language statutorily overrides medical decision-making. CalACEP concludes that creating a new untested system with no standards or requirements for training of EMS personnel, patient safety protocols, or anti-discrimination protections, as currently proposed by this bill is an unnecessary threat to public safety.

   The California Professional Firefighters (CPF) are oppose unless amended and notes that reviewing data from the pilot programs, alternate destination programs have proved successful in diverting non-emergent patients from the emergency room, with only 2% of patients transported to either a mental health crisis center or a sobering center requiring subsequent transport to the ED. The current regulatory system is built to ensure this type of patient outcome. CPF believes that by placing the requirements of this bill in code sections separate from the pilot programs will have the effect of mandating the adoption of alternate destination programs in each community without the statutory structure that is currently contained in Health and Safety Code and subsequent regulations adopted by EMSA.

6) **PREVIOUS LEGISLATION.**

   **a)** AB 767 adds short-term, post discharge follow-up for persons recently discharged from a hospital to the list of eligible community paramedicine services and requires the Emergency Medical Authority (EMSA) to amend existing regulations to include that service. Extends the sunset date of the community paramedicine program from January 1, 2024, to January 1, 2031.

   **b)** AB 1544 establishes the Community Paramedicine or Triage to Alternate Destination Act of 2020, which permits LEMSAs, with approval by EMSA, to develop programs to provide community paramedic or triage to alternate destination services in one of the following specialties: i) providing directly observed tuberculosis therapy; ii) providing case management services to frequent emergency medical services users; iii) providing hospice services to treat patients in their homes; and, iv) providing patients with transport to an alternate destination, which can either be an authorized mental health facility, or an authorized sobering center.

7) **DOUBLE REFERRAL**. This bill is double referred, upon passage in this Committee, this bill will be re-referred to the Assembly Committee on Emergency Management.

8) **SUGGESTED AMENDMENTS.** As currently drafted this bill places a statewide expansion of the triage to alternate destination provisions of the Community Paramedicine Pilot Project. In order to address concerns raised by Cal-ACEP and the California Professional Firefighters, the author may wish to consider amending this bill to clarify that the alternate destination programs implemented by this bill will be subject to existing EMSA regulations.

**REGISTERED SUPPORT / OPPOSITION**:

**Support**

California Association of Alcohol and Drug Program Executives, INC.
California Consortium of Addiction Programs and Professionals
California Hospital Association
Californians for Safety and Justice
Ella Baker Center for Human Right
Freedom 4 Youth
Initiate Justice
MILAP Collective
National Sobering Collaborative
Phoenix Houses of California, INC.
Prosecutors Alliance of California, a Project of Tides Advocacy
Rubicon Programs
Steinberg Institute
The California Association of Local Behavioral Health Boards and Commissions
The Kennedy Forum
The Miles Hall Foundation
Wellspace Health
Youth Leadership Institute

**Opposition**

California Nurses Association

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

Date of Hearing: April 9, 2024

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 2701 (Villapudua) – As Introduced February 14, 2024

**SUBJECT**: Medi-Cal: dental cleanings and examinations

**SUMMARY**: Requires Medi-Cal dental coverage of one additional prophlaxis cleaning and periodic dental exam per year for adults age 21 and over, thereby aligning standards that apply to adults and children by allowing both services to be billed twice a year for all Medi-Cal enrollees.

**EXISTING LAW**:

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

2) Establishes a schedule of benefits under the Medi-Cal program, which includes federally required and optional Medicaid benefits. [WIC §14132]

3) Specifies coverage of adult dental benefits. [WIC § 14131.10]

4) To the extent funds are made available in the annual Budget Act, covers one prophlaxis cleaning and periodic dental exam per year for adults age 21 and over. [WIC § 14132.88]

**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 will expand California's Medi-Cal Dental benefits to include a second cleaning and exam for adults aged 21 and over. With a second cleaning and exam, the author asserts, dentists can detect any oral health complications, prevent tooth loss, and even detect early heart problems as several reports suggest poor dental health is linked to diabetes, dementia, and cardiovascular diseases. The author concludes a second cleaning and exam is essential to maintain good oral health and overall health. This bill is sponsored by the California Dental Association (CDA).

2) **BACKGROUND.**

   a) **Medicaid Requirements and State Optional Benefits**. State Medicaid programs are required to provide certain benefits, and may choose to provide others at state option. All Medicaid programs cover dental services for all child enrollees as part of a comprehensive set of benefits, referred to as the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefit. A referral to a dentist is required for every child in accordance with the periodicity schedule set by a state (in California, the American Academy of Pediatrics "Bright Futures" periodicity schedule of preventive health care).

   Adult dental benefits are optional for states, meaning they have flexibility to determine what dental benefits are provided to adult Medicaid enrollees. According to the Centers

for Medicare and Medicaid Services, while most states provide at least emergency dental services for adults, less than half of the states currently provide comprehensive dental care. There are no minimum federal requirements for adult dental coverage.

**b) Medi-Cal Adult Dental Coverage and Recent Adult Dental Changes**. Medi-Cal now covers a fairly comprehensive set of adult dental benefits at the state's option. However, along with a list of other optional Medi-Cal benefits, adult dental benefits were eliminated from Medi-Cal in 2009 as a budget cost-cutting solution. In May 2014, pursuant to AB 82 (Committee on Budget), Chapter 23, Statutes of 2013, Medi-Cal adult dental benefits were partially restored. The 2014 restored benefits included basic preventive, diagnostic, restorative, anterior tooth endodontic treatment, complete dentures and complete denture reline/repair services. SB 97 (Committee on Budget and Fiscal Review), Chapter 52, Statutes of 2017, fully restored adult optional dental benefits that were not restored in May 2014, effective January 1, 2018, including additional exams, deep cleanings (scaling and root planing), laboratory crowns, partial dentures, and root canals in back teeth.

Medi-Cal will pay up to $1,800 in a year for covered dental services for adults, although there are exceptions for pregnancy and medically necessary services that exceed the $1,800 limit on a case by case basis.

**c) This Change Appears Consistent with Professional Recommendations and Other Dental Coverage…** Dentists recommend twice yearly dental visits, and commercial plans generally cover the services at this cadence. According to Delta Dental, a large California dental insurer, their plans cover twice yearly dental visits for diagnostic and preventive care, and even incentivize utilization of these services by covering them with zero copayment and without counting the cost against the maximum plan benefit. In addition, it is self-evident that having a checkup more than once a year is opportunity for the dentist to catch early signs of cavities or other oral health diseases before they progress. According to the Centers for Disease Control and Prevention, 26% of adults in the U.S. have untreated tooth decay. Adults who are low-income are two times more likely to have untreated cavities than comparison groups. Establishing parity with commercial coverage for those insured by Medi-Cal would make coverage more equitable and provide greater opportunity to maintain oral health. Furthermore, according to the CareQuest Institute for Oral Health Medicaid Adult Dental Coverage Checker, 28 other state Medicaid programs allow two or more cleanings per year.

**d) …But the Evidence Basis is Surprisingly Thin.** The U.S. Preventive Services Task Force makes recommendations for preventive health care, such as screenings, exams, and vaccines, and is known as a trusted source of exhaustively vetted, evidence-based, and expert recommendations. There does not appear to be a similarly authoritative, evidence-based source for preventive dental care, nor any firm professional guideline. Although the twice yearly cadence is commonly accepted in the dental community and the American Dental Association (ADA) issues a number of other evidence-based clinical practice guidelines, systematic reviews, and studies, the ADA does not appear to have an evidence-based guideline that twice yearly exams and cleanings is the "right" number for all adults. However, it is certain that covering up to two visits in Medi-Cal would provide a benefit for adults for which twice yearly visits are necessary based on their particular oral health circumstances. Finally, CDA indicates twice yearly is the standard of care.

Further research on the effectiveness of once yearly versus twice yearly visits would be a valuable contribution to the scientific literature.

**e) Dental Provider Shortage and Low Utilization**. It is important to consider the expansion of adult dental benefits in context of current utilization of the Medi-Cal dental program and overall challenges in access to dental providers. According to the February 2024 Dental Fee-For-Service and Dental Managed Care Performance Fact Sheet published by DHCS, Dental Utilization in Adults Ages 21+, only about a quarter of adults have had an annual dental visit over the last several years. This is among adults enrolled in fee-for-service Medi-Cal Dental (the majority of Medi-Cal enrollees), while utilization among adults enrolled in most dental plans in Sacramento and Los Angeles counties were even lower.

According to the Health Services Resource Administration, 2.9 million Californians live in 535 designated health professional shortage areas. Dentists even in areas with an adequate workforce are less likely to accept new patients insured by Medicaid.

**3) SUPPORT.** This bill is supported by consumer advocacy organizations, the County Health Executives Association of California (CHEAC), and Association of Regional Center Agencies, among others. According to CHEAC, the Centers for Disease Control and Prevention notes dental disease and tooth loss is disproportionately high among individuals who have lower incomes, and over 40% of low-income non-Hispanic Black adults have untreated tooth decay which impacts the quality of life and productivity of those individuals. CDA indicates the current limit is contradictory to the standard of care, which is a minimum of two exams and cleanings a year, or every six months, to ensure maximum preventive care against dental diseases.

**4) RELATED LEGISLATION.** SB 980 (Wahab) expands Medi-Cal dental coverage for crowns and dental implants. SB 980 is pending in the Senate Appropriations Committee.

**5) PREVIOUS LEGISLATION.**

**a)** SB 184 (Committee on Budget and Fiscal Review), Chapter 47, Statutes of 2022, requires DHCS to consider evidence-based practices consistent with the American Academy of Pediatric Dentistry and the ADA guidelines for all covered dental benefits, and provides Medi-Cal dental coverage of laboratory-processed crowns on posterior teeth for adults older when medically necessary to restore a posterior tooth back to normal function.

**b)** AB 82 partially restored Medi-Cal adult dental benefits including basic preventive, diagnostic, and restorative services.

**c)** SB 97 fully restored adult optional dental benefits that were not restored through AB 82.

**REGISTERED SUPPORT / OPPOSITION**:

**Support**

California Dental Association (sponsor)
Association of Regional Center Agencies

California Pan - Ethnic Health Network
California Retired Teachers Association
County Health Executives Association of California
Justice in Aging
Western Center on Law & Poverty, Inc.

**Opposition**

None on file.

**Analysis Prepared by**: Lisa Murawski / HEALTH / (916) 319-2097

Date of Hearing: April 9, 2024

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 2749 (Wood) – As Amended March 18, 2024

**SUBJECT**: California Health Benefit Exchange: financial assistance.

**SUMMARY**: Revises the criteria for a qualifying individual to receive financial assistance as a result of a labor dispute under California's Health Benefit Exchange (the Exchange or Covered California). Requires an employer or labor organization to notify Covered California before employer-provided coverage is affected by a strike, lockout, or labor dispute (labor dispute). Requires the Exchange to suspend the financial assistance provided, including suspending new enrollments, if funds accrued exceed the appropriation for Covered California's financial assistance program for labor disputes. Specifically, **this bill**:

1) Revises Covered California's financial assistance program to apply to qualified individuals instead of prospective enrollees.

2) Requires an individual to be a qualified individual for purposes of financial assistance, including premium assistance and cost-sharing reduction subsidies, if all of the following are met:
   a) The individual loses minimum essential coverage (MEC) from an employer as a result of a labor dispute;
   b) The employer that provided the MEC to the individual is involved in the labor dispute; and,
   c) The individual provides a self-attestation confirming that they lost MEC from an employer as a result of a labor dispute, and that the employer that provided them the MEC is involved in the labor dispute.

3) Revises the effective date of coverage to be the first day of the month of application submission and plan selection or the first day of the following month, at the discretion of the qualified individual.

4) Prohibits an individual, upon resolution of labor dispute, from being eligible for financial assistance under this bill when the Exchange verifies that employer-provided MEC from the employer has been reinstated for that individual and dependents and only after prior notification to the qualified individual of loss of financial assistance under this bill.

5) Requires an employer or labor organization to notify the Exchange before employer-provided coverage is affected by a labor dispute pursuant to a process established by the Exchange. Allows the Exchange to contact an employer, labor organization, or other appropriate representative to determine the status of a labor dispute, its impact to coverage, and any other information necessary to determine eligibility for financial assistance under this bill.

6) Specifies the Exchange's duties to implement this program are contingent upon an appropriation from the Legislature. Requires the Exchange to suspend the financial assistance provided pursuant to this bill, including suspending new enrollments in the program, if funds accrued under the program exceed the appropriation.

7) Defines the following: employer-provided coverage; labor dispute; labor organization; lockout; and, strike consistent with existing law.

**EXISTING LAW**:

1) Establishes the federal Patient Protection and Affordable Care Act (ACA), which enacts various health care coverage market reforms, including the availability of health insurance exchanges, coverage of essential health benefits, a prohibition against imposing a preexisting condition provision, a requirement to maintain MEC, imposing a shared responsibility penalty (individual mandate) on an applicable individual who does not maintain MEC, to fairly and affirmatively offer, market, and sell all of the health plan's health benefit plans that are sold in the individual and small group market, and to provide federal financial assistance to eligible individuals. [42 United States Code 300gg, *et seq*.]

2) Establishes Covered California as the Exchange for individual and small business purchasers and authorized under the ACA. [Government Code (GOV) § 100500 -100522]

3) Requires an Individual Shared Responsibility Penalty to be imposed for failure to meet the requirement of the MEC Individual Mandate. [GOV § 100705]

4) Creates the Health Care Affordability Reserve Fund, and, requires the Fund to be utilized, in addition to any other appropriations made by the Legislature for the same purpose, for the purpose of health care affordability programs operated by Covered California. [GOV § 100520.5]

5) Creates, until January 1, 2023, the Individual Market Assistance Program, which authorizes the Exchange to provide health care coverage financial assistance to California residents with household incomes at or below 600% of the federal poverty level (FPL), including advanced premium assistance subsidies. [GOV § 100800]

6) Requires Covered California to, beginning July 1, 2023, and upon appropriation by the Legislature, administer a program of financial assistance to help Californians obtain and maintain health benefits through the Exchange if they lose employer-provided health care coverage as a result of a labor dispute. [GOV § 100523]

7) Specifies that an individual who has lost MEC from an employer or joint labor management trust fund as a result of a labor dispute is a prospective enrollee for purposes of financial assistance, including premium assistance and cost-sharing reduction subsidies, provided that the individual meets all eligibility requirements, as specified. Prohibits any household income of the prospective enrollee above 138.1% of the FPL for a family of the prospective enrollee's size from being taken into account for the prospective enrollee and the members of their tax household. Requires an individual to be screened for eligibility for the federal Medicaid program consistent with existing federal law and rules. [GOV § 100523(a)(1)]

8) Requires an individual to receive subsidies for health insurance premiums and cost-sharing reductions that provide the same assistance that is provided to other individuals with incomes of 138.1% of FPL who qualify for financial assistance under 6) above. Requires the cost-sharing reductions to use a standard benefit design that has an actuarial value of 94% or greater, and, effective January 1, 2024, the program design to have zero deductibles for any

covered benefit if the standard benefit design for this income has zero deductibles. Prohibits the modified adjusted gross income (MAGI) or household income of an individual described in 7) above from being calculated to include strike benefits, lockout benefits, or unemployment compensation. [GOV § 100523(a)(2)-(3)]

9) Requires an individual to provide a self-attestation regarding the loss of MEC as a result of a dispute to receive financial assistance under 6) above. Requires the Exchange to contact the affected collective bargaining agent and contact the employer if further documentation is required. [GOV § 100523((b)(1)]

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

**COMMENTS**:

**PURPOSE OF THIS BILL.** According to the author, AB 2530 (Wood), Chapter 695, Statutes of 2022, provides workers who lose health benefits due to a labor dispute a slightly improved version of the most affordable coverage package offered by Covered California. This is similar to what the federal American Rescue Plan has done for those on unemployment insurance during the COVID-19 pandemic, providing premium subsidies and cost-sharing assistance as if the worker's income was just over the Medi-Cal eligibility level. AB 2530 was an instrumental step in the right direction, but further clarification is needed. This bill would further clarify eligibility to ensure that the program helps the intended consumers. The author concludes that this bill provides definitions and clarifies language to allow for the successful implementation of the program by Covered California.

**1) BACKGROUND.**

**a) ACA**. Enacted in March 2010, the ACA provides the framework, policies, regulations and guidelines for the implementation of comprehensive health care reform by the states and expands access to quality, affordable insurance and health care. Under the ACA, qualified individuals are able to obtain financial assistance for health insurance purchased on the Exchange. A person must be a citizen or lawfully present, must have qualifying income, and not be eligible for government programs or not have affordable coverage through an employer. This bill clarifies eligibility requirements for Covered California to administer a financial assistance program for workers without employer sponsored health insurance coverage due to a labor dispute.

**b) Coverage Options For Employees on Strike**. No federal or state law requires an employer to continue employee health insurance coverage for unionized employees while they are out on strike. Workers on strike have the following health care coverage options:

**i) COBRA**: The federal Consolidated Omnibus Budget Reconciliation Act (COBRA) gives workers and their families who lose their health benefits the right to choose to continue group health benefits provided by their group health plan for limited periods of time under certain circumstances such as voluntary or involuntary job loss, reduction in the hours worked, transition between jobs, death, divorce, and other life events. Qualified individuals may be required to pay the entire premium for coverage up to 102% of the cost to the plan. Under COBRA, group health plans must provide temporary continuation of group health coverage that might otherwise end (for example, through layoffs or voluntarily leaving job). COBRA continuation coverage

is available to covered employees and their spouses, former spouses and dependent children if certain events would otherwise end their group health coverage. Costs vary and are often more expensive that what is paid before, since the employer no longer covers any part of the cost. An individual generally must apply within 60 days of receiving a COBRA election notice;

ii) **Medi-Cal**: If a worker loses employer coverage, the individual may be eligible for Medi-Cal for income under $20,000 a year and based on family income at the time of application, and,

iii) **Covered California**: While a worker who loses employer coverage is eligible for Covered California, this coverage may be much less affordable than union benefits (prior to the establishment of AB 2530). There may also be potential delays in coverage as coverage does not kick in until the first of the next month (or even the first of the month after that depending on when you sign up). Federal subsidies are available in advance, based on income information provided to Covered California, household size, age, and the cost of coverage in the area where individuals live. Federal subsidies are reconciled based on actual income when a person files income taxes. Eligibility under the ACA is calculated by the household MAGI which is governed by the Internal Revenue Service, Medicaid, and Treasury regulations. If the worker's income goes up (when the strike ends), the worker may owe money on their federal income taxes. Beginning July 2023, AB 2530 eliminated the threat of loss of health benefits during a labor dispute for private sector workers in California. AB 2530 provides immediate enhanced subsidies through Covered California to workers when their employers drop their health coverage during a labor dispute. Workers and their families qualify the day after they apply for coverage. AB 2530 allows workers to access subsidies to keep coverage affordable, reducing costs for workers and their families by hundreds of dollars a month in premiums. This bill revises the effective date of coverage to be the first day of the month the application was submitted and plan selection or the first day of the following month, at the discretion of the qualified individual.

c) **2023 Labor Strikes.** An unprecedented strike wave hit California with strikes covered daily in the press by actors, writers, auto workers, and a narrowly averted strike of UPS drivers in 2023. While not all strikes result in workers losing health coverage, some workers did lose their benefits this past year. According to Covered California, 75 consumers, on an average of 2.2 months, for approximately $40,000, were eligible under AB 2530 (with implementation beginning July 2023). The 2023 Budget Act included expenditure authority from the Health Care Affordability Reserve Fund of $2 million to support health care for striking workers under AB 2530. It should be noted that stakeholders are requesting an increase through a 2024 budget proposal to address concerns that a $2 million capped appropriation would not have been sufficient. This bill also specifies that the Exchange suspend financial assistance, including suspending new enrollments in the program, if funds accrued under AB 2530 exceed the appropriation.

2) **SUPPORT IF AMENDED.** A coalition of labor unions (coalition), including California Labor Federation, American Federation of State, County, and Municipal Employees, California Conference Board of the Amalgamated Transit Union, California Conference of Machinists, Engineers and Scientists of California, Service Employees International Union,

UNITE HERE!, and Utility Workers Union of America, write in support if amended to remove the provisions regarding suspension of financial assistance until the coalition can secure a continuous appropriation in the budget. The coalition notes that labor disputes are unpredictable as to both magnitude and duration. Earlier estimates of the cost of the Covered California program had been based on the prior decade when there were few strikes and mostly of short duration, mostly less than a month. Based on the experience of 2023, the coalition has a budget request for a continuous appropriation with an estimate that the 2023 strikes could have cost as much as $20 million. But the reality is that Covered California has not yet expended the $2 million appropriated for the current year. As such, the coalition requests for a continuous appropriation to implement this law with funding as needed, or hopefully, not needed at all, as strikes are quickly resolved given that employers cannot use the threat of dropping coverage.

3) **RELATED LEGISLATION.** AB 4 (Arambula) requires the Exchange to administer a program to allow persons otherwise not able to obtain coverage by reason of immigration status to enroll in health insurance coverage in a manner as substantially similar to other Californians as feasible given existing federal law and rules. Requires the Exchange to undertake outreach, marketing, and other efforts to ensure enrollment. Requires the Exchange to adopt an annual program design for each coverage year to implement the program, and requires the Exchange to provide appropriate opportunities for stakeholders, including the Legislature, and the public to consult on the design of the program. AB 4 is pending in the Senate Appropriations Committee.

4) **PREVIOUS LEGISLATION.**

   **a)** AB 2530 requires the Exchange to, upon appropriation by the Legislature, administer a program of financial assistance beginning July 1, 2023, to help Californians obtain and maintain health benefits through the Exchange if they lose employer-provided health care coverage as a result of a labor dispute.

   **b)** ABX1 2 (Pan), Chapter 1, Statutes of 2013-14 First Extraordinary Session and SBX1 2 (Hernandez), Chapter 2, Statutes of 2013-14 First Extraordinary Session, establish health insurance market reforms contained in the ACA specific to individual purchasers, such as prohibiting insurers from denying coverage based on preexisting conditions; and, make conforming changes to small employer health insurance laws resulting from final federal regulations.

   **c)** AB 1602 (John A Pérez), Chapter 655, Statutes of 2010, and SB 900 (Alquist), Chapter 659, Statutes of 2010, establish the Exchange in California and delineate its powers and duties.

5) **AUTHOR'S AMENDMENTS**. To address concerns regarding the funding under Covered California's financial assistance program, the author proposes to amend this bill as follows:

   Financial assistance provided pursuant to this section shall be funded upon appropriation by the Legislature. ~~The Exchange's duties to implement this section are contingent upon an appropriation from the Legislature for purposes of implementing the requirements of this section. The Exchange shall suspend the financial assistance provided pursuant to this section, including suspending new enrollments in the program, if funds accrued under the program exceed the appropriation.~~

**REGISTERED SUPPORT / OPPOSITION**:

**Support**

None on file.

**Opposition**

None on file.

**Analysis Prepared by**: Kristene Mapile / HEALTH / (916) 319-2097

Date of Hearing: April 9, 2024

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 2871 (Maienschein) – As Introduced February 15, 2024

**SUBJECT**: Overdose fatality review teams.

**SUMMARY**: Authorizes a county to establish an interagency overdose fatality review team to assist local agencies in identifying and reviewing overdose fatalities, facilitate communication among persons and agencies involved in overdose fatalities, and integrate local overdose prevention efforts through strategic planning, data dissemination, and community collaboration. Specifically, **this bill**:

1) Authorizes a county to establish an interagency overdose fatality review team to assist local agencies in identifying and reviewing overdose fatalities, facilitate communication among persons and agencies involved in overdose fatalities, and integrate local overdose prevention efforts through strategic planning, data dissemination, and community collaboration.

2) Authorizes a county to develop standardized protocols for postmortem examinations involving an overdose to assist coroners and other persons who perform postmortem examinations in determining whether drugs contributed to a death or were the actual cause of death.

3) Permits an overdose fatality review team to be comprised of, but not limited to, the following:

    a) Experts in the field of forensic pathology;
    b) Medical personnel with expertise in overdose fatalities;
    c) Coroners and medical examiners;
    d) District attorneys and city attorneys;
    e) County or local staff, including, but not limited to, all of the following:
        i) Behavioral health services staff;
        ii) County counsel;
        iii) Emergency medical services staff;
        iv) Unhoused services staff;
        v) Medical care services staff;
        vi) Medical examiner staff; and,
        vii) Public health staff.
    f) County, state, and federal law enforcement personnel;
    g) Local drug trafficking experts;
    h) Public health or behavioral health experts;
    i) Drug treatment providers;
    j) Representatives of local health plans, nonprofits, religious, or other organizations who work with individuals at high risk of overdose fatalities; and,
    k) Local professional associations of persons described in this subdivision.

4) Requires an oral or written communication or a document shared within or produced by an overdose fatality review team to be confidential.

5) Requires an oral or written communication or a document provided by a third party to an overdose fatality review team, or between a third party and an overdose fatality review team, to be confidential.

6) Permits recommendations of an overdose fatality review team, upon the completion of a review, to be disclosed at the discretion of a majority of the members of the overdose fatality review team.

7) Permits an organization represented on an overdose fatality review team to share information in its possession concerning the decedent who is the subject of review, information received from a person who was in contact with the decedent, or other information deemed by the organization to be pertinent to the review with other members of the team. Requires information shared by an organization to be confidential.

8) Permits an overdose fatality review team to request information, as specified. Permits written and oral information, as specified, to be disclosed to an overdose fatality review team.

9) Requires information gathered, and recommendations made, by an overdose fatality review team to be used by the county to develop education, prevention, and intervention strategies that will lead to improved coordination of treatment services and prevent future overdose deaths.

10) States legislative findings that in order to protect the privacy of persons who have died due to a drug fatality, including confidential medical information, and to encourage the provision of comprehensive information about drug fatalities to the review teams, it is necessary to limit general access to information regarding those persons.

**EXISTING LAW**:

1) Permits a county to establish an interagency domestic violence death review team to assist local agencies in identifying and reviewing domestic violence deaths and near deaths, including homicides and suicides, and facilitating communication among the various agencies involved in domestic violence cases. [Penal Code (PEN) §11163.3]

2) Permits a county to establish a homeless death review committee to assist local agencies in identifying the root causes of death of homeless individuals and facilitating communication among persons who perform autopsies and the various persons and agencies involved in supporting the homeless population. [PEN §11163.72]

3) Permits a county to establish an interagency child death review team to assist local agencies in identifying and reviewing suspicious child deaths and facilitating communication among persons who perform autopsies and the various persons and agencies involved in child abuse or neglect cases. [PEN §11174.32]

4) Permits a county to establish an interagency elder and dependent adult death review team to assist local agencies in identifying and reviewing suspicious elder and dependent adult deaths and facilitating communication among persons who perform autopsies and the various persons and agencies involved in elder and dependent adult abuse or neglect cases. [PEN §1174.5]

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

**COMMENTS**:

1) **PURPOSE OF THIS BILL.** According to the author, confronting California's overdose epidemic will take collaboration across all sectors. The author argues that by providing the specific statutory authorization needed to create Overdose Fatality Review Teams, this bill will allow counties to look system-wide at individual deaths to find opportunities to increase safety and health in the future. The author states that other death review teams for children, domestic violence, and elder abuse have yielded tremendous results with opportunities for improvement identified and acted on at both the system-wide and individual levels. The author concludes that being able to implement drug fatality review teams would allow counties to maximize insights on how they can address the drug and opioid crisis locally for a growing crisis throughout the state.

2) **BACKGROUND.** California is facing an overdose epidemic. According to a California Health Care Foundation report, 9% of Californians have met the criteria for a Substance Use Disorder (SUD) within the last year. While the health care system is moving toward acknowledging SUDs as a chronic illness, only about 10% of people with an SUD within the last year received treatment. 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 ten-fold increase in fentanyl related deaths between 2015 and 2019. DPH's Opioid Overdose Dashboard reported 7,385 deaths related to "any" opioid overdose in 2022, with 6,473 (87.7%) of those deaths fentanyl related.

   a) **Fentanyl.** Fentanyl is a potent synthetic opioid drug approved by the FDA for use as an analgesic and anesthetic. It is approximately 50 times stronger than heroin and 100 times stronger than morphine. First developed in 1959, it was introduced in the 1960's as an intravenous anesthetic. Fentanyl is legally manufactured and distributed in the United States; however, there are two types of fentanyl: pharmaceutical fentanyl and illicitly manufactured fentanyl. Both are considered synthetic opioids. Pharmaceutical fentanyl is prescribed by doctors to treat severe pain, especially after surgery and for advanced-stage cancer. Most recently, cases of fentanyl-related overdoses are linked to illicitly manufactured fentanyl that is distributed through illegal drug markets for its heroin-like effect. It is often added to other drugs because of its extreme potency, which makes drugs cheaper, more powerful, more addictive, and more dangerous.

   b) **Existing Death Review Teams.** Los Angeles County established the nation's first Child Death Review Team (CDRT) in 1978. A major role of CDRTs is to function as a case-investigating agency, providing in-depth analysis by many agencies on the possible causes of infant deaths in specific cases. California's CDRTs also assist in identifying agency and systems problems and developing recommendations to prevent future child deaths. According to the National Center for Fatality Review and Prevention, CDRTs have influenced state and local policy changes on issues ranging from child homicide sentencing, safely surrendered babies, children left alone in cars, child maltreatment reporting, data collection, and more.

      Building on the success of CDRTs, in 1995 the California Legislature authorized counties to establish interagency Domestic Violence Death Review Teams to ensure that incidents

of domestic violence and abuse are recognized and to develop recommendations for policies and protocols for community prevention and intervention initiatives. In 2001, the Legislature authorized counties to establish interagency elder death teams to examine deaths associated with suspected elder abuse and neglect, identify, and work towards the implementation of prevention strategies to protect our elder population. In 2010 the statute was expanded to allow the review teams to also assist in dependent adult death reviews. Most recently, in 2023 the Legislature authorized counties to establish homeless death review committees to identify the root causes of death of unhoused individuals and facilitate communication among persons and agencies involved in supporting the unhoused population. This bill builds upon these models to authorize overdose fatality review teams.

3) **SUPPORT.** The County of San Diego (County) is sponsoring this bill, stating that addressing California's drug fatality crisis will require a system-wide effort from local health, social service, and public safety agencies, nonprofits, community groups, and others who have expertise or work with people who are most at risk. The County continues that while overdose fatality reviews can currently be conducted to a limited degree, the ability to share information about individuals, much of which is confidential by law, is limited. The County argues that other death review teams for children, domestic violence, and elder abuse have yielded tremendous results. The County concludes by stating that this bill would unlock the ability for counties and other agencies to better work together to prevent and address future occurrences, as well as to improve coordination and effectiveness of interventions.

4) **SUPPORT IF AMENDED.** The County of Fresno supports this bill if amended, stating that preparation for these types of review would require additional staff time in gathering general information; summarizing general and medical information; organization of ongoing meetings; standardizing reports; establish criteria for which cases to review; communication with family to obtain missing information; and conduct additional forensic testing if information is missing. The County of Fresno continues that there is no mention of additional funding sources or establishing criteria for data assessment in this bill.

5) **PREVIOUS LEGISLATION.**

   **a)** AB 271 (Quirk-Silva), Chapter 135, Statutes of 2023, authorizes counties to establish homeless death review committees.

   **b)** SB 863 (Min), Chapter 986, Statutes of 2022, authorizes a county domestic violence death review team to assist local agencies in identifying and reviewing domestic violence near-death cases, as defined.

   **c)** AB 2654 (Lackey) of 2021 would have reconvened the State Child Death Review Council by removing the requirement that funds are appropriated for it in the Budget Act in order to be operative. AB 2654 was held in the Assembly Appropriations Committee.

   **d)** AB 2660 (Maienschein) of 2021 would have required each county to establish an interagency child death review team no later than January 1, 2024. AB 2660 was vetoed by the Governor.

6) **DOUBLE REFERRAL.** This bill is double referred, upon passage of this Committee it will be referred to the Assembly Committee on Privacy and Consumer Protection.

**REGISTERED SUPPORT / OPPOSITION**:

**Support**

County of San Diego (sponsor)
County Health Executives Association of California
Rural County Representatives of California
San Diego County District Attorney's Office

**Opposition**

None on file.

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

Date of Hearing: April 9, 2024

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 2899 (Gabriel) – As Amended April 1, 2024

**SUBJECT**: General acute care hospitals: licensed nurse-to-patient ratios.

**SUMMARY**: Requires the Department of Public Health (DPH), when transmitting the action to be taken on a substantiated violation of Nurse-to-Patient Ratios to a general acute care hospital (GACH), to simultaneously transmit the same information to the person who filed the claim of violation and their collective bargaining agent or representative if any. **Specifically,** this bill:

1) Requires DPH, when transmitting the action to be taken on a substantiated violation of Nurse-to-Patient Ratios to a GACH, to simultaneously transmit the same information to the person who filed the claim of violation and their collective bargaining agent or representative if any.

2) Requires DPH, if the action to be taken does not include a fine, to simultaneously transmit a statement of the reasoning for not imposing a fine to the person who filed the claim of violation and their collective bargaining agent or representative, if any.

3) Requires the statement of reasoning described in 2) above, to discuss the manner in which the violation came to the attention of DPH, the investigatory steps taken by DPH to investigate the claim of the violation, the determinations made by DPH regarding the claimed violation, any mitigating evidence relied upon by DPH to justify the decision not to impose a fine, and an analysis of the potential danger to patients posed by the violation.

**EXISTING LAW**:

1) Licenses and regulates health facilities by DPH, including GACHs, acute psychiatric hospitals, and special hospitals (hospitals). [Health and Safety Code (HSC) §1250, *et seq*.]

2) Requires DPH to periodically inspect hospitals no less that once every three years, and as often as necessary to ensure the quality of care being provided. [HSC §1279]

3) Requires DPH to adopt regulations that establish minimum, specific, and numerical licensed nurse-to-patient ratios, by licensed nurse classification and by hospital unit, for hospitals, and requires these ratios to constitute the minimum number of registered and licensed nurses that must be allocated. [HSC §1276.4]

4) Establishes, in regulations, required nurse-to-patient ratios by unit or clinical area. Requires, the nurse-to-patient ratio in critical care units to be 1:2 or fewer at all times, and defines "critical care unit" as a nursing unit of a general acute care hospital that provides one of the following services: an intensive care service; a burn center; a coronary care service; an acute respiratory service; or, an intensive care newborn nursery service. [California Code of Regulations Title 22, §70217]

5) Establishes a structure under which DPH is permitted to assess administrative fines to hospitals for violation of any of their licensing laws and regulations. Requires DPH to

promulgate regulations establishing the criteria to assess these administrative penalties, and requires these criteria to include, but not be limited to, the probability and severity of the risk that the violation presents to the patient, the facility's history of compliance with related state and federal statutes and regulations, the demonstrated willfulness of the violation, and the extent to which the facility detected the violation and took steps to immediately correct the violation and prevent the violation from recurring. [HSC §1280.3]

6) Permits DPH to assess an administrative penalty against a hospital, for a deficiency constituting an immediate jeopardy violation, as defined, up to a maximum of $75,000 for the first administrative penalty, up to $100,000 for the second administrative penalty, and up to $125,000 for the third and every subsequent administrative penalty. [HSC §1280.3 (a)]

7) Permits DPH to assess an administrative penalty of up to $25,000 per violation for those not deemed to constitute immediate jeopardy. Prohibits DPH from assessing an administrative penalty for minor violations. [HSC §1280.3 (b) and (c)]

8) Requires DPH, notwithstanding the penalty provisions for other violations as described in 5) and 6) above, to assess hospitals a $15,000 penalty for a first violation of nurse-to-patient staffing ratios, and $30,000 for the second and each subsequent violation. However, specifies that a hospital is not subject to an administrative penalty if the hospital can demonstrate to the satisfaction of DPH all of the following:
   a) That any fluctuation in required staffing levels was unpredictable and uncontrollable;
   b) Prompt efforts were made to made to maintain required staffing levels; and,
   c) In making these efforts, the hospital immediately used and subsequently exhausted the hospitals' on-call list of nurses and the charge nurse. [HSC §1280.3(f)]

**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 nurse staffing ratios in existing law need to be uniformly enforced. More importantly, the nursing workforce and the general public need to understand that they are being enforced. The author states that this bill will ensure that DPH is transparent about its enforcement efforts with regard to nurse staffing ratios. It does so by requiring DPH to notify the complaining nurses or their representative any time it takes action against a hospital for a violation of staffing ratios, and will require DPH to provide a statement of reasons for failing to impose a fine on a hospital in such cases.

**2) BACKGROUND.**

**a) Nurse-to-patient ratios and patient classification systems**. In 2004, regulations implementing nurse-to-patient ratios in California hospitals pursuant to AB 394 (Kuehl), Chapter 945, Statutes of 1999, went into effect. However, long before California had specific nurse-to-patient ratios, hospitals were required by regulation to establish a patient classification system. This patient classification system is a method by which hospitals establish staffing requirements by unit, patient, and shift, and includes a method by which the amount of nursing care needed for each category of patient is validated for each unit. The regulations implementing the AB 394 nurse-to-patient ratios set the minimum ratio of nurses to patient by unit, including 1:1 in operating rooms, 1:2 in intensive care units

(ICUs), and 1:5 in general medical-surgical units. These regulations also incorporated the patient classification system requirement. In essence, the specific nurse-to-patient ratios establish the minimum number of nurses by unit, while the patient classification system determines whether there needs to be a higher level of staffing beyond the minimum ratio after taking into consideration factors such as the severity of the illness, the need for specialized equipment and technology, and the complexity of clinical judgment needed to evaluate the patient care plan, among other factors. The nurse-to-patient ratio regulations require that minimum ratios be met at all times.

**California registered nurse (RN) to Patient Staffing Ratios**

| *Type of Care* | *RN to Patients* |
|---|---|
| Intensive/Critical Care | 1:2 |
| Neo-natal Intensive Care | 1:2 |
| Operating Room | 1:1 |
| Post-anesthesia Recovery | 1:2 |
| Labor and Delivery | 1:2 |
| Antepartum | 1:4 |
| Postpartum couplets | 1:4 |
| Postpartum people only | 1:6 |
| Pediatrics | 1:4 |
| Emergency Room (ER) | 1:4 |
| ICU Patients in the ER | 1:2 |
| Trauma Patients in the ER | 1:1 |
| Step Down, Initial | 1:4 |
| Step Down, 2008 | 1:3 |
| Telemetry, Initial | 1:5 |
| Telemetry, 2008 | 1:4 |
| Medical/Surgical, Initial | 1:6 |
| Medical/Surgical, 2008 | 1:5 |
| Other Specialty Care, Initial | 1:5 |
| Other Specialty Care, 2008 | 1:4 |
| Psychiatric | 1:6 |

**b) Effectiveness of nurse-to-patient ratios**. According to a study by researchers at the University of Pennsylvania, “Implications of the California Nurse Staffing Mandate for Other States,” 29% of nurses in California experienced high burnout, compared with 34% of nurses in New Jersey and 36% of nurses in Pennsylvania, states without minimum staffing ratios during the period of research. The study also found that 20% of nurses in California reported dissatisfaction with their jobs, compared with 26% and 29% in New Jersey and Pennsylvania. California nurse staffing ratios also accompanied a lower likelihood of in-patient death within 30 days of hospital admission than in New Jersey or Pennsylvania; there was also a lower likelihood of death from failing to properly respond to symptoms. A 2013 study from the University of California, Davis, "California's nurse-

to-patient ratio law and occupational injury," found that the ratios reduced occupational injury and illness rates for both RNs and licensed practical nurses by up to 33% compared to the expected rate without the law.

c) **Administrative penalties for hospitals.** DPH has the authority to assess administrative penalties for violations of the laws pertaining to the licensing of hospitals. There are two levels of penalties: violations that constitute immediate jeopardy to the health and safety of a patient; and, violations that do not constitute immediate jeopardy. Immediate jeopardy violations are subject to a fine of up to up to $75,000 for the first penalty, $100,000 for the second penalty, and $125,000 for the third and subsequent penalties. All other violations (except minor violations, for which DPH is prohibited from assessing a violation) are subject to a fine of up to $25,000.

DPH promulgated regulations establishing the criteria to assess administrative penalties, and listed eight factors on which to base the criteria, including the patient's physical and mental condition, the nature, scope and severity of the violation, and the demonstrated willfulness of the violation. DPH adopted these regulations in late 2013, and they went into effect on April 1, 2014. These regulations established the penalty matrix in the table below, which can be modified upward or downward according to certain specified factors. The percentages in the table below are to be applied to the statutory maximum penalty amounts as described in 5) and 6) of existing law above:

| | | SCOPE | | |
|---|---|---|---|---|
| | | **Isolated** | **Pattern** | **Widespread** |
| **SEVERITY** | **Level 6: Immediate jeopardy to patient health or safety—Death** | **100%** | **100%** | **100%** |
| | **Level 5: Immediate jeopardy to patient health or safety—Serious injury** | **60%** | **70%** | **80%** |
| | **Level 4: Immediate jeopardy to patient health or safety—Likely to cause serious injury or death** | **40%** | **50%** | **60%** |
| | **Level 3: Actual patient harm that is not immediate jeopardy** | **60%** | **80%** | **100%** |
| | **Level 2: No actual patient harm but with potential for more than minimal harm, not immediate jeopardy** | **20%** | **50%** | **70%** |
| | **Level 1: No actual patient harm but with potential for no more than minimal harm** | **No penalty** | | |
| | **Minor Violation** | **No penalty** | | |

d) **Nurse-to-Patient Ratio violations and enforcement.** AB 1063 (Gabriel) of 2023 would have required DPH to conduct an annual review of its enforcement of the nurse-to-patient ratio regulations and submit a report to the Legislature on its findings. AB 1063 was vetoed by Governor Newsome, who in his veto message instructed DPH to update their hospital citations tracking system to include a category specific to nurse-to-patient ratio violations, and to publish this on the DPH Center for Health Care Quality's State Enforcement Tracking Dashboard (Dashboard). DPH updated the existing Electronic

Licensing Management System (ELMS) on March 4, 2024 to include a category specific to nurse-to-patient ratio violations. ELMS is an internal database that tracks all facility licensure information including applications, licensure history, administration, program flexibility, penalties, etc. As new nurse-to-patient ratio deficiencies are finalized they will begin showing on the Dashboard. DPH states that finalization of any administrative penalties involves an internal management and legal review process. Any nurse-to-patient ratio violation from March 4, 2024 going forward would follow the same process as all other administrative penalties but would be keyed in the system differently for tracking purposes. The Dashboard contains a search tool that provides online access to all state enforcement actions. Users may search the database by enforcement action attributes such as penalty type, facility, or issue date, or with a key word search against the investigation narratives.

In the last three years DPH has received a total of 1,328 nurse-to-patient ratio violation complaints and facility reported incidents (FRIs). DPH may receive multiple complaints for the same violation (e.g., three nurses at the same facility report the same understaffed shift to DPH). Each complaint received represents a single entry in ELMS. However, DPH district level investigators will identify multiple complaints for the same violation and will consolidate their investigation activities as appropriate. Subsequently, the publicly accessible State Enforcement Actions Dashboard will reflect a single deficiency that was substantiated.

Of the 1,328 complaints and FRIs received in the last three years, 1,071 complaints were substantiated with deficiencies and 28 FRIs were substantiated with deficiencies. All 1,099 complaints and FRIs substantiated with deficiencies required a Plan of Correction. DPH imposed a fine for 25 of these violations; five of those were issued in conjunction with a finding of harm to the patient and there were five adverse events that involved a nurse-patient ratio violation.

This bill requires DPH to notify an individual making a complaint regarding ratio violations and their collective bargaining agents of the action to be taken on substantiated violations, and if the action to be taken does not include a fine, to include a statement of the reasoning for not imposing a fine. This bill requires the statement of reasoning to discuss the manner in which the violation came to the attention of DPH, the investigatory steps taken by DPH to investigate the claim of the violation, the determinations made by DPH regarding the claimed violation, any mitigating evidence relied upon by DPH to justify the decision not to impose a fine, and an analysis of the potential danger to patients posed by the violation.

3) **SUPPORT.** The United Nurses Associations of California/Union of Health Care Professionals (UNAC/UHCP) is the sponsor of this bill and states that when DPH finds a substantiated violation of nurse staffing ratios, it is required to send information to the hospital regarding the action to be taken on that violation. However, the party filing a report of a staffing violation, typically an overworked nurse in the hospital, is not alerted as to any action taken by DPH. UNAC/UHCP notes that this bill will require DPH to provide a statement of reasons for not imposing a fine despite finding a substantiated violation. UNAC/UHCP concludes that this bill brings sunlight to a complaint investigation process that currently creates suspicion and distrust among the nursing staff at hospitals, and that

providing the information will help the nursing community better understand the regulator landscape surround the enforcement of nurse staffing ratios.

**4) PREVIOUS LEGISLATION.**

**a)** AB 1063 (Gabriel) of 2023 would have required DPH to conduct an annual review of its enforcement of the nurse-to-patient ratio regulations and submit a report to the Legislature on its findings. AB 1063 was vetoed by Governor Newsom, who stated, in part: "I agree it is important to ensure nurse-to-patient staffing ratios are enforced properly for patient safety and maintaining the nursing workforce. However, much of the information this bill seeks to document is already publicly available. Further, this Administration prioritizes ongoing and open engagement with stakeholders. A biennial, public hearing is unnecessary for the state to receive input and make changes. I am directing DPH to continue actively consulting with nurses and their representative labor groups to identify additional opportunities to increase transparency and communication. Further, I have asked DPH to update their hospital citations tracking system to include a category specific to nurse-to-patient ratio violations, and to publish this on the Center for Health Care Quality's State Enforcement Tracking Dashboard."

**b)** AB 1422 (Gabriel), Chapter 716, Statutes of 2021, requires applications by health facilities for program flexibility to designate a bed in a critical care unit as requiring a lower level of care to be posted on DPH's website, and requires DPH to solicit public comment on the application for at least 30 days.

**c)** SB 637 (Newman) of 2021, as passed by the Senate Health Committee, would have required hospitals to report weekly during a health-related state of emergency, and monthly at all other times, information on whether the hospital is experiencing a staffing shortage of nurses, or has experienced any layoffs, furloughs, or repeated shift cancellations of nurses. SB 637 would have required hospitals to report weekly during a health-related state of emergency, and monthly at all other times, until January 1, 2025, information regarding COVID-19-positive staff, including number of staff and facility personnel who have tested positive, or are suspected positive, and total number of deaths of staff who are positive or suspected positive for COVID-19. Additionally, SB 637 would have required a licensed health facility to post any approval granted by DPH for program flexibility immediately adjacent to the health facility's license. These provisions were amended out of SB 637.

**d)** SB 227 (Leyva), Chapter 843, Statutes of 2019, requires periodic inspections of hospitals by DPH to include reviews of compliance with nurse staffing ratios, and establishes administrative penalties for nurse staffing ratio violations of $15,000 for a first violation, and $30,000 for each subsequent violation.

**5) SUGGESTED AMENDMENT.** As currently drafted this bill requires DPH to provide an analysis of the potential danger to patients posed by a violation of the nurse-to-patient ratios, however, it is unclear what metric DPH would use to assess "potential danger." The Committee may wish to strike that provision from this bill.

**REGISTERED SUPPORT / OPPOSITION**:

**Support**

United Nurses Associations of California/Union of Health Care Professionals (sponsor)
American Federation of State, County, and Municipal Employees (AFSCME, AFL-CIO)
California Labor Federation, AFL-CIO

**Opposition**

None on file

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

Date of Hearing: April 9, 2024

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 2998 (McKinnor) – As Amended April 1, 2024

**SUBJECT**: Minors: consent to medical care.

**SUMMARY**: Permits minors 12 years of age and above to consent to receiving, carrying, and administering naloxone hydrochloride (NH) or another opioid antagonist approved by the United States Food and Drug Administration (FDA) for overdose reversal if approved by a physician or physician assistant. Specifically, **this bill**:

1) Permits minors 12 years of age and above to consent to receiving, carrying, and administering NH or another opioid antagonist approved by the FDA for overdose reversal on a school campus, park or recreational center, or other places of public accommodations, if approved by a physician or physician assistant.

2) Provides protection from civil liability or criminal prosecution for minors who are permitted to administer an opioid antagonist, in good faith, to a person who appears to be experiencing an opioid overdose.

**EXISTING LAW**:

1) Authorizes a minor who is 12 years of age or older to consent to medical care and counseling relating to the diagnosis and treatment of a drug- or alcohol-related problem, excluding replacement narcotic abuse treatment. [Family Code (FAM) § 6929]

2) Authorizes a minor 16 years of age or older to consent to replacement narcotic abuse treatment that uses buprenorphine, without the consent of the minor's parent or guardian only if, and to the extent, expressly permitted by federal law. [FAM § 6929 - 6929.1]

3) Establishes ongoing funding for county offices of education (COEs) to purchase and maintain sufficient stock of emergency NH or another opioid antagonist for local educational agencies within its jurisdiction. [Education Code (EDC) § 49414.8]

4) Authorizes school districts, COEs, and charter schools to provide emergency NH or another opioid antagonist to school nurses or trained volunteer personnel for the purpose of providing emergency medical aid to persons suffering, or reasonably believed to be suffering, from an opioid overdose. [EDC § 49414.3 *et seq.*]

5) Authorizes public and private elementary and secondary schools to voluntarily determine whether or not to make emergency NH or another opioid antagonist and trained personnel available at its school. Requires a school to evaluate the emergency medical response time to the school and determine whether initiating emergency medical services is an acceptable alternative to NH or another opioid antagonist and trained personnel. [EDC § 49414.3 (c)]

6) Requires the Superintendent of Public Instruction (SPI) to establish minimum standards of training for the administration of NH or another opioid antagonist and to review the minimum standards of training every five years, or sooner, as deemed necessary. Requires

the SPI to consult with organizations and providers with expertise in administering NH or another opioid antagonist and administering medication in a school environment, including, the California Society of Addiction Medicine, the Emergency Medical Services Authority, the California School Nurses Organization, the California Medical Association, and the American Academy of Pediatrics. [EDC § 49414.3(e)]

7) Permits a pharmacy to furnish NH or another opioid antagonist to a school district, COE, or charter school pursuant to existing law if certain requirements are met. [Business and Professions Code §4119.8]

8) Authorizes the State Department of Public Health (DPH), in order to reduce the rate of fatal overdose from opioid drugs including heroin and prescription opioids, to award funding to local health departments, local government agencies, or on a competitive basis to community-based organizations, regional opioid prevention coalitions, or both, to support or establish programs that provide naloxone, or any other opioid antagonist that is approved by the FDA for the treatment of an opioid overdose, to first responders and to at-risk opioid users through programs that serve at-risk drug users, including, but not limited to, syringe exchange and disposal programs, homeless programs, and substance use disorder treatment providers. [Health and Safety Code §1179.80]

9) Prohibits a person who possesses or distributes an opioid antagonist pursuant to a prescription or standing order from being subject to professional review, being liable in a civil action, or being subject to criminal prosecution for this possession or distribution. Prohibits a person who is not otherwise licensed to administer an opioid antagonist, but trained as required, who acts with reasonable care in administering an opioid antagonist, in good faith and not for compensation, to a person who is experiencing or is suspected of experiencing an overdose, from being subject to professional review, being liable in a civil action, or being subject to criminal prosecution for this administration. [Civil Code §1714.22]

**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 addresses the urgent need to expand access to naloxone by allowing minors aged 12 and above to administer the medication during opioid overdoses. The author argues that this bill empowers individuals to intervene effectively and potentially save lives in emergency situations, contributing to our efforts to combat the opioid epidemic in California.

2) **BACKGROUND.** California is facing an overdose epidemic. According to a California Health Care Foundation report, 9% of Californians have met the criteria for a Substance Use Disorder (SUD) within the last year. While the health care system is moving toward acknowledging SUDs as a chronic illness, only about 10% of people with an SUD within the last year received treatment. 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 DPH, fentanyl-related overdose deaths increased 625% among youth ages 10 to 19 from 2018 to 2020. DPH's Opioid Overdose Dashboard reported there were 177 fentanyl-

related overdose deaths and 1,165 opioid-related overdose emergency departments visits among youth ages 10 to 19 years old in 2022.

**a) Fentanyl.** Fentanyl is a potent synthetic opioid drug approved by the FDA for use as an analgesic and anesthetic. It is approximately 50 times stronger than heroin and 100 times stronger than morphine. First developed in 1959, it was introduced in the 1960's as an intravenous anesthetic. Fentanyl is legally manufactured and distributed in the US; however, there are two types of fentanyl: pharmaceutical fentanyl and illicitly manufactured fentanyl. Both are considered synthetic opioids. Pharmaceutical fentanyl is prescribed by doctors to treat severe pain, especially after surgery and for advanced-stage cancer. Most recently, cases of fentanyl-related overdoses are linked to illicitly manufactured fentanyl that is distributed through illegal drug markets for its heroin-like effect. It is often added to other drugs because of its extreme potency, which makes drugs cheaper, more powerful, more addictive, and more dangerous.

The California Department of Education (CDE), in conjunction with DPH, provides local educational agencies (LEAs) with resources and information that they can provide to parents and students. The Fentanyl Awareness and Prevention toolkit page offer information about the risks of fentanyl and how to prevent teen use and overdoses. In addition to the toolkit, DPH's Substance and Addiction Prevention branch also provides resources for parents, guardians, caretakers, educators, schools, and youth-serving providers.

**b) Reversing opioid overdoses.** NH is the generic name for an opioid antagonist that rapidly reverses an opioid overdose. It attaches to opioid receptors and reverses and blocks the effects of other opioids. NH can quickly restore normal breathing to a person if their breathing has slowed or stopped because of an opioid overdose. NH comes in two FDA-approved forms: injectable and prepackaged nasal spray. Narcan nasal spray was first approved by the FDA in 2015 as a prescription drug.

According to the FDA, in accordance with a process to change the status of a drug from prescription to nonprescription, the manufacturer of Narcan provided data demonstrating that the drug is safe and effective for use as directed in its proposed labeling. The manufacturer also showed that consumers can understand how to use the drug safely and effectively without the supervision of a healthcare professional. The application to approve Narcan nasal spray for over-the-counter (OTC) use was granted priority review status and was the subject of an advisory committee meeting in February 2023, where committee members voted unanimously to recommend it be approved for marketing without a prescription.

As of July 2023 the FDA approved Narcan and RiVive, for OTC, nonprescription use. These are the first NH products approved for use without a prescription. This approval will allow the medications to be sold directly to consumers in drug stores, grocery stores, as well as online. According to an FDA Commissioner, "The approval of OTC NH nasal spray will help improve access to NH, increase the number of locations where it's available and help reduce opioid overdose deaths throughout the country. We encourage the manufacturer to make accessibility to the product a priority by making it available as soon as possible and at an affordable price."

According to the Substance Abuse and Mental Health Services Administration, there are no federal age restrictions on who may purchase nonprescription Narcan.

**c) NH Availability in California school districts.** The 2023-24 state budget appropriated $3,500,000 annually for COEs to purchase and maintain a sufficient stock of emergency opioid antagonists for school districts and charter schools within their jurisdiction, and to maintain a minimum of two units at each middle school, junior high school, high school, and adult school site. As a condition of receiving the funding, each school or charter school must ensure two staff members meet minimum training standards.

**d) DPH statewide standing order for NH.** NH can help reduce opioid overdose deaths in California, but many organizations find it difficult to obtain the required standing order to obtain NH from health care providers. According to DPH, of the 7,175 opioid-related overdose deaths in 2021, 83% or 5,961 were related to fentanyl. The number of deaths each year involving fentanyl increased dramatically between 2012 and 2021. During this time period fentanyl related overdose deaths increased by more than 7,250% from 82 to 5,961 in 2021. DPH issued a standing order, in 2017, to address this need and support equitable NH access. The standing order:

**i)** Allows community organizations and other entities in California that are not currently working with a physician, to distribute NH 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 NH 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 NH under the order are colleges and universities. An individual at risk of experiencing an 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 NH must be trained. They are also required to provide training to individuals who receive NH 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 due to its OTC status, all other formulations remain available by prescription only and require a standing order to distribute and administer.

**e) Naloxone Distribution Project.** A separate distribution program administered through the Department of Health Care Services (DHCS), the Naloxone Distribution Project (NDP) allows various entities, including schools, universities and colleges, to apply for and obtain NH at no cost to the institution. As of February 20, 2024 the NDP has approved more than 10,800 applications for NH (17% of which are from schools and universities), distributed more than 3.8 million kits of NH and reversed more than 245,000 opioid overdoses. DHCS reports that less than one percent of the overdose reversals reported in the NDP occurred in schools and universities.

In their NDP frequently asked questions, DHCS states “California has no statute requiring minors to obtain parental or guardian consent prior to receiving NH. Additionally, Civil Code §1714.22 indicates that NH may be distributed to a family member, friend, or other person in a position to assist a person at risk of a suspected opioid-related overdose.”

3) **SUPPORT.** The Los Angeles Unified School District (LAUSD) is the sponsor of this bill, stating "in October of 2022, LAUSD began receiving over the counter Narcan through California's NDP to be provided to school nurses or other trained personnel; however, in the moment of crisis these nurses or trained persons may not be available to attend to student's needs. In February of 2023, as an extra layer of defense against the fentanyl epidemic, LAUSD created a policy that clarifies students will not face disciplinary actions if they carry the medication on campus. In addition, this bill protects youth from liability and criminal prosecution for administering the naloxone in good faith to combat an opioid overdose."

4) **RELATED LEGISLATION.**

   **a)** AB 1915 (Arambula) requires DPH to develop by July 1, 2026, a training program and toolkit for public school pupils in grades nine to 12, to gain skills in how to identify and respond to an opioid overdose, including the administering of a federally approved opioid overdose reversal medication. AB 1915 is currently pending in Assembly Health Committee.

   **b)** AB 3271 (Joe Patterson) requires each individual public school operated by a school district, county office of education, or charter school that has elected to make a school nurse or trained personnel available at the school to maintain at least two units of naloxone hydrochloride or another opioid antagonist on campus. AB 3271 is pending in Assembly Health Committee.

5) **PREVIOUS LEGISLATION.**

   **a)** AB 816 (Haney), Chapter 456, Statutes of 2023, creates an exception that allows a minor who is at least 16 years of age or older to consent to narcotic replacement therapy as part of their substance abuse treatment plan.

   **b)** AB 1748 (Mayes), Chapter 557, Statutes of 2016, authorizes school nurses and other trained personnel to use NH or another opioid antagonist to provide emergency medical aid to persons suffering, or reasonably believed to be suffering, from an opioid overdose.

   **c)** SB 1438 (Pavley), Chapter 491, Statutes of 2014, required the development of training and other standards for the administration of NH by emergency medical technicians and other pre-hospital emergency care personnel.

   **d)** AB 635 (Ammiano), Chapter 707, Statutes of 2013, revised certain provisions from a pilot program authorizing prescription of opioid antagonists for treatment of drug overdose and limiting civil and criminal liability, expanded these provisions statewide, and removed the 2016 sunset date for the pilot program. Permits a licensed health care provider who is authorized by law to prescribe an opioid antagonist, if acting with reasonable care, to prescribe and subsequently dispense or distribute an opioid antagonist to a person at risk of an opioid-related overdose or a family member, friend, or other person in a position to assist the person at risk, and limited the professional and civil liability of licensed health care providers and persons who possess or distribute opioid antagonists.

6) **DOUBLE REFERRAL.** This bill is double-referred, upon passage of this Committee, it will be referred to the Assembly Judiciary Committee.

7) **SUGGESTED AMENDMENT.** There is no state or federal law that prohibits minors from accessing, carrying, receiving, or administering NH. Additionally, minors are allowed to purchase OTC NH without a physician's approval. This bill as drafted could unintentionally require physician approval for NH access and create barriers to access that don't currently exist. Additionally, a physician traditionally prescribes a medication that a patient takes themselves. But NH is not self-administered, it is administered to a third party in event of an overdose. It is unclear how a physician would provide approval for a minor to administer NH to another person. Instead of altering minor consent laws, the committee may wish to consider amending this bill to instead make it clear that students are allowed to carry and administer NH on campus, which is the intended goal of the author and sponsors.

**REGISTERED SUPPORT / OPPOSITION**:

**Support**

Los Angeles Unified School District (sponsor)
American Academy of Pediatrics, California
Association of California School Administrators
California Association of Alcohol and Drug Program Executives, Inc.
The Los Angeles Trust for Children's Health

**Opposition**

None on file.

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

Date of Hearing: April 9, 2024

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 3030 (Calderon) – As Amended March 21, 2024

**SUBJECT**: Health care services: artificial intelligence.

**SUMMARY**: Requires specified health care providers to disclose the use of a generative artificial intelligence (GenAI) tool when it is used to generate responses that are communicated to a patient. Specifically, **this bill**:

1) Requires a health facility, clinic, physician's office, or office of a group practice (provider) that uses a GenAI tool to generate online or telephone responses for health care providers to communicate with patients to include both of the following in such communication:
   a) A disclaimer that indicates to the patient that a communication was generated by artificial intelligence; and,
   b) Clear instructions for the patient to navigate the entity's internet website or other platforms to communicate directly with a health care provider (defined as communication without using responses generated by artificial intelligence).

2) Defines facilities subject to the requirements in 1) above, by applying a current-law definition of health facility (i.e., a facility to which patients are admitted for a 24-hour stay or longer, including hospitals, nursing facilities, and hospice facilities).

3) Allows, if a response communicated through an online interface is reviewed by a human health care provider, the applicable provider to indicate that the response was generated by artificial intelligence and reviewed by a human.

4) Exempts providers who do not comply with the above requirements from disciplinary action related to licensure or certification, as well as from civil and criminal liability, related to their noncompliance.

5) Defines "GenAI tool" as a tool that uses machine learning systems capable of generating text, images, code, or other types of content, often in response to a prompt entered by a user.

**EXISTING LAW**:

1) Establishes the California Department of Public Health (DPH) which, among other functions, licenses and regulates health facilities. Defines "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, including, but not limited to, hospitals, nursing facilities, and hospice facilities. [Health and Safety Code § 1250]

2) Establishes the Department of Consumer Affairs, which licenses and oversees health care professionals through various healing arts boards [Business and Professions Code (BPC) § 100 and BPC§ 500 *et seq*.]

3) Establishes the California Privacy Protection Agency (CPPA) to implement and enforce the California Privacy Rights Act of 2020, and provides the CPPA with the full administrative power, authority and jurisdiction to implement and enforce the California Consumer Privacy Act of 2018, including responsibilities to update existing regulations and adopt new regulations. [Civil Code § 1798.100 *et seq.*]

**FISCAL EFFECT**: None.

**COMMENTS**:

1) **PURPOSE OF THIS BILL.** According to the author, across the state, pilot programs are testing the use of GenAI as a tool to assist clinicians with patient communications. As AI becomes increasingly integrated in our healthcare systems, it is important to maintain the trust between a patient and their provider, while ensuring the accuracy of information being communicated to patients. This bill would require healthcare providers who use this technology to provide a disclaimer that the communication was AI-generated, along with clear instructions for how a patient can directly communicate with a healthcare provider.

2) **BACKGROUND.**

   a) **AI And GenAI.** In a draft regulation, the CPPA defines AI as follows:

      > AI means a machine-based system that infers, from the input it receives, how to generate outputs that can influence physical or virtual environments. The AI may do this to achieve explicit or implicit objectives. Outputs can include predictions, content, recommendations, or decisions. Different AI varies in its levels of autonomy and adaptiveness after deployment. For example, AI includes generative (GenAI) models, such as large language models (LLMs), that can learn from inputs and create new outputs, such as text, images, audio, or video; and facial- or speech-recognition or -detection technology.

   GenAI is a subset of AI that can be trained in a variety of ways and applied to a large and growing set of use cases in across economic sectors. GenAI uses a type of machine learning called "deep learning" that uses multilayer neural networks, similar to the structure of a human brain, to process input and generate novel responses. LLMs are a type of GenAI model that has been specifically designed to understand, generate, and work with human language. These models are trained on vast quantities of text sourced from the internet and historical literature. GPT-4 and Copilot are examples of recently launched, publicly available interactive LLMs. Because of the extraordinary potential of novel GenAI applications, it will have enormous implications for industries across the economy and for labor and the workforce, as well as in daily life.

   b) **Recent Federal and State Activity.** As GenAI has exploded into popular knowledge and use, here has been a flurry of activity among states and the federal administrative and regulatory agencies. Below is a high-level overview of some recent activity:

      i) **State Executive Order (EO)**. In September 2023, Governor Gavin Newsom signed an EO to study the development, use, and risks of AI technology throughout the state and to develop a deliberate and responsible process for evaluation and deployment of AI within state government. The EO includes a number of provisions:

**(1) Risk-Analysis Report**: Direct state agencies and departments to perform a joint risk-analysis of potential threats to and vulnerabilities of California's critical energy infrastructure by the use of GenAI.

**(2) Procurement Blueprint**: To support a safe, ethical, and responsible innovation ecosystem inside state government, agencies will issue general guidelines for public sector procurement, uses, and required training for application of GenAI – building on the White House's Blueprint for an AI Bill of Rights and the National Institute for Science and Technology's AI Risk Management Framework. State agencies and departments will consider procurement and enterprise use opportunities where GenAI can improve the efficiency, effectiveness, accessibility, and equity of government operations.

**(3) Beneficial Uses of GenAI Report**: Direct state agencies and departments to develop a report examining the most significant and beneficial uses of GenAI in the state. The report will also explain the potential harms and risks for communities, government, and state government workers.

**(4) Deployment and Analysis Framework**: Develop guidelines for agencies and departments to analyze the impact that adopting GenAI tools may have on vulnerable communities. The state will establish the infrastructure needed to conduct pilots of GenAI projects, including California Department of Technology approved environments or "sandboxes" to test such projects.

**(5) State Employee Training**: To support California's state government workforce and prepare for the next generation of skills needed to thrive in the GenAI economy, agencies will provide trainings for state government workers to use state-approved GenAI to achieve equitable outcomes, and will establish criteria to evaluate the impact of GenAI to the state government workforce.

**(6) GenAI Partnership and Symposium**: Establish a formal partnership with the University of California, Berkeley and Stanford University to consider and evaluate the impacts of GenAI on California and what efforts the state should undertake to advance its leadership in this industry. The state and the institutions will develop and host a joint summit in 2024 to engage in meaningful discussions about the impacts of GenAI on California and its workforce.

**(7) Legislative Engagement**: Engage with Legislative partners and key stakeholders in a formal process to develop policy recommendations for responsible use of AI, including any guidelines, criteria, reports, and/or training.

**(8) Evaluate Impacts of AI on an Ongoing Basis**: Periodically evaluate for potential impact of GenAI on regulatory issues under the respective agency, department, or board's authority and recommend necessary updates as a result of this evolving technology.

The administration is implementing the EO, including moving forward to evaluate procurement proposals by state agencies, two of which relate to health care: one

proposal to improve efficiency in inspections of health facilities by DPH, and another within the California Health and Human Services Agency to improve translations.

ii) **CPPA Pending Regulations**. The CPPA is charged with protecting the privacy of Californians pursuant to landmark privacy-related ballot measures passed in 2018 and 2020. CPPA proposed draft regulations in December 2023, which would impose requirements for businesses using "automated decision-making technology" (ADMT) in any of the following ways:
   **(1)** For decisions that tend to have the most significant impacts on consumers' lives. This would include, for example, decisions about their employment or compensation.
   **(2)** Profiling an employee, contractor, applicant, or student. This would include, for example, using a keystroke logger to analyze their performance, and tracking their location.
   **(3)** Profiling consumers in publicly accessible places, such as shopping malls, medical offices, and stadiums. This would include, for example, using facial-recognition technology or automated emotion assessment to analyze consumers' behavior.
   **(4)** Profiling a consumer for behavioral advertising. This would include, for example, evaluating consumers' personal preferences and interests to display advertisements to them.

   For the above uses of ADMT, the draft regulations would provide consumers with specified protections. However, the draft CPPA regulations on ADMT do not appear to explicitly address the disclosure issue raised by this bill.

iii) **Federal Blueprint for an AI Bill of Rights**. According to the White House, the 2023 Blueprint for an AI Bill of Rights is a set of five principles and associated practices to help guide the design, use, and deployment of automated systems to protect the rights of the American public in the age of artificial intelligence. Developed through extensive consultation with the American public, the principles are a blueprint for building and deploying automated systems that are aligned with democratic values and protect civil rights, civil liberties, and privacy. The five principles are:

   **(1) Safe and Effective Systems**. You should be protected from unsafe or ineffective systems.

   **(2) Algorithmic Discrimination Protections**. You should not face discrimination by algorithms and systems should be used and designed in an equitable way.

   **(3) Data Privacy**. You should be protected from abusive data practices via built-in protections and you should have agency over how data about you is used.

   **(4) Notice and Explanation**. You should know that an automated system is being used and understand how and why it contributes to outcomes that impact you.

   **(5) Human Alternatives, Consideration, and Fallback**. You should be able to opt out, where appropriate, and have access to a person who can quickly consider and remedy problems you encounter.

This bill appears generally aligned with principles (4) and (5) above described in the federal Blueprint for an AI Bill of Rights, in that it requires notification that an AI was used, and requires access to a non-AI fallback option. For instance, principle (4) above indicates "you should know how and why an outcome impacting you was determined by an automated system, including when the automated system is not the sole input determining the outcome." However, to some extent the "devil is in the details," as principle (4) above also states the notice should be calibrated to the level of risk based on the context, and notes automated systems should provide explanations that are technically valid, meaningful and useful. Given limited attention, the possibility of notification fatigue, and a range of reactions someone might have to such a disclosure, it certainly may be the case, but it is not self-evident, that the disclosure proposed by this bill meets the criteria of being useful and meaningful to the end user.

iv) **Federal EO**. As summarized by the Congressional Research Service, on October 30, 2023, the Biden Administration released EO 14110 on Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence. The EO establishes a government-wide effort to guide responsible AI development and deployment through federal agency leadership, regulation of industry, and engagement with international partners. The EO directs over 50 federal entities to engage in more than 100 specific actions to implement the guidance set forth across eight overarching policy areas:

**(1) Safety and security**. The EO promotes the development and implementation of repeatable processes and mechanisms to understand and mitigate risks related to AI adoption, including with respect to biosecurity, cybersecurity, national security, and critical infrastructure.

**(2) Innovation and competition**. The EO compels actions to attract AI talent to the United States, understand novel intellectual property questions, protect inventors and creators, and promote AI innovation, including at startups and small businesses.

**(3) Worker support**. The EO states that AI adoption may be disruptive to the workforce and directs agencies to research and develop potential mitigations against such disruptions.

**(4) Consideration of AI bias and civil rights**. The EO states that AI models may perpetuate biases and their implementation may lead to civil rights violations. The EO includes a section on equity and civil rights considerations for use of AI in the criminal justice system and the administration of federal government programs and benefits.

**(5) Consumer protection**. The EO instructs agencies to enforce existing, technology-agnostic authorities in an effort to minimize harms to consumers, and to identify needed authorities related to AI.

**(6) Privacy**. The EO calls for the evaluation and mitigation of privacy risks—potentially exacerbated by AI— associated with the collection, use, and retention of user data.

**(7) Federal use of AI**. The EO requires the Office of Management and Budget to establish an interagency council to coordinate AI use by federal agencies and develop guidance on AI governance and risk management activities for agencies. It acknowledges the ubiquity of GenAI tools, and directs agencies to move toward adoption with safeguards in place. The EO also calls for additional agency hiring and training activities to increase the AI workforce capacity across the federal government.

**(8) International leadership**. The EO declares that the United States should be a global leader in AI development and adoption by engaging with international allies and partners, leading efforts to develop common AI regulatory and accountability principles, and advancing responsible global technical standards for AI.

**v) Federal Health Data, Technology, and Interoperability Final Rule**. On January 9, 2024, the Department of Health and Human Services through the Office of the National Coordinator for Health Information Technology (ONC) published the "Health Data, Technology, and Interoperability," final rule, which includes first-of-its-kind federal requirements for AI and machine learning-(ML) based predictive software in health care. ONC states it believes AI and ML—increasingly powered by data from certified health IT and injected into day-to-day workflows within certified health IT—will have a growing impact on how health decisions are made, particularly those directly affecting patients' lives. ONC notes the technology should be deployed in a manner that is fair, appropriate, valid, effective, and safe ("FAVES"). They state the final rule based on a rapidly growing industry consensus that greater transparency into how AI is developed, evaluated, and performs is a crucial first step to achieving responsible and safe use in health care. ONC defines a predictive decision support intervention or "Predictive DSI" as a technology that supports decision-making based on algorithms or models that derive relationships from training data and then produce an output that results in prediction, classification, recommendation, evaluation, or analysis. The rule states users of certified health IT must be able to access complete and up-to-date technical and performance information—referred to as source attributes—for predictive DSIs made available to them. It also requires risk management practices be adopted, and specifies that risk management practices must cover topics including validity, reliability, robustness, fairness, intelligibility, safety, security, and privacy. ONC concludes that wide adoption of responsible AI in health care is a shared responsibility across numerous stakeholders.

The rule is focused on transparency and disclosure around the design and performance of AI systems, but does not appear to specifically address the type of disclosure proposed by this bill.

**c) Assembly Informational Hearing.** On February 27, 2024, the Assembly Privacy and Consumer Protection Committee held an informational hearing titled, "Understanding AI: Myths, Magic, and Machine Learning." The briefing paper notes AI is already embedded into most online systems, that it is integral to many aspects of modern society, and that the advent of GenAI will undoubtedly lead to an even greater number of applications. It also notes, however, that AI is not an inherently benevolent technology – it is a tool, and it can be used for good or ill. It suggests policymakers will need to design regulatory

guardrails to limit harmful uses while allowing for the development and refinement of tools that benefit society. The paper discusses negative aspects of AI that imply a role for regulation, and a variety of troubling applications of AI. Specifically, it discusses bias and discrimination, effect on labor, deepfakes, (the creation of realistic text, imagery, video, and audio by GenAI), questionable originality and copyright issues, and the inability to remove data from a trained model. With respect to health care, it notes that when AI tools are deployed in healthcare, biased historical data can lead to patients being recommended substandard care on the basis of their race or ethnicity. It also notes the capacity for GenAI to "hallucinate," or generate output that has no basis in reality, is a unique risk if GenAI is embedded in health care applications. Disclosure and digital watermarking (the practice of embedding visible or invisible markers into a GenAI product) are presented as stopgap measures to prevent harms in the short term.

**d) GenAI in Health Care.** The Government Accountability Office (GAO) published a report in 2020 noting AI tools have shown promise for augmenting patient care in the following two areas:

**i)** Clinical AI tools have shown promise in predicting health trajectories of patients, recommending treatments, guiding surgical care, monitoring patients, and supporting population health management (i.e., efforts to improve the health outcomes of a community). These tools are at varying stages of maturity and adoption, but many, with the exception of population health management tools, had not achieved widespread use at that time.

**ii)** Administrative AI tools have shown promise in reducing provider burden and increasing efficiency by recording digital notes, optimizing operational processes, and automating laborious tasks. These tools are also at varying stages of maturity and adoption, ranging from emerging to widespread.

However, GAO also noted use of AI-enabled tools in health care raises a variety of ethical, legal, economic, and social concerns. GAO identified the following challenges surrounding AI tools, which may impede their widespread adoption:

**i)** **Data access**. Developers experience difficulties obtaining the high-quality data needed to create effective AI tools.

**ii)** **Bias**. Limitations and bias in data used to develop AI tools can reduce their safety and effectiveness for different groups of patients, leading to treatment disparities.

**iii)** **Scaling and integration**. AI tools can be challenging to scale up and integrate into new settings because of differences among institutions and patient populations.

**iv)** **Lack of transparency**. AI tools sometimes lack transparency—in part because of the inherent difficulty of determining how some of them work, but also because of more controllable factors, such as the paucity of evaluations in clinical settings.

**v)** **Privacy**. As more AI systems are developed, large quantities of data will be in the hands of more people and organizations, adding to privacy risks and concerns.

**vi)** **Uncertainty over liability**. The multiplicity of parties involved in developing, deploying, and using AI tools is one of several factors that have rendered liability associated with the use of AI tools uncertain. This may slow adoption and impede innovation.

To address the challenges, GAO identified policy options including:

**i)** Best Practices (Policymakers could encourage relevant stakeholders and experts to establish best practices for development, implementation, and use of AI technologies); and,
**ii)** Oversight Clarity (Policymakers could collaborate with relevant stakeholders to clarify appropriate oversight mechanisms).

In a January 2024 article in Health Affairs Forefront, "Generative AI In Health Care: Opportunities, Challenges, And Policy," author Niam Yaraghi notes GenAI performs optimally in environments characterized by high repetition and low risk. This effectiveness stems from the technology's reliance on historical data to identify patterns and make predictions, under the premise that future conditions will mirror those of the past. Using that framework, the article assesses the following applications for suitability in the health care setting:

**i)** **Information Collection and Reporting**. GenAI can perform suitably for routine information gathering, such as collecting the medical histories of their patients by posing specific questions in a conversational manner.
**ii)** **Diagnostics**. Although there are promising applications in health care diagnostics, providers should exercise caution in deploying generative AI for diagnostics until they can train the AI on extensive medical (non-public) datasets.
**iii)** **Treatment.** AI currently lacks the advanced technological capability to replicate the nuanced tasks physicians perform. Treatments are often highly individualized, which does not align with AI's strengths in high-repetition, low-risk tasks. Given these complexities and risk, the integration of AI into medical treatment processes appears unlikely in the near future.
**iv)** **Post-Treatment Monitoring and Follow-Up.** This is a promising area that can encourage better two-way communication and better adherence to a treatment plan.
**v)** **Population Health Management**. AI has significant potential in population health management; however, the use of predictive analytics must be employed with care and may be enhanced with integration of information gathered from wearable technologies and smart devices.

The article offers policy recommendations, including emphasizing transparency, informed consent, and the exchange of data through Health Information Exchange to enhance deployment of AI systems capable of learning from vast and diverse medical records.

**e)** **American Medical Association (AMA) Principles.** The AMA Board of Trustees adopted "Principles for Augmented Intelligence Development, Deployment, and Use" on November 14, 2023. With respect to transparency, AMA writes that as implementation of AI-enabled tools and systems continues to increase, it is essential that use of AI in health care be transparent to both physicians and patients. Transparency requirements should be tailored in a way that best suits the needs of the end users. Disclosure should contribute to physician and patient knowledge and not create unnecessary administrative burden. When AI is utilized in health care decision-making, that use should be disclosed and documented in order to limit risks to, and mitigate inequities for, both physicians and patients, and to allow each to understand how decisions impacting patient care or access to care are made. While transparency does not necessarily ensure AI-enabled tools are

accurate, secure, or fair, it is difficult to establish trust if certain characteristics are hidden. In addition, AMA writes:

**i)** When AI is used in a manner which directly impacts patient care, access to care, or medical decision making, that use of AI should be disclosed and documented to both physicians and/or patients in a culturally and linguistically appropriate manner. The opportunity for a patient or their caregiver to request additional review from a licensed clinician should be made available upon request.

**ii)** When AI is used in a manner which directly impacts patient care, access to care, medical decision making, or the medical record, that use of AI should be documented in the medical record.

**iii)** AI tools or systems cannot augment, create, or otherwise generate records, communications, or other content on behalf of a physician without that physician's consent and final review.

This bill appears aligned with AMA's principles, specifically i) above.

**3) CONCERNS.** Pending further analysis of the bill, the California Radiological Society (CRS) writes to express concern with the scope of the bill, and the impact it may have on these existing practices, including the necessity of such disclosures even if approved or signed off by a health care provider. CRS notes some of the complex ways AI may be utilized in many ways in the clinical setting, particularly radiology. According to CRS, AI can help triage imaging studies based on urgency. For instance, it can identify critical findings, such as a brain hemorrhage on a CT scan, and prioritize it for immediate review, thus potentially saving lives by reducing diagnostic turnaround times. CRS notes AI tools can also generate preliminary reports by identifying common findings in images. These reports are then often reviewed and finalized by a radiologist, significantly speeding up the reporting process. Finally, CRS indicates there may be clinical notes that might be generated partially by AI but still signed off by a human, or an email that may use AI to start a response but is then edited and completed by the physician.

**4) RELATED LEGISLATION.**

**a)** AB 3211 (Wicks) establishes the California Provenance, Authenticity, and Watermarking Standards. Among other requirements related to watermarking of digital content, AB 3211 requires a conversational AI system operating through an audio modality to verbally disclose that the conversational AI system receives synthetic content, as defined. It also requires a conversational AI system to obtain a user's affirmative consent prior to beginning a conversation. AB 3211 is pending in Assembly Privacy and Consumer Protection Committee.

**b)** AB 2905 (Low) and AB 2512 (Jim Patterson) are identical bills, and both include telephone calls made using an artificial voice under the Public Utilities Commission's (PUC) current regulatory regime that applies to automatic dialing-announcing devices ("robocalls"). Both bills are pending in Assembly Communications and Conveyance Committee.

**c)** AB 2811 (Lowenthal) requires an attorney to submit an affidavit with each document filed in a state or federal court that discloses the use of GenAI, as specified. AB 2811 is pending in the Assembly Judiciary Committee.

**d)** SB 896 (Dodd) requires specified state agencies to take a number of actions related to analysis, risk assessment and use of GenAI. SB 896 includes requirements similar to those in this bill, i.e., it requires all state agency to disclose use of GenAI when interacting with the public and provide a person clear instructions how to directly communicate with a person from the state agency. SB 896 is pending in the Senate Governmental Organization Committee.

**5) PREVIOUS LEGISLATION.** SB 313 (Dodd) contained similar requirements related to state agency interaction with the public as those in SB 896, as explained above. SB 313 was held on the suspense file of the Senate Appropriations Committee.

**6) POLICY COMMENTS.**

**a) Alignment with Other Efforts.** As discussed in the Background on recent state and federal activity, this bill aligns with existing frameworks promoting disclosure to the end user when AI is being used in potentially consequential ways. It does not appear misaligned with other state or federal efforts, though other bills under consideration by the Legislature address disclosure of the use of an AI system in other applications. Alignment

**b) Definitions.** One of the significant challenges in any regulatory regime is clearly defining and specifying the entity or behavior that is being regulated. This bill is only one of a large number of bills proposing regulation of AI, and it only applies in the health care sphere. Definitions—for instance, of GenAI— will have to be reconciled across bills to have a coherent regulatory approach.

**c) Is A State-Level Regulation Appropriate For This Issue?** Federal rules do not appear to address the particular situation raised in this bill, and the state is responsible for regulation of health facilities and professionals, making a state requirement appear reasonable. However, it is possible that federal rules or standards may supersede or conflict with these requirements at some future time.

**d) Is a Health Care-Specific Rule Appropriate For This Issue?** As noted above, there are principles in AI best practices or regulation that can be applied more broadly. The application of AI in health care poses particular risks and no doubt there are some unique applications that can only be addressed by a health care-specific approach. However, disclosure to a consumer of the use or assistance of an AI system in interacting with any provider of a service may be something that can be effectively addressed through a broader lens of consumer protection.

**e) Where Do We Draw The Line Between GenAI-Assisted Content Generation And Automation Generally**? Should GenAI uniquely trigger disclosure or is disclosure also appropriate for automated (non-GenAI) content? If a draft response is simply automated based on programmed rules and then reviewed by a clinician before being shared by a patient, should that also trigger a mandatory disclosure? As compared to a sophisticated but automated system that is not GenAI— is this particular application of GenAI

different enough from automation, and/or does it pose a higher level of risk, that justifies the need for disclosure?

**f)** **How Is This Requirement Enforced**? This bill does not create any enforcement regime or penalty for noncompliance, in fact, it specifies no liability or penalty for failure to comply with its requirements. The author explains the lack of "teeth" in enforcement is intended to send a market signal that the state expects private entities to take this approach and maintain a cautious balance between under-regulation and overregulation.

**g)** **Risk of Paralysis by Analysis**. GenAI is a revolutionary technology with— it is safe to say— unimaginable potential for benefits and harms. It is also moving and evolving at light speed. The inherent complexity and difficulty of regulating the technology in a coherent and balanced way can be discouraging. However, choosing to do nothing while a powerful and volatile technology is loosed on a world that is still quite naïve to its incredible potential and multitudes of uses also has significant downside risk. In general, although this regulatory approach and other proposals raise a host of deep and novel questions, we cannot expect neat, satisfying answers as a condition of pursing regulation. We should expect our initial attempts at ensuring GenAI works well for humans will not be perfect, but that is a reason to collectively do our level best to work through the issues piece by piece, not to be paralyzed by waiting for a perfect, elegant solution that is unlikely to emerge.

**7)** **DOUBLE REFERRAL**. This bill is double referred. Upon passage in this Committee, this bill will be re-referred to the Assembly Committee on Privacy and Consumer Protection.

**8)** **POLICY COMMENT.** This bill includes a provision exempting providers from civil and criminal liability associated with the failure to provide the required notification. The provision is unnecessary as the bill creates no specific civil or criminal consequence for failure to comply with its provisions, it risks creating ambiguity about liability for actions outside of the failure to disclose, its nature as a blanket exemption is a bad precedent for nascent AI regulation and it risks creating a patchwork of liability provisions for different requirements that conflict with other broader, liability frameworks. California will be better-served with a coherent framework for liability associated with AI.

**REGISTERED SUPPORT / OPPOSITION**:

**Support**

None on file.

**Opposition**

None on file.

**Analysis Prepared by**: Lisa Murawski / HEALTH / (916) 319-2097

Date of Hearing: April 9, 2024

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 3129 (Wood) – As Introduced February 16, 2024

**SUBJECT**: Health care system consolidation.

**SUMMARY**: Authorizes the Attorney General (AG) to grant, deny, or impose conditions to a change of control or an acquisition between a private equity (PE) group or hedge fund and a health care facility or provider group to ensure these transactions are in the public interest. Requires a PE group or a hedge fund to provide written notice to, and obtain the written consent of, the AG at least 90 days prior to a change of control or an acquisition between the PE group or hedge fund and a health care facility or provider group with specified annual revenue. Reinforces the existing bar on the corporate practice of medicine by prohibiting a PE group or hedge fund involved in any manner with a physician or psychiatric practice doing business in this state, from controlling or directing that practice. Specifically, **this bill**:

1) Requires, unless the AG has provided a written waiver pursuant to 7) below, a PE group or hedge fund to provide written notice to, and obtain the written consent of, the AG prior to a change of control or an acquisition between the PE group or hedge fund and a health care facility or provider group.

2) Requires the notice to be submitted at the same time that any other state or federal agency is notified pursuant to state or federal law, and otherwise to be provided at least 90 days before the change in control or acquisition, and to contain information sufficient to evaluate the nature of the acquisition or change of control and information sufficient for the AG to determine that the criteria set forth in 10) and 11) below have been met or that a waiver may be granted.

3) Authorizes the AG to extend this 90-day period for one additional 45-day period, in addition to any time for which the period is stayed, if any of the following conditions apply:
   a) The extension is necessary to obtain additional information;
   b) The proposed acquisition or change of control is substantially modified after the original notice was provided to the AG; or,
   c) The proposed acquisition or change of control involves a multifacility or multiprovider health system serving multiple communities, rather than a single facility or entity.

4) Authorizes the AG to extend any time period set forth in 10) or 11) below by 14 days if the AG decides to hold a public meeting as specified in 13) below.

5) Requires a PE group, or hedge fund, to provide advance written notice to the AG prior to a change of control or acquisition between a PE group or hedge fund and a nonphysician provider or between a PE group or hedge fund and a provider, where the nonphysician provider has annual revenue of more than four million dollars ($4,000,000) or the provider has annual revenue between four million dollars ($4,000,000) and 10 million dollars ($10,000,000). Exempts transactions between a PE group or hedge fund and a nonphysician provider, or transactions between a PE group or hedge fund and a provider, that are required to be notified (but not reviewed) from being subject to consent by the AG.

6) Authorizes the AG to stay any time period in this bill upon notice to the parties to the acquisition or change of control, pending any review by a state or federal agency that has also been notified as required by federal or state law.

7) Prohibits written notice to, and the consent of, the AG from being required pursuant to 1) above, if the AG has given the PE group or hedge fund a written waiver as to the proposed acquisition or change of control. Authorizes the AG to grant a waiver if all of the following conditions apply:
   a) The party makes a waiver request by submitting, in writing, a description of the proposed acquisition or change of control, a copy of all documents that effectuate any part of the proposed acquisition or change of control, an explanation of why the waiver should be granted, and any other information the AG determines is required to evaluate the waiver request;
   b) The party's operating costs have exceeded its operating revenue in the relevant market for three or more years and the party cannot meet its debts as they come due;
   c) The party is at grave risk of immediate business failure and can demonstrate a substantial likelihood that it will have to file for bankruptcy under Chapter 11 of the federal Bankruptcy Act absent the waiver;
   d) The party would likely be substantially unable to reorganize successfully under Chapter 11 of the Bankruptcy Act;
   e) The acquisition or change of control will ensure continued health care access in the relevant markets; and,
   f) The party has made commercially reasonable best efforts in good faith to elicit reasonable alternative offers that would keep its assets in the relevant markets and that would pose a less severe danger to competition and access to care than the proposed acquisition or change of control.

8) Allows any consideration of a party's finances under this bill to include consideration of the finances of any affiliates that are under common control or are under the control of the party.

9) Requires the AG to grant or deny the waiver request within 60 days after all information needed to evaluate the waiver request has been submitted to the AG. Requires the AG, in determining whether to grant a waiver, to consider whether any of the decisional factors set forth 10) and 11) below are applicable to the proposed acquisition or change of control. Allows a waiver to be denied if any of these decisional factors require full AG review of the proposed agreement or transaction. Authorizes the AG to condition the grant of a waiver in a manner that eliminates the need for full AG review.

10) Authorizes the AG to grant, deny, or impose conditions to a change of control or an acquisition between a PE group or hedge fund and a health care facility, provider group, or both, if the change of control of an acquisition could have a substantial likelihood of anticompetitive effects or create a significant effect on the access or availability of health care services to the affected community.

11) Requires the AG, in making a determination to grant, deny, or impose conditions pursuant to this section, to apply the public interest standard. Defines the term "public interest" as being in the interests of the public in protecting competitive and accessible health care markets for prices, quality, choice, accessibility, and availability of all health care services for local communities, regions, or the state as a whole. Prohibits acquisitions or changes of control

from being presumed to be efficient for the purpose of assessing compliance with the public interest standard.

12) Requires the AG to make the determination required in 9) above in writing, and provide the basis for the determination.

13) Authorizes the AG, prior to issuing a written determination to hold a public meeting, which may be held in any of the counties in which the acquisition or change of control will take place, or, in case of a declaration of an emergency in any of those counties or in the state, online, to hear comments from interested parties. Requires, prior to holding a public meeting, the AG to provide notice of the time and place of any meetings by electronic publication, or publication in newspapers of general circulation, to consumers that may be affected by the acquisition or change of control.

14) Authorizes, within 10 days of the AG's notice of the decision to consent to, give conditional consent to, or not consent to the acquisition or change of control, any party to the acquisition or change of control to make an application to the AG to reconsider the decision and to modify, amend, or revoke the prior decision in whole or in part based upon new or different facts, circumstances, or law.

15) Authorizes, if the AG does not consent or gives conditional consent to an acquisition or change of control, any of the parties to the acquisition or change of control to, within 30 calendar days of a decision, seek judicial review of the AG's final determination by a writ of mandate to the superior court.

16) Requires, barring extraordinary circumstances or the consent of the parties, the superior court to issue its response to the petition within 180 days of receipt of the petition. Authorizes, after a review of the records, including any administrative record and any material submitted in support of the petition, the court to grant the petition upon finding that the decision was a gross abuse of discretion.

17) Requires the AG's determination to be based on an administrative record that must be provided to the court and to the parties to the acquisition or change of control in the event that the parties notify the AG of their intent to appeal the AG's final determination. Requires the administrative record to consist of any evidence submitted by the parties to the acquisition or change of control, any comments offered by interested parties at a public meeting, any official reports by any experts hired by the AG to review the transaction, any evidence obtained by the AG from the parties to the acquisition or change of control or third parties, and any other evidence or information relied on by the AG in making the determination.

18) Prohibits a PE group or hedge fund involved in any manner with a physician or psychiatric practice doing business in this state, including as an investor in that physician or psychiatric practice or as an investor or owner of the assets of that practice, from controlling or directing that practice, including, but not limited to, influencing or entering into contracts on behalf of that practice or physicians or psychiatrists in that practice with any third party, influencing or setting rates for that practice or physicians or psychiatrists in that practice with any third party, or influencing or setting patient admission, referral, or physician or psychiatrist availability policies.

19) Prohibits any physician or psychiatric practice, whether a sole proprietorship, a partnership, a foundation, or corporate entity of any kind, doing business in this state from entering into any agreement, or arrangement, with any entity controlled in part or in whole directly or indirectly by a PE group or hedge fund in which that PE group or hedge fund manages any of the affairs of the physician or psychiatric practice in exchange for a fee to be charged to that practice or passed through by that practice directly or indirectly to any health plan, insurer product, or patient. Specifies that this provision does not bar revenue-sharing between any such practice and any PE group or hedge fund.

20) Prohibits any contract involving the management of a physician or psychiatric practice doing business in this state by, or the sale of real estate or other assets owned by a physician or psychiatric practice doing business in this state to, a PE group or hedge fund from explicitly or implicitly including any clause barring any provider in that practice from competing with that practice in the event of a termination or resignation of that provider from that practice, or from disparaging, opining, or commenting on that practice in any manner as to any issues involving quality of care, utilization of care, ethical or professional challenges in the practice of medicine, or revenue-increasing strategies employed by the PE group or hedge fund. Makes any such explicit or implicit contractual clauses void, unenforceable, and against public policy.

21) Makes the AG be entitled to injunctive relief, and other equitable remedies, a court deems appropriate for enforcement of this section and entitled to recover attorney's fees and costs incurred in remedying any violation of this bill.

22) Authorizes the AG to adopt regulations to implement this bill, including, but not limited to, regulations to extend time periods or to provide a process for requesting a waiver.

23) Defines the following, for purposes of this bill:

    a) "Acquisition" to mean the direct or indirect purchase in any manner, including, but not limited to, lease, transfer, exchange, option, receipt of a conveyance, creation of a joint venture, or any other manner of purchase, by a PE group or hedge fund of a material amount of the assets or operations. Specifies that a transfer includes, but is not limited to, any arrangement, written or oral, that alters voting control of, responsibility for, or control of the governing body of the health care facility or provider.

    b) "Change of control" to mean an arrangement in which a PE group or hedge fund establishes a change in governance or sharing of control over health care services provided by a health care facility or provider doing business in this state, or in which a PE group or hedge fund otherwise acquires direct or indirect control over the operations of a health care facility or provider in whole or in substantial part doing business in this state. Provides, for purposes of this bill, an "arrangement" includes any agreement, association, partnership, joint venture, or other arrangement that results in a change of governance or control. States that a change of control does not exist where a health facility only extends an offer of employment to, or hires, a provider.

    c) "Health care facility" to means a facility, nonprofit or for-profit corporation, institution, clinic, place, or building where health-related physician, surgery, or laboratory services are provided, including, but not limited to, a hospital, clinic, long-term health care

facility, ambulatory surgery center, treatment center, or laboratory or physician office located outside of a hospital.

d) "Health plan" means a health care service plan or a specialized health care service plan, as defined in the Knox-Keene Health Care Service Plan Act of 1975.

e) "Hedge fund" means a pool of funds by investors, including a pool of funds managed or controlled by private limited partnerships, if those investors or the management of that pool or private limited partnership employ investment strategies of any kind to earn a return on that pool of funds.

f) "Hospital" means a general acute care hospital, acute psychiatric hospital, or special hospital, as those terms are defined.

g) "Insurance products" means any product provided by the following:
   i) A health insurer licensed to provide health insurance;
   ii) A publicly funded health care program, including, but not limited to, Medi-Cal and Medicare;
   iii) A third-party; or,
   iv) Any other public or private entity, other than an individual, that pays for or reimburses for any part of the cost for the provision of health care.

h) "Nonphysician provider" to mean a group of two or more individuals that are licensed as defined under Division 2 (commencing with Section 500) of the BPC that does not provide health-related physician, surgery, or laboratory services to consumers.

i) "PE group to mean an investor or group of investors who engage in the raising or returning of capital and who invests, develops, or disposes of specified assets.

j) "Provider" to mean any group of two to nine individuals, except for a provider group, that provides health-related physician, psychiatric, surgery, or laboratory services to consumers.

k) "Provider group" to mean a group of providers of ten or more providers that provide health-related physician, psychiatric, surgery, or laboratory services to consumers or a group of providers of two to nine individuals that provide health-related physician, psychiatric, surgery, or laboratory services to consumers that generate annual revenue of ten million dollars ($10,000,000) or more. Specifies that this definition includes licensed health care providers such as dentists, optometrists, and pharmacists who provide health-related surgery or laboratory services within the scope of their practice as licensees.

24) Provides that these definitions do not apply to acquisitions or changes of control entered into prior to January 1, 2025, including subsequent renewals, as long as those acquisitions or changes of control do not involve a material change in the corporate relationship between the PE group or hedge fund and a health care facility or provider group, on or after January 1, 2025.

25) States that this bill is intended to address health care practices by PE groups, and hedge funds that can lead to higher prices for services, lower quality at a given price for services, less

cost-efficient services, restricted access to, or the closure of services, and less choice for services, which ultimately leads to higher prices and more inconvenience for consumers, and higher total cost of care for services.

26) Requires this bill to be construed, as a matter of state law, to be enforceable up to, but no further than, the maximum possible extent consistent with federal law and constitutional requirements, even if that construction is not readily apparent, as these constructions are authorized only to the extent necessary to save the statute from judicial invalidation.

27) Makes the provisions of this bill severable. Prohibits, if any provision of this bill or its application is held invalid, that invalidity from affecting other provisions or applications that can be given effect without the invalid provision or application.

**EXISTING LAW**:

1) Establishes the state Department of Justice (DOJ) and AG to bring civil and criminal legal actions against individuals and businesses acting in restraint of trade under the Cartwright Act, which is the state's antitrust law prohibiting anti-competitive activity, mirroring the federal Sherman Antitrust Act and the Clayton Antitrust Act. [BPC §16600 *et seq*.]

2) Requires any non-profit corporation that operates or controls a health facility, as defined, to provide written notice to, and obtain the written consent of, the AG prior to entering into any agreement or transaction to do either of the following:

   a) Sell, transfer, lease, exchange, option, convey, or otherwise dispose of, its assets to a for-profit corporation or entity, or another non-profit corporation; or,
   b) Transfer control, responsibility, or governance of a material amount of the assets or operations of the non-profit corporation to any for-profit corporation or entity, or another non-profit corporation. [Corporations Code (CORP) §5914, §5920]

2) Requires the AG, within 90 days of the receipt of a written notice of a proposed transaction involving a non-profit health facility, to notify the non-profit corporation in writing of the decision to consent to, give conditional consent to, or not consent to the agreement or transaction. [CORP §5915, §5920]

3) Permits the AG to extend the 90-day deadline described above for one additional 45-day period if any of the following conditions are satisfied: the extension is necessary to obtain specified information, the proposed transaction is substantially modified after the first public meeting conducted by the AG, or the proposed transaction involves a multi-facility health system serving multiple communities. [CORP §5915, §5920]

4) Requires the AG to conduct one or more public meetings to hear comments from interested parties prior to issuing any written decision regarding a transaction involving a nonprofit health facility. [CORP §5916, §5922]

5) Provides the AG with the discretion to consent to, give conditional consent to, or not consent to any agreement or transaction involving a nonprofit health facility based on the consideration of any factors that the AG deems relevant, including but not limited to:

a) Whether the agreement or transaction is at fair market value;
b) Whether the proposed use of the proceeds from the transaction is consistent with the charitable trust on which the assets are held by the health facility or by the affiliated nonprofit health system;
c) Whether the transaction would create significant effects on the availability or accessibility of health care services to the affected community; or,
d) Whether the transaction is in the public interest. [CORP §5917, §5923]

6) Prohibits the AG from consenting to a health facility transaction in which the seller restricts the type or level of medical services that may be provided at the health facility that is the subject of the transaction. [CORP §5917.7]

7) Establishes the Office of Health Care Affordability (OHCA) within the Department of Health Care Access and Information (HCAI). Identifies OHCAs three primary responsibilities: managing spending targets, monitoring system performance, and assessing market consolidation. Requires OHCA to collect, analyze, and publicly report data on total health care expenditures, and enforce spending targets set by a Health Care Affordability Board. Requires health care entities to provide written notice of agreements and transactions that merge and if OHCA finds that the change is likely to have a risk of a significant impact on market competition, the state's ability to meet cost targets, or costs for purchasers and consumers, requires OHCA to conduct a cost and market impact review. Authorizes OHCA to coordinate with other state agencies to address consolidation as appropriate. [Health and Safety Code §127501]

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

**COMMENTS**:

1) **PURPOSE OF THIS BILL.** According to the author, PE acquisitions in health care have exploded in the past decade. From 2013 to 2016, PE firms acquired 355 physician practices. In the four years that followed, PE acquired 578 additional practices and has poured nearly $1 trillion into nearly 8,000 health care transactions during the past decade. More than 90% of PE consolidations fall below the $101 million threshold that triggers an antitrust review by the Federal Trade Commission and the U.S. Justice Department. The author states that emerging data shows these acquisitions demand attention and increased regulatory oversight to ensure that these transactions are in the public interest. These PE firms aim to secure high returns on their investments, as much as 20% in just three to five years, by making them more lucrative, which can conflict with the goal of delivering affordable, accessible, high-value health care. Studies consistently show that PE ownership in the health care industry has resulted in higher health care costs, poor quality and less access to care. The author concludes that transparency and scrutiny of these deals is needed because without proper oversight and regulation, these practices will continue and patients and consumers are likely to experience anticompetitive effects.

2) **BACKGROUND**. According to the January 2020 California Health Care Foundation (CHCF) report entitled *"*Getting to Affordability: Spending Trends and Waste in California's Health Care System," per capita spending has grown steadily over time for all sources of coverage: employer-sponsored insurance, Medi-Cal, Medicare, and private health insurance.

Private health insurance coverage had the highest growth rates at 4% per year. Most of the spending comes from inpatient hospital stays and office-based medical provider services ($60 billion each) followed by prescription drugs ($45.6 billion). A critical factor in the fast growth of prices in California compared with the rest of the country is market concentration. This market concentration, including hospital and physician consolidation, has been proliferating in the state along with price acceleration according to a 2019 CHCF report entitled, "Sky's the Limit: Health Care Prices and Market Consolidation in California." As market concentration rises, so do prices.

A 2020 *Journal of American Medicine* article, "Private Equity Acquisitions of Physician Medical Groups Across Specialties," notes that PE has started to play a role in this consolidation in recent years. These firms typically invest in businesses by taking a majority stake with the goal of increasing the value of the business and potentially selling it at a profit. One study found that PE firms acquired 355 physician practices (1,426 sites and 5,714 physicians) from 2013 to 2016.

**a) The PE model**. According to a 2023 study published in the *International Journal of Health Economics and Management*, "Private equity and its effect on patients: a window into the future," (the IJHEM study) in a typical acquisition by PE, 70% of the overall cost is financed by debt and the remaining 30% equity stake is funded through limited partners (e.g. endowments, pension funds, wealthy individuals), who expect an annual return of 20% or more. The PE firm which manages the business usually funds 2% of the overall equity stake. Usually, the PE firm will exit the investment within three to seven years from the time of acquisition and usually keep 20% profit from the sale of the entity with the rest going to the limited partners. The typical investment model that PE uses in acquiring healthcare entities is the leverage buyout, where the PE firm pledges the targets assets as collateral for the debt to finance the purchase. Notably, it is the acquired entity that bears the responsibility of paying the debt.

**b) Effect of PE in Healthcare.** Over the past decade, there has been a sharp rise in PE and hedge fund acquisitions of health care companies nationwide. According to a 2021 Petris Center on Health Care Markets and Consumer Welfare Report (Petris report), "Soaring Private Equity Investment in the Healthcare Sector: Consolidation Accelerated, Competition Undermined, and Patients at Risk," estimated deal values have totaled $750 billion between 2010 and 2019. The Petris report also notes that when a short-term profit-driven business model is applied to the health care system, there is an incentive to raise prices, cut costs, and pay out any revenue to PE investors. This often leads to staffing shortages, failures to pay vendors, and increased costs for patients and employers. Instead of practicing medicine in the best interest of patients, physicians are directed to hit patient quotas and push more profitable procedures. Over time, this directly leads to the closure or scaling back of health care services.

According to the IJHEM study, in health care facilities, PE backed acquisitions have led to a higher rate of serious medical errors in hospitals and increased mortality in nursing homes. Increased deaths among seniors in nursing homes is likely due to a combination of lower staffing levels and cutting corners on meeting standards of care. Also, appointment times can be curtailed and waiting times increased.

**c) Current Regulatory Oversight of Consolidation.** Among the key provisions in U.S. antitrust law is one designed to prevent anticompetitive mergers or acquisitions. Three major federal anti-trust laws, the Sherman Antitrust Act, the Clayton Act, and the Federal Trade Act, are used by both state and federal government to review the effects on competition from health care entity conduct and consolidations. Under the Hart-Scott-Rodino Act, the Federal Trade Commission and the DOJ review most of the proposed transactions that affect commerce in the United States and are over a certain size, and either agency can take legal action to block deals that it believes would "substantially lessen competition." California has its own anti-trust law, the Cartwright Act.

**d) OHCA.** In 2022, the California Health Care Quality and Affordability Act (SB 184 (Committee on Budget and Fiscal Review), Chapter 47, Statutes of 2022) established the OHCA within HCAI. Recognizing that health care affordability has reached a crisis point as health care costs continue to grow, OHCA's enabling statute emphasizes that it is in the public interest that all Californians receive health care that is accessible, affordable, equitable, high-quality, and universal. OHCA will collect, analyze, and publicly report data on total health care expenditures, and enforce spending targets set by a new Health Care Affordability Board. To ensure a balanced approach to slow spending growth, OHCA will monitor system performance by measuring quality, equity, adoption of alternative payment models, investment in primary care and behavioral health, and workforce stability. Through cost and market impact reviews, OHCA will analyze transactions that are likely to significantly impact on market competition, the state's ability to meet targets, or affordability for consumers and purchasers. Based on results of the review, OHCA will then coordinate with other state agencies to address consolidation as appropriate.

**e) Existing AG oversight of nonprofit transactions**. As noted in existing law, above, California law requires the AG's review and consent for any sale or transfer of a health care facility owned or operated by a nonprofit corporation whose assets are held in public trust. This requirement covers health care facilities that are licensed to provide 24-hour care, such as hospitals and skilled nursing facilities. The review process includes public meetings and, when necessary, preparation of expert reports. The AG's decision often requires the continuation of existing levels of charity care, continued operation of emergency rooms and other essential services, and other actions necessary to avoid adverse effects on healthcare in the local community. Specifically, the law provides the AG with the discretion to consent to, give conditional extent to, or not consent to any agreement or transaction involving a nonprofit health facility based on the consideration of any factors that the AG deems relevant, including but not limited to:

- **i)** Whether the agreement or transaction is at fair market value;
- **ii)** Whether the proposed use of the proceeds from the transaction is consistent with the charitable trust on which the assets are held by the health facility or by the affiliated nonprofit health system;
- **iii)** Whether the transaction would create significant effects on the availability or accessibility of health care services to the affected community; or,
- **iv)** Whether the transaction is in the public interest.

The law also prohibits the AG from consenting to a health facility transaction in which the seller restricts the type or level of medical services that may be provided at the health

facility that is the subject of the transaction. The AG is authorized to contract with experts when deciding whether to give consent to a transaction, or to monitor ongoing compliance with the terms and conditions of any transaction, and requires the nonprofit corporation to reimburse the AG for all reasonable and necessary costs to conduct the review or monitoring ongoing compliance.

This bill would expand that authority by extending the AG's authority to review transactions prior to a change of control or an acquisition between a PE group or hedge fund and a health care facility or provider group in order to address concerns about the expansion of PE into the healthcare sector and the effects on costs, quality, equity and access.

**f) Ban on the Corporate Practice of Medicine.** California has one of the strongest prohibitions on the Corporate Practice of Medicine (CPOM), with more active enforcement than most other states with a CPOM doctrine. Corporations may not practice medicine nor facilitate the practice of medicine (e.g. engage with contractor physicians). The California ban on the corporate practice of medicine extends to other licensed clinical professions, including the work of dentists, chiropractors, psychologists, therapists, optometrists, speech therapists, occupational therapists, and others. Corporations may not "indirectly" practice medicine by unduly controlling a physician's work. Over the years, several AG opinions have upheld this CPOM doctrine, which is defined by both case law (developed over the last century) as well as laws on medical licensure. The Medical Practice Act prohibits entities without a valid licensure from practicing, attempting to practice, or advertising medical practice. The term "person" is restricted to natural individuals, denying corporations the right to practice medicine. However, exceptions exist. California law allows certain entities, like professional medical corporations, partnerships, HMOs, and nonprofit organizations, to practice medicine.

This bill would prohibit a private equity group or hedge fund involved in any manner with a physician or psychiatric practice doing business in this state, from controlling or directing that practice.

3) **SUPPORT.** AG Rob Bonta is the sponsor of this bill and states that over the past decade, there has been a sharp rise in PE and hedge fund acquisitions of health care companies nationwide. Estimated deal values have totaled $750 billion between 2010 and 2019. When a short-term profit-driven business model is applied to our health care system, there is an incentive to raise prices, cut costs, and pay out any revenue to PE investors. This often leads to staffing shortages, failures to pay vendors, and increased costs for patients and employers. Instead of practicing medicine in the best interest of patients, physicians are directed to hit patient quotas and push more profitable procedures. Over time, this directly leads to the closure or scaling back of health care providers. PE transactions are leading to further consolidation in the health care market through a practice called "roll ups" where health care providers purchase smaller providers in a given area or specialty to aggregate market power. Comparing communities where PE dominate physician specialties to other U.S. markets, price increases are up to three times higher. The AG concludes that by establishing review of PE and hedge fund acquisitions of health care facilities and provider groups and enhancing oversight of the relationship between these corporate entities and health care providers, this bill would protect health care access, availability, choice, cost, and quality for California

communities across the state.

Health Access California (HAC) supports this bill and notes that oversight is needed to ensure that consumers are protected in these acquisitions. For over 30 years, California Attorneys General has used their authority to protect consumers from negative impacts of nonprofit hospital mergers. This bill extends this authority, allowing the AG to provide public scrutiny on these PE and hedge fund acquisitions and changes in control of health facilities, and be able to approve, deny or approve with conditions to address key issues. Specifically, this bill will require: a) PE groups and hedge funds to provide written notice to the AG prior to their change in control or acquisition of a provider group or health facility; b), For nonphysician providers with annual revenue of more than $4 million and a provider with revenue between $4 million and $10 million they will only be required to provide notice to the AG; and, c) For all health facilities, and physician groups with annual revenue greater than $10 million, those transactions will be required to seek consent from the AG and undergo a 90-day review process. HAC concludes that this bill allows for a waiver process for financially distressed health facilities and physician groups, and for the AG to consider the impact of the transaction on the public interest, competition and the health of the community when considering the waiver.

Reproductive Freedom for All (RFFA) supports this bill and states that PE acquisitions in healthcare are on the rise and studies show that healthcare services have suffered as a result. Private ownership has resulted in higher health care costs, poor quality, and less access to care. Between 2013 and 2020, 933 physician practices have been acquired by PE firms. Today, over 30% of practices in almost 30% of metropolitan areas are owned by PE. The driving force of these investments is not positive healthcare outcomes, it is profit. RFFA notes that with the increase in PE acquisitions of healthcare facilities, reproductive healthcare is often one of the first to be impacted. Many private facilities decline to offer a full host of reproductive health services, including abortion, or simply close their reproductive healthcare practice for profitability margins. RFFA concludes that this bill will ensure that everyone has access to quality reproductive healthcare regardless of their location in the state of California.

4) **OPPOSITION.** The American Investment Council (AIC) is opposed to this bill and states that if passed, this bill will result in less capital being available to fund health care services and research in California, diminished access to care for patients throughout the state, and additional failures in the health care system. AIC contends that the underlying premise of the bill is flawed and the bill fails to provide OHCA with sufficient time to collect and report data informative to the legislature regarding health care expenditures and cost trends in order to develop data-informed policies.

More broadly, AIC believes the enactment of this bill would send the wrong message to private capital investors. California has long been the top destination for private capital investment and innovation. The state ranks first in the country for attracting private capital investment dollars, averaging around $100 billion per year. In 2022 alone, private equity invested $173 billion in California's economy, many supporting medical technologies, life sciences and access to health care. Private equity is responsible for 1,475,000 direct jobs and another 2.3 million indirect jobs in the state. California is home to over 750 private equity firms that are responsible for some of the state's most innovative and successful companies. The premise inherent in this bill that one of the state's most important economic contributors is the "culprit" for the many issues faced by California's health care system diminishes the

importance of these investments and will send a strong message that private capital investment is no longer welcome.

AIC also states, that this bill also proposes to ban investors and investor-owned businesses from entering into any agreement that "manages any of the affairs" of a physician practice in exchange for a fee, which would presumably include management, administrative and business support services agreements. This ban would essentially end the physician practice management model in California and would potentially go far beyond this to prohibit common vendor arrangements between physician practices and investor-owned businesses such as revenue cycle management services agreements and other outsourced non-clinical service arrangements. The practice management model is a well-developed structure that has been implemented in compliance with California's stringent corporate practice of medicine prohibition for many years.

The California Hospital Association (CHA) is opposed to this bill and states that across California, patients are experiencing delays in emergency care and behavioral health services, as well as other medical procedures. The current hospital capacity crisis can only be alleviated by continued investment in the expansion and retention of services. The state's policy should be to encourage investment in the California health care marketplace rather than making it more difficult. CHA contends that this bill creates barriers to new investment when exactly the opposite is needed. Some of CHAs' concerns with this bill are outlined below.

**The definition of "PE group" is too broad.** The bill adopts an extraordinarily broad definition of "PE group" as "an investor or group of investors who engage in the raising or returning of capital and who invests, develops, or disposes of specified assets." This is really a definition of an "investor," not a definition of a "PE group." This bill would deem every investor to be a PE group, including a nonprofit hospital, physician, bank, mutual fund, CalPERS, or even a single individual. It is difficult to think of any individual or organization that invests money that would not meet the bill's definition of a "PE group."

**The standards for DOJ review are unclear.** Without clear standards, entities will struggle to determine whether DOJ approval is required, slowing much-needed capital investment in health care. The bill's definition of "change of control" is also unclear, including "indirect" control and "sharing of control" where there are even minor changes in governance. The bill explicitly calls out "altering voting control of" a provider as requiring notice. This bureaucratic red tape would stifle needed investment.

**This bill is premature and unnecessary.** Existing law requires, as of April 1, 2024, OHCA to analyze the transactions covered by AB 3129. OHCA is the state agency responsible for gathering data about California's health care marketplace and understanding the health care delivery system, payment system, access, and costs. Existing law prohibits transactions from closing until 60 days after OHCA publishes its final impact analysis — which gives the DOJ time to go to court if it believes the transaction violates any laws. The DOJ has long had the ability to investigate and prosecute anticompetitive behavior, as do federal government authorities.

**5) PREVIOUS LEGISLATION.**

**a)** AB 2080 (Wood) of 2022 would have established the Health Care Consolidation and Contracting Fairness Act of 2022, which prohibited a contract issued, amended, or renewed on or after January 1, 2023, between a health care service plan (health plan) or health insurer and a health care provider or health facility from including anti-competitive terms, such as restricting the health plan or insurer from offering incentives to encourage enrollees or insureds to utilize higher quality, low cost health care providers. AB 2080 was not heard in the Senate Health Committee.

**b)** SB 184 (Committee on Budget and Fiscal Review), Chapter 47, Statutes of 2202, establishes OHCA within HCAI. Identifies OHCAs three primary responsibilities: managing spending targets, monitoring system performance, and assessing market consolidation. Requires OHCA to collect, analyze, and publicly report data on total health care expenditures, and enforce spending targets set by a Health Care Affordability Board.

**c)** AB 1132 (Wood) of 2021 would have expanded the AG's existing authority to approve or deny a change in ownership of a nonprofit health facility to include oversight and approval or denial of for-profit changes in ownership and control. AB 1132 would have prohibited health care providers, insurers, health plans and health care facilities from engaging in specific contracting practices and expanded regulatory oversight over certain health plan transactions, including when a health plan merged or acquired other entities. AB 1132 was subsequently amended to address a different issue area.

**d)** SB 977 (Monning) of 2020 would have required the AG, beginning July 1, 2021, to establish the Health Policy Advisory Board for the purpose of evaluating and analyzing health care markets in California and providing recommendations to the AG's office. Would have required a health care system, as defined, a PE group, or hedge fund to provide written notice to, and obtain the written consent of, the AG prior to a change in control, or an acquisition**,** as defined, between the entity and a health care facility or provider. Provides for an expedited review process for transactions under $1 million, county facilities, and academic centers, as defined. Would have required a health care system, PE group, or hedge fund to provide advance written notice to the AG prior to a change of control or acquisition between a health care system, PE group, or hedge fund and a non-physician provider, as defined. Would have made it unlawful for one or more health care systems, either independently or dependently, to use their market power to, among other things, cause anticompetitive effects, as described, and authorizes the AG to bring a civil action for a violation of this unlawful conduct. Would have sunset the AG's authority to review changes of control on January 1, 2026. SB 977 was not taken up for a vote on the Assembly Floor.

**e)** SB 538 (Monning) of 2018 would have established the Health Care Market Fairness Act of 2018, and would have prohibited contracts between hospitals, as defined, and contracting agents, health care service plans, or health insurers from containing certain provisions, including, but not limited to, setting payment rates or other terms for nonparticipating affiliates of the hospital, and requiring the contracting agent, plan, or insurer to keep the contract's payment rates confidential from any payor, as defined, that is or may become financially responsible for the payment. SB 538 was held at the request of the author in the Assembly Health Committee.

**f)** AB 595 (Wood), Chapter 292, Statutes of 2018, requires a health plan that intends to merge or consolidate with, or enter into an agreement resulting in its purchase, acquisition, or control by, any entity, as defined, including another health care service plan or a licensed health insurer, to give notice to, and secure prior approval from, the Department of Managed Health Care Director.

**g)** SB 932 (Hernandez) of 2016 would have banned seven specified provisions from contracts between health care providers and payers and would have required prior approval from DMHC for mergers and other transactions between health plans, risk-based and other organizations. SB 932 was held at the request of the author in the Senate Appropriations Committee.

6) **DOUBLE REFERRAL.** This bill has been double-referred; upon passage of this committee, it will be referred to the Assembly Judiciary Committee.

7) **SUGGESTED AMENDMENTS.** The Committee is suggesting technical and clarifying amendments to more clearly define the entities, health professionals, provider groups and health care facilities involved in the acquisitions and changes of control by PE or hedge funds covered by this legislation.

**REGISTERED SUPPORT / OPPOSITION**:

**Support**

Attorney General Rob Bonta (sponsor)
American Academy of Emergency Medicine
California Physicians Alliance
California State Association of Psychiatrists (CSAP)
California State Council of Service Employees International Union (SEIU California)
Health Access California
NextGen California
Reproductive Freedom for All

**Opposition**

American Investment Council
California Chamber of Commerce
California Hospital Association
United Hospital Association

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

Date of Hearing: April 9, 2024

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 3161 (Bonta) – As Amended April 1, 2024

**SUBJECT**: Health and care facilities: patient safety and antidiscrimination.

**SUMMARY**: Requires the Department of Public Health (DPH) to collect self-reported patient demographics when receiving complaints regarding adverse events from hospitals, as defined. Requires hospitals to provide demographic data when reporting adverse events (AEs). Requires DPH to review, analyze, and publish trends among patient safety events in a manner consistent with patient privacy. Requires hospital patient safety plans to include specified methods to address racism and discrimination in health care, including procedures for staff to anonymously report instances of racial bias. Requires DPH to publish hospital patient safety plans. Establishes a partnership between DPH, the California Department of Civil Rights (DCR), and Department of Justice (DOJ) to share data on racial bias in health care specific to patient AEs. Specifically, **this bill**:

1) Adds the following demographic data to the reporting requirements a hospital must provide to DPH regarding an AE:

    a) Age;
    b) Race;
    c) Ethnicity;
    d) Gender identity, to the extent known;
    e) Sexual orientation, to the extent known;
    f) Primary language spoken;
    g) Disability status, as defined; and,
    h) Expected payer.

2) Requires DPH to include a section on the "Complaint Against a Health Care Facility/Provider form on DPH's website, and provide a means for complaints submitted via mail, fax, or by telephone, for complaints involving a hospital to collect the following information about the affected patient:

    a) Age;
    b) Race;
    c) Ethnicity;
    d) Gender identity;
    e) Sexual orientation;
    f) Primary language spoken;
    g) Disability status; and,
    h) Expected payer.

3) Requires DPH to inform complainants that the information collected pursuant to 2) above is used to ensure that all patients receive the best care possible. Requires DPH to inform complainants that providing this information is optional and will not affect DPH's

investigation process in any way.

4) Requires DPH to provide complainants with the option to refer the complaint to the Civil Rights Department. Requires DPH include a statement indicating that referring a complaint is optional and will not affect DPH's investigation process. Requires DPH to provide the full complaint to the DCR when requested by the complainant.

5) Requires DPH, by January 1, 2026, and annually thereafter, to provide information regarding reports of substantiated AEs and the outcome of inspections and investigation conducted, including demographic information on the DPH website.

6) Requires DPH, upon request, to compile and make available to the DCR and the DOJ, data regarding reports of substantiated AEs, and the outcomes of inspections and investigations.

7) Defines, for purposes of this bill, "complaint" to mean any oral or written notice to DPH, other than a report from the hospital, of an alleged violation of applicable requirements of state or federal law, or an allegation of facts that might constitute a violation of applicable requirements of state or federal law.

8) Requires hospitals to include anonymous reporting options in their patient safety reporting system.

9) Requires hospitals, when analyzing root causes of patient safety events, to also include analysis of events by a process for addressing racism and discrimination, and its impacts on patient health and safety, that includes, but is not limited to:
   a) Monitoring sociodemographic disparities in patient safety events and developing interventions to remedy known disparities; and,
   b) Encouraging facility staff to report suspected instances of racism and discrimination.

10) Requires, commencing January 1, 2026, and biannually thereafter, hospitals to submit patient safety plans to DPH's licensing and certification division.

11) Authorizes DPH to impose a fine not to exceed five thousand dollars ($5,000) on hospitals for failure to adopt, update, or submit patient safety plans.

12) Authorizes DPH to grant a hospital an automatic 60-day extension for submitting biannual patient safety plans.

13) Requires DPH to make all patient safety plans submitted by health facilities available to the public on its internet website.

**EXISTING LAW**:

1) Establishes DPH, which among other functions, licenses and regulates hospitals, including general acute care hospitals (GACHs), acute psychiatric hospitals (APHs) and special hospital (hospitals). [Health and Safety Code (HSC) § 1250, *et seq.*]

2) Requires hospitals to report an adverse event to DPH no later than five days after the adverse event has been detected, or, if that event is an ongoing urgent or emergent threat to the

welfare, health, or safety of patients, personnel, or visitors, not later than 24 hours after the adverse event has been detected. [HSC §1279]

3) Requires DPH, in any case in which DPH receives a report from a hospital pursuant to 2) above, or a written or oral complaint involving a hospital described in 1) above, that indicates an ongoing threat of imminent danger of death or serious bodily harm, to make an onsite inspection or investigation within 48 hours or two business days, whichever is greater, of the receipt of the report or complaint and to complete that investigation within 45 days. [HSC §1279.2]

4) Requires hospitals to develop, implement, and comply with a patient safety plan for the purpose of improving the health and safety of patients and reducing preventable patient safety events. Requires the patient safety plan to be developed by the facility, in consultation with the facility's various health care professionals and, at a minimum, provide for the establishment of all of the following:

   a) A patient safety committee or equivalent committee in composition and function. Requires the committee to be composed of the facilities' various health care professionals, including, but not limited to, physicians, nurses, pharmacists, and administrators. Requires the committee to do all of the following:

      i) Review and approve the patient safety plan;

      ii) Receive and review reports of patient safety events;

      iii) Monitor implementation of corrective actions for patient safety events;

      iv) Make recommendations to eliminate future patient safety events; and,

      v) Review and revise the patient safety plan, at least once a year, but more often if necessary, to evaluate and update the plan, and to incorporate advancements in patient safety practices.

   b) A reporting system for patient safety events that allows anyone involved, including, but not limited to, health care practitioners, facility employees, patients, and visitors, to make a report of a patient safety event to the health facility.

   c) A process for a team of facility staff to conduct analyses, including, but not limited to, root cause analyses of patient safety events. Requires the team to be composed of the facility's various categories of health care professionals, with the appropriate competencies to conduct the required analyses.

   d) A reporting process that supports and encourages a culture of safety and reporting patient safety events.

   e) A process for providing ongoing patient safety training for facility personnel and health care practitioners.

5) Requires hospitals to prepare an annual equity report that includes an analysis of health status and access to care disparities for patients, measures from the Agency for Healthcare Research and Quality's Quality Indicators, and pay data to the Department of Fair Employment and Housing. Requires the Department of Health Care Access and Information (HCAI) to make all equity reports available on their website and annually prepare a report that includes a list of all hospitals that failed to submit equity reports. [HSC §127372]

6) Establishes a structure under which DPH is permitted to assess administrative fines to hospitals for violation of any of their licensing laws and regulations. Requires DPH to promulgate regulations establishing the criteria to assess these administrative penalties, and requires these criteria to include, but not be limited to, the probability and severity of the risk that the violation presents to the patient, the facility's history of compliance with related state and federal statutes and regulations, the demonstrated willfulness of the violation, and the extent to which the facility detected the violation and took steps to immediately correct the violation and prevent the violation from recurring. [HSC §1280.3]

7) Permits DPH to assess an administrative penalty against a hospital, for a deficiency constituting an immediate jeopardy violation, as defined, up to a maximum of $75,000 for the first administrative penalty, up to $100,000 for the second administrative penalty, and up to $125,000 for the third and every subsequent administrative penalty. [HSC §1280.3 (a)]

8) Establishes the DCR to protect the people of California from unlawful discrimination in employment, housing and public accommodations (businesses) and from hate violence and human trafficking in accordance with the Fair Employment and Housing Act, Unruh Civil Rights Act, Disabled Persons Act, and Ralph Civil Rights Act. [Government Code §12900 *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, racial bias in healthcare disproportionately affects communities of color. The author notes that, according to the National Institute of Health, racial and ethnic minority groups are more likely to live in segregated and disadvantaged neighborhoods, largely due to structural discrimination and racism. Structural discrimination and racism in health care leads to limited access to treatment and preventive health care, which in turn, increases risks for morbidity and mortality. Further, Black, Indigenous, People of Color (BIPOC) communities experience higher rates of medical misdiagnoses and patient adverse events when compared to white patients. This bill will require hospitals to analyze patient safety events by sociodemographic factors to identify disparities in these events. The author concludes that this bill also requires hospital safety plans to include a process for addressing racism and discrimination and its impacts on patient health and safety, including monitoring sociodemographic disparities in patient safety events and developing interventions to remedy known disparities, and encouraging facility staff to report suspected instances of racism and discrimination.

2) **BACKGROUND.** According to the Institute of Medicine, patient safety is "freedom from accidental injury due to medical care or medical errors" and represents a fundamental domain of inpatient quality of care. Hospital-acquired illnesses and injuries have direct consequences

on patient health and erode the trust patients place in providers and health systems. A July 2021 Urban Institute report, "Do Black and white patients experience similar rates of adverse safety events at the same hospital?" found that in the 26 states with available data for 2017, Black adult patients experienced higher rates of hospital-acquired injuries or illnesses than white patients and that some of the differences in patient safety can be attributed to differences in the quality of hospitals that Black patients are admitted to relative to white patients. A related but unresolved research question is whether Black and white patients experience similar rates of adverse patient safety events when admitted to the same hospital. Investigating within-hospital racial differences in patient safety is critical to understanding what progress, if any, has been made in improving racial equity in health care.

**a) The Impact of Racism on Patient Safety in Health Care Settings.** The RAND Corporation and MedStar researchers examined the intersection of patient safety and racism in an August 2022 report, "Identifying and Understanding Ways to address the Impact of Racism on Patient Safety in Health Care Settings." The RAND report focused on patient safety and health equity from clinician leaders' perspectives. An overarching emphasis of the work concerned the impact of racism and other related factors (i.e., bias) on patient safety events and potential interventions or changes (such as creating a culture of speaking up about racism in care) that can help prevent such events. Key Findings included:

- **i)** While patient safety events, overall, were characterized by racial and ethnic disparities, methodological challenges, primarily related to data availability, limited in-depth analysis of this finding;
- **ii)** Racism and its impact on patient safety events was more often discussed in editorials than in peer-reviewed and gray literature;
- **iii)** Subject-matter expert interviews indicated that various levels of racism ranging from internalized and interpersonal to institutional and systemic directly impact the risk of patient safety events and highlighted the interplay between racism and social determinants of health; and,
- **iv)** The authors also identified patient, provider, and systems factors that contribute to disparities in patient safety events.

The RAND report made the following recommendations:

- **i)** Health systems should collect patient safety data with equity in mind so that these systems can analyze patient safety events by sociodemographic factors and look for disparities in these events;
- **ii)** Health systems and patient safety reporting vendors must develop more-efficient and user-friendly formal reporting systems so that health care providers are more likely to report patient safety events;
- **iii)** Health care as an industry and medicine as a discipline need to create a culture of speaking up that prevents patient safety events caused by racism from happening; and,
- **iv)** Health insurance reform is needed to address some of the underlying drivers of disparities in patient safety events.

As noted in 4) in existing law above, hospitals are required to develop patient safety plans which include a process for a team of facility staff to conduct analyses, including, but not

limited to, root cause analyses of patient safety. This bill additionally requires hospital patient safety plans to include specified methods to address racism and discrimination in health care, including procedures for staff to anonymously report instances of racial bias.

**b) AEs and Complaints.** AEs, are incidents or conditions that could have resulted, or did result, in harm to a patient. Facilities are currently required to report AEs to DPH. Complaints are any report to DPH of a facility's alleged noncompliance with state and/or federal laws and regulations. Anyone can file a complaint against a facility or provider, and can do so anonymously. Complaints can be about the same events/incidents that facilities are required to report, or about anything else that an individual believes is a violation of the law. Reports of AEs and complaints both trigger an investigation by DPH.

**c) Current AE reporting requirements.** On September 12, 2021 DPH notified hospitals, through an All Facility Letter (AFL), that adverse event (AE) reporting regulations had been updated. The AFL notes that, consistent with existing law, hospitals are required to report AEs no later than five days after the AE is detected. If the event is an ongoing urgent or emergent threat to the welfare, health, or safety of patients, personnel, or visitors, the hospital must report no later than 24 hours after detection. The detection of or allegation of sexual assault is considered an ongoing or emergent threat and must be reported within 24 hours. In addition, the regulations specify the hospital is subject to an onsite investigation when DPH determines that an adverse event or complaint is an ongoing threat of imminent danger of death or serious bodily harm. The regulations require hospitals to report AEs via DPH's secure electronic web-based portal. DPH provides alternative means, by email or telephone, for submission if the web-based portal is unavailable. This requirement preserves patient confidentiality and standardizes reporting requirements. Hospitals are also required to develop policies and procedures for the internal reporting of preventable patient safety events, conducting a root cause analysis, and assessing the hospital's culture of safety every 24 months.

There is currently no requirement that demographic data be included in AE reports. This bill includes the requirement that demographic data be reported with respect to AE's, and requires DPH to update the reporting forms, as well as provide an opportunity for an individual making a complaint to provide demographic data.

**d) Current data on AEs, complaints and investigations.** The DPH Center for Health Care Quality (CHCQ) is responsible for regulatory oversight of licensed health care facilities and health care professionals to assess the safety, effectiveness, and health care quality for all Californians. CHCQ fulfills this role by conducting periodic inspections and complaint investigations of health care facilities to determine compliance with federal and state laws and regulations. CHCQ licenses and certifies over 14,000 health care facilities, including hospitals, and agencies in California in over 30 different licensure and certification categories. The table below shows the number of complaint investigations for APHs and GACHs (the hospitals subject to the requirements of this bill) from July 1, 2022 to June 30, 2023:

**Number of Complaint Investigations by Facility Type**
**(July 1, 2022 to June 30, 2023)**

| Facility Type | APH | GACH |
|---|---|---|
| Complaints Received During Reporting Period | 543 | 6,555 |
| Complaints Completed During Reporting Period | 592 | 6,355 |
| Growth/Reduction in Open Complaints | -49 | 200 |
| Immediate Jeopardy (24 hours LTC-2 days NLTC) Number Received | 58 | 493 |
| Immediate Jeopardy (24 hours LTC-2 days NLTC) Percent Initiated Timely | 98% | 97% |

The table below shows the number of facility-reported incident investigations by facility type from July 1, 2022 to June 30, 2023:

**Number of Facility-Reported Incident Investigations by Facility Type**
**Entity Reported Incidents (ERI)**
**(July 1, 2022 to June 30, 2023)**

| Facility Category | APH | GACH |
|---|---|---|
| ERIs Received During Reporting Period | 897 | 5,454 |
| ERIs Completed During Reporting Period (Regardless of Receipt Date) | 1,076 | 4,591 |
| Growth/Reduction in Open ERIs | -179 | 863 |
| Immediate Jeopardy (24 hours LTC-2 days NLTC) Number Received | 55 | 376 |
| Immediate Jeopardy (24 hours LTC-2 days NLTC) Percent Initiated Timely | 100% | 96% |

Over this time period DPH's CHCQ issued 219 deficiencies to APH's and 2,868 deficiencies to GACH's based on the results of periodic inspections, facility-reported incidents, and complaint investigations.

**e) Administrative penalties for hospitals.** DPH has the authority to assess administrative penalties for violations of the laws pertaining to the licensing of hospitals. There are two levels of penalties: violations that constitute immediate jeopardy to the health and safety of a patient; and, violations that do not constitute immediate jeopardy. Immediate jeopardy violations are subject to a fine of up to up to $75,000 for the first penalty, $100,000 for the second penalty, and $125,000 for the third and subsequent penalties. All other violations (except minor violations, for which DPH is prohibited from assessing a violation) are subject to a fine of up to $25,000.

DPH promulgated regulations establishing the criteria to assess administrative penalties, and listed eight factors on which to base the criteria, including the patient's physical and mental condition, the nature, scope and severity of the violation, and the demonstrated willfulness of the violation. DPH adopted these regulations in late 2013, and they went into effect on April 1, 2014. These regulations established the penalty matrix in the table below, which can be modified upward or downward according to certain specified factors. The percentages in the table below are to be applied to the statutory maximum penalty amounts as described in 5) and 6) of existing law above:

| | | SCOPE | | |
|---|---|---|---|---|
| | | **Isolated** | **Pattern** | **Widespread** |
| **SEVERITY** | Level 6: Immediate jeopardy to patient health or safety—Death | 100% | 100% | 100% |
| | Level 5: Immediate jeopardy to patient health or safety—Serious injury | 60% | 70% | 80% |
| | Level 4: Immediate jeopardy to patient health or safety—Likely to cause serious injury or death | 40% | 50% | 60% |
| | Level 3: Actual patient harm that is not immediate jeopardy | 60% | 80% | 100% |
| | Level 2: No actual patient harm but with potential for more than minimal harm, not immediate jeopardy | 20% | 50% | 70% |
| | Level 1: No actual patient harm but with potential for no more than minimal harm | No penalty | | |
| | Minor Violation | No penalty | | |

3) **SUPPORT.** The California Pan-Ethnic Health Network (CPEHN) is a cosponsor of this bill and states that implicit and racial bias is inevitable in health care. Extensive research demonstrates communities of color experience higher rates of patient adverse events when compared to white patients. Patient adverse events are when patients experience outcomes that cause permanent harm, live-saving intervention, or possible death. These examples can include surgical equipment left inside a patient, administering the wrong medication, or poor maternal health outcomes. CPEHN notes that a recent study found that nearly one in four hospital patients who died, or were transferred to intensive care, had experienced some sort of diagnostic error in their care. Furthermore, an estimated 795,000 patient pass away or become permanently disabled because of the misdiagnosis. Unfortunately, these trends disproportionately harm women and communities of color. CPEHN states that current law requires hospitals to report patient adverse events to DPH and while DPH has oversight of these facilities and must review reported cases, DPH currently does not review any trends or underlying behaviors that may be problematic, while current law allows an individual to pursue a civil rights pathway to remedy their experience, there is no requirement to provide support or resources to families and this often means navigating the complicated due process system on your own. CPEHN states that this bill will require DPH to collect self-reported demographics from hospitals such as race, ethnicity, sexual orientation, gender identity, language, income, and disability status when reporting the occurrence of patient safety events. This will allow DPH to review and analyze trends based on demographics and begin to identify if there are facilities that may warrant further investigation. This bill would also require DPH to publish adverse event trends based on demographic trends in a manner that is consistent with patient confidentiality. The current case-by-case approach does not support an ability to understand if there are repetitive behaviors of bias at certain facilities. CPEHN concludes that providing publicly available information to everyday people on any potential AE trends at their local hospital will enable community members to find a medical facility that best fits their needs.

Black Women for Wellness Action Project (BWWAP) is a cosponsor of this bill and states that it works to address racial and implicit bias in health care and provide pathways for

justice for community members who experience trauma from racial discrimination in their health care. BWWAP notes that this is a critical step towards ensuring that health care facilities are upholding California's promise of quality health care for all regardless of race, ethnicity, sexual orientation, language, or disability status.

4) **OPPOSE UNLESS AMENDED.** Oakland Privacy is opposed to this bill unless it is amended, and states that they would like for the patient to have the option to provide the demographic information that they feel is relevant to their incident, which may include some or all of the listed items, and not be required to provide all of it or not report at all. One size does not fit all and some of these items may be completely superfluous to what happened to them. Oakland privacy notes that it bears mentioning that in a legal proceeding for civil damages and compensation, a patient may be incentivized to reveal more information because they stand to receive compensation that they need. For the purposes of a government report on a website and a hospital safety plan, they may or may not be willing and that should be within their rights to decide. Oakland Privacy states that as they read the bill, making a report is optional, but once a person agrees to make that report, what is included in it is not optional, and we believe that should be changed to give patients a higher level of control in what they report to DPH or DCR.

5) **RELATED LEGISLATION.** AB 2319 (Wilson and Weber) expands the types of health care providers who must participate in implicit bias training pursuant to the California Dignity in Pregnancy and Childbirth Act (the Act.) Requires initial basic training on implicit bias to be completed by June 1, 2025, and requires facilities subject to the provisions of the Act to provide the DPH with proof of compliance by February 1 of each year. AB 2319 passed the Assembly Health Committee on April 2, 2024 with a vote of 121 2 and is currently pending hearing in the Assembly Appropriations Committee.

6) **PREVIOUS LEGISLATION.**

   **a)** AB 1204 (Wicks), Chapter 751, Statutes of 2021, established the Medical Equity Disclosure Act which requires hospitals to prepare and annually submit an equity report to HCAI and, expands the definition of "vulnerable populations" related to community benefit plans and reports. Requires a hospital's equity report to include a health equity plan to achieve disparity reductions, with measurable objectives and specific timeframes.

   **b)** SB 464 (Mitchell), Chapter 533, Statutes of 2019, requires hospitals and alternative birth centers to implement an implicit bias program for all health care providers involved in the perinatal care of patients within those facilities, including requiring these healthcare providers to complete initial basic training through the implicit bias program and a refresher course every two years thereafter. Requires DPH to track and publish data on maternal death and severe morbidity, and, adds to the list of written information a hospital is required to provide to each patient upon admission, information on how to file a discrimination complaint with DPH or the Medical Board of California if the patient feels they were discriminated against.

   **c)** SB 1301 (Alquist), Chapter 647, Statutes of 2006, requires the Department of Health Services (DHS, now DPH) to implement a statewide system for reporting AE) to DHS. SB 1301 enacted, in part, HSC section 1279.1, which specifies the seven categories of AEs required to be reported by hospitals to DHS within prescribed timelines.

**d)** SB 158 (Florez), Chapter 294, Statutes of 2008, requires that hospitals develop, implement, and comply with a patient safety plan to improve the health and safety of patients and reduce preventable patient safety events. The patient safety plan must include a reporting system for patient safety events, pursuant to HSC section 1279.

**7) DOUBLE REFERRAL.** This bill has been double-referred; upon passage of this committee, it will be referred to the Assembly Judiciary Committee.

**REGISTERED SUPPORT / OPPOSITION**:

**Support**

Black Women for Wellness Action Project (cosponsor)
California Pan-Ethnic Health Network (cosponsor)
Able Community Development Foundation
API Equality-LA
Asian Resources INC.
California Black Health Network
California Immigrant Policy Center
California Rural Legal Assistance Foundation
California State Association of Psychiatrists (CSAP)
California State Council of Service Employees International Union (SEIU California)
Center for Empowering Refugees and Immigrants
Courage California
Disability Rights California
Empowerment Association
Equality California
Health Access California
Hispanas Organized for Political Equality (HOPE)
Imperial Valley Equity & Justice Coalition
Indian Health Center of Santa Clara Valley
Latino Coalition for A Healthy California
Maternal and Child Health Access
Mighty Community Advocacy
National Health Law Program
Reproductive Freedom for All CA
Southeast Asia Resource Action Center
UC San Diego Refugee Health Unit
Western Center on Law & Poverty, INC.
Mixteco Indigena Community Organizing Project (MICOP)

**Opposition**

None on file.

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

Date of Hearing: April 9, 2024

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 3218 (Wood) – As Amended April 1, 2024

**SUBJECT**: Unflavored Tobacco List.

**SUMMARY**: 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 (UTL). Specifically, **this bill:**

1) Requires every manufacturer and importer of tobacco products to submit to the AG a list of all brand styles of tobacco products that they manufacture or import for sale or distribution in or into California that lack a characterizing flavor. Authorizes the AG to deem each submission to be a request that the brand style be included on the UTL. Requires any submission to be accompanied by a certification by the manufacturer or importer, under penalty of perjury, that does all of the following:
   a) Describes each brand style, brand, and tobacco product category. Requires categories to include, but not be limited to, cigarettes, cigars, little cigars, chewing tobacco, pipe tobacco, snuff, electronic cigarettes, electronic pipes, and electronic hookahs;
   b) Certifies that each brand style is not adulterated as defined, or misbranded as defined in the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 United States Code, Sec. 301 et seq.); and,
   c) Certifies that each brand style lacks a characterizing flavor.

2) Requires a manufacturer or importer, upon request of the AG, to provide additional information and factual substantiation regarding a brand style's lack of characterizing flavor.

3) Requires information submitted to the AG by a manufacturer or importer pursuant to this bill to be considered confidential and corporate proprietary information. Prohibits this information from being subject to disclosure under the California Public Records Act.

4) Requires, upon the request of the AG, a manufacturer or importer to provide additional information and documentation regarding packaging or marketing of a brand style.

5) Requires the AG to presume a brand style to have a characterizing flavor if the manufacturer or importer, or any employee or agent of the manufacturer or importer, in the course of their employment by the agency, has made a statement or claim directed to consumers or to the public that the tobacco product has or produces a characterizing flavor, including, but not limited to, any text, color, or images on the product's labeling or packaging, that explicitly or implicitly communicates that the tobacco product has a characterizing flavor. Allows this presumption to be rebutted by the manufacturer or importer.

6) Requires the AG to decline to include on the UTL any brand style that the AG reasonably determines has a characterizing flavor. Authorizes the AG to decline to include on the UTL any brand style that is adulterated as defined or misbranded as defined in the FFDCA, or that is otherwise required to obtain and has not received a formal authorization, approval, or order

from the FFDCA.

7) Requires the AG to remove from the UTL any brand style that the AG determines has a characterizing flavor. Authorizes the AG to remove from the UTL any brand style that is adulterated or misbranded as defined in the FFDCA, or that is required to obtain and has not received a formal authorization, approval, or order from the FFDCA. Requires the AG to promptly provide the manufacturer or importer that submitted a certification regarding a brand style with written notice when the AG removes it from the UTL. Requires this notice to include the basis for the AG's determination.

8) Makes the removal of a brand style from the UTL effective 30 days after the manufacturer or importer is given notice pursuant to 7) above.

9) Authorizes a manufacturer or importer to provide additional materials that the manufacturer or importer deems relevant to the determination described in 7) above within 30 days of the notice.

10) Requires information submitted to the AG by a manufacturer or importer pursuant 9) above to be considered confidential and corporate proprietary information. Prohibits this information from being subject to disclosure under the California Public Records Act.

11) Requires any brand style not on the UTL to be deemed a flavored tobacco product, as defined.

12) Requires every manufacturer and importer that has made a submission under the provisions of this bill to submit updated information to the AG whenever it no longer manufactures or imports for sale or distribution in or into the state a brand style listed on the UTL or when the brand style it manufactures or imports no longer lacks a characterizing flavor. Requires this updated information to be provided to the AG by the manufacturer or importer prior to or on the date upon which the manufacture or importation of the brand style ceases, or prior to or on the date upon which the brand style no longer lacks a characterizing flavor.

13) Requires every manufacturer or importer that submits a product pursuant to this bill to also do all of the following:

    a) Consent to the jurisdiction of the California courts for the purpose of enforcement, and for enforcement of regulations adopted pursuant to this bill;
    b) Appoint a registered agent for service of process in this state;
    c) Identify the registered agent to the AG; and,
    d) Waive any sovereign immunity defense that may apply in an action to enforce this bill or to enforce regulations adopted pursuant to this bill.

14) Authorizes the AG to require a manufacturer or importer of tobacco products that are sold or distributed in or into California, whether directly or indirectly through a distributor, wholesaler, or retailer, to submit to the AG a list of all brand styles of tobacco products that they manufacture or import into the state.

15) Allows, upon receiving notice from the AG that a brand style is either removed from the UTL or that the AG declines to include it on the list, the manufacturer or importer that

provided the certification to the AG that the brand style lacks a characterizing flavor, to challenge the AG's determination as erroneous, seek to rebut any presumption relied upon by the AG, and seek relief from the determination, by filing a writ of mandate in the Superior Court of the County of Sacramento, or as otherwise provided by law. Prohibits the filing of the petition from operating to stay the AG's determination except upon a ruling of a court of competent jurisdiction.

16) Authorizes a manufacturer or importer to challenge a decision by the AG pursuant to 15) above, in addition to providing additional materials to the AG pursuant to 9) above.

17) Requires the AG to publish the UTL beginning on or before December 31, 2025.

18) Prohibits any person from affixing, or causing to be affixed, any tax stamp or meter impression to a package of cigarettes, or paying any tax levied on a tobacco product unless the brand style of the cigarettes or tobacco products is included on the UTL.

19) Authorizes the AG to seek injunctive relief and a civil penalty not to exceed fifty thousand dollars ($50,000) and recover reasonable attorney's fees, investigation costs, and expert fees against an entity or individual that certifies to the AG that a brand style lacks a characterizing flavor when the certifying entity or individual had no reasonable basis to believe the certification was true.

20) Prohibits any distributor from selling any tobacco product not appearing on the UTL to any retailer, wholesaler, or other person for sale in California. Authorizes the AG, for each tobacco product sold in violation of this bill, to assess civil penalties against the distributor according to the following schedule:
    a) A civil penalty of not more than two thousand dollars ($2,000) for the first violation;
    b) A civil penalty of not more than three thousand five hundred dollars ($3,500) for the second violation;
    c) A civil penalty of not more than five thousand dollars ($5,000) for the third violation within a five-year period;
    d) A civil penalty of not more than six thousand five hundred dollars ($6,500) for the fourth violation within a five-year period; and,
    e) A civil penalty of not more than ten thousand dollars ($10,000) for a fifth or subsequent violation within a five-year period.

21) Requires, whenever the AG prevails in a civil action to enforce this section, the court to award to the AG all costs of investigating and prosecuting the action, including expert fees, reasonable attorney's fees, and costs. Requires rewards under this bill to be paid to the Public Rights Law Enforcement Special Fund.

22) Authorizes the AG to adopt those rules and regulations the AG deems necessary to implement the purposes of this bill, including regulations further delineating characterizing flavor determinations, requiring a fee for manufacturer and importer certifications, and adopting an administrative process for the imposition of civil penalties. Makes the regulations adopted to implement this bill emergency regulations, and required to be considered by the Office of Administrative Law to be necessary for the immediate preservation of the public health, safety, and welfare.

23) States that this bill does not preempt or otherwise prohibit the adoption of a local ordinance that is more restrictive than this bill, that references or incorporates the UTL, or that imposes standards or definitions for a characterizing flavor that are more restrictive than those in this bill.

24) Defines the following, for the purposes of this bill:

    a) "Brand style" to mean a style of tobacco product within a brand that is differentiated from other styles of that brand by weight, volume, size, Universal Product Code, Stock Keeping Unit, nicotine content, characterizing flavor, logo, symbol, motto, labeling, marketing, materials, packaging, or other indicia of product identification;
    b) "Characterizing flavor" to mean a taste or odor, distinguishable by an ordinary consumer either prior to or during the consumption of a tobacco product, other than the taste or odor of tobacco, including, but not limited to, tastes or odors relating to any fruit, chocolate, vanilla, honey, candy, cocoa, dessert, alcoholic beverage, menthol, mint, wintergreen, herb, or spice, or cooling or numbing sensation distinguishable by an ordinary consumer during the consumption of a tobacco product;
    c) "Tobacco product" to mean a tobacco product as defined in existing law, but excluding looseleaf tobacco, premium cigars, and shisha tobacco products, as those terms are defined; and,
    d) "Flavored tobacco product" to means any tobacco product that contains a constituent that imparts a characterizing flavor. "Flavored tobacco product" includes any tobacco product, other than looseleaf tobacco, a premium cigar, or a shisha tobacco product, that is not listed on the UTL established and maintained by the AG.

25) Requires cigarettes or tobacco products seized by the California Department of Tax and Fee Administration (CDTFA) to which are affixed California cigarette tax stamps or meter impressions, or for which tax is paid, that are offered for sale, possessed, kept, stored, or owned by any person with the intent to sell the cigarettes or tobacco products in violation of this bill to be forfeited to the state.

26) Authorizes an employee of CDTFA, upon presentation of appropriate identification, to enter any building, facility, site, or place where evidence of a violation of the ban on the sale of flavored tobacco products has been discovered.

27) Makes the provisions of this bill severable. Provides that if any provision of this bill or its application is held invalid, that invalidity will not affect other provisions or applications that can be given effect without the invalid provision or application.

28) Finds and declares that in order to facilitate manufacturer submissions of information related to brand styles of tobacco products for consideration by the AG, it is necessary to protect the confidential and proprietary nature of that information.

**EXISTING LAW**:

1) Establishes the Department of Public Health (DPH) to protect the public's health and help shape positive health outcomes for individuals, families and communities. Establishes the California Tobacco Control Branch within DPH, which leads statewide and local health programs, services and activities that promote a tobacco free environment. CITE….

2) Requires CDTFA, under the Cigarette and Tobacco Products Licensing Act, to administer a statewide program to license cigarette and tobacco products manufacturers, importers, distributors, wholesalers, and retailers. Prohibits selling tobacco products without a valid license, and makes violations punishable as a misdemeanor. Retailers are required to obtain a separate license for each retail location that sells cigarettes and tobacco products and pay to an annual license fee. CITE>>>>>>

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) Permits an enforcing agency 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, except for military personnel 18 years of age or older, any tobacco product, instrument, or paraphernalia that is designed for the smoking or ingestion of tobacco products ranging from $400 to $6,000 for a first, second, third, fourth, or fifth violation within a five-year period. [BPC §22958]

7) 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," as defined, or a "tobacco product flavor enhancer," and authorizes an enforcing agency (DPH, the AG, or a local law enforcement agency) to assess civil penalties against any person or entity that violates this provision. [HSC §104559.5]

8) Requires DPH, in addition to the civil penalties in 6) above, upon the assessment of a civil penalty for the third, fourth, or fifth violation, to notify CDTFA of the violation. Requires CDTFA to assess a civil penalty of $250 and suspend or revoke a retailer's license. [*Ibid.*]

9) Defines "flavored tobacco product" as any tobacco product that contains a constituent that imparts a characterizing flavor. Defines "tobacco product flavor enhancer" as a product designed, manufactured, produced, marketed, or sold to produce a characterizing flavor when added to a tobacco product. [*Ibid.*]

10) Defines "characterizing flavor" to mean a distinguishable taste or aroma, or both, other than the taste or aroma of tobacco, imparted by a tobacco product or any byproduct produced by the tobacco product. Includes, but are not limited to, tastes or aromas relating to any fruit, vanilla, chocolate, honey, candy, cocoa, dessert, alcoholic beverage, menthol, mint, wintergreen, herb, or spice. Prohibits a tobacco product from being determined to have a

characterizing flavor solely because of the use of additives or flavorings or the provision of ingredient information and instead, it is the presence of a distinguishable taste or aroma, or both, that constitutes a characterizing flavor.

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

**COMMENTS**:

1) **PURPOSE OF THIS BILL.** According to the author, despite the prohibition of flavored tobacco products in California, it remains readily available within our communities and on the shelves of too many retailers. The vast majority of children who use tobacco, use flavored tobacco products. The author notes that market ploys and products that facilitate addictive behavior and harm health, especially among youth, have no business in California and we must make implementation of these laws well defined and the enforcement sound. The author concludes that this bill will provide small scale retailers much needed clarity on which products are legal, enable the AG to hold those enabling the wide scale distribution of illicit flavored tobacco products in California accountable, and empower law enforcement agencies to seize those illegal products.

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) **Centers for Disease Control and Prevention (CDC) data on tobacco use**. African American youth and young adults have significantly lower prevalence of cigarette smoking than Hispanics and whites, and although the prevalence of cigarette smoking among African American and white adults is the same, African Americans smoke fewer cigarettes per day. On average, African Americans initiate smoking at a later age compared to whites; however, they are more likely to die from smoking-related diseases than whites.

      American Indian/Alaska Native youth and adults have the highest prevalence of cigarette smoking among all racial/ethnic groups in the U.S, however, it is important to note that some American Indians use tobacco for ceremonial, religious, or medicinal purposes. Regional variations in cigarette smoking exist among American Indians/Alaska Natives, with lower prevalence in the Southwest and higher prevalence in the Northern Plains and Alaska.

      Hispanic/Latin adults generally have lower prevalence of cigarette smoking and other tobacco use than other racial/ethnic groups, with the exception of Asian Americans. However, prevalence varies among sub-groups within the Hispanic population, for

example, 50% of Cuban men and more than 35% of Cuban women report smoking 20 or more cigarettes per day, and Mexican men and women are less likely than other Hispanic/Latinx groups to report that they smoke 20 or more cigarettes per day.

Although Asian Americans, Native Hawaiians, and Pacific Islanders are often combined together as one group in survey data due to smaller numbers of the individual groups surveyed, they are actually three distinct groups. Cigarette smoking among Asian American/Pacific Islander adults is lower than other racial ethnic groups, however, prevalence among Asian sub-groups varies and can be higher than that of the general population. Like many other minority groups, the LGBTQ+ community has been the target of tobacco industry marketing for several decades. As a result, smoking rates are disproportionately higher among LGBTQ+ individuals than the general population. About one in four LGBTQ+ adults smoke cigarettes compared with about one in six heterosexual/straight adults. More than twice as many LGBTQ+ students report having smoked a cigarette before the age of 13 compared to heterosexual students.

**b) 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.

Immediately after the passage of SB 793, the tobacco industry qualified a referendum for the ballot asking the voters to decide whether or not SB 793 should take effect, and enforcement of the ban was halted pending the November 8, 2022 election. The ballot measure, Proposition 31, was approved, thus upholding SB 793. The next day, R.J. Reynolds, the maker of Newport menthol cigarettes and top-selling vaping products filed a federal lawsuit challenging California's ban on flavored tobacco. However, in December of 2022 the Supreme Court refused to block the law, clearing the way for the ban to take effect the next week. The law states that a tobacco retailer, or agent or employee of a tobacco retailer, in violation of this section is guilty of an infraction and will be punished by a fine of two hundred fifty dollars ($250) for each violation. This law does not specify where the enforcement authority of this statute resides, which implies local jurisdictions have authority to enforce this law.

**c) Misbranded or adulterated tobacco products pursuant to the FFDCA.** Under federal law, a tobacco product is deemed to be misbranded if: i) its labeling is false or misleading in any particular; ii) if in package form unless it bears a label containing the name and

place of business of the tobacco product manufacturer, packer, or distributor, an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; and, an accurate statement of the percentage of the tobacco used in the product that is domestically grown tobacco and the percentage that is foreign grown tobacco. A tobacco product shall be deemed to be adulterated if it consists in whole or in part of any filthy, putrid, or decomposed substance, or is otherwise contaminated by any added poisonous or added deleterious substance that may render the product injurious to health.

**d)** G**randfathered tobacco products.** Generally, to be legally marketed in the U.S., the FFDCA requires "new tobacco products" to have a premarket authorization order in effect. A "new tobacco product" is any tobacco product that was not commercially marketed in the U.S. as of February 15, 2007, or any modified tobacco product that was commercially marketed after February 15, 2007. A marketing authorization is required for a new tobacco product unless: i) the manufacturer of the product submitted a report under the FFDCA Act and FDA issues an order finding the product substantially equivalent to a predicate tobacco product; or, ii) the manufacturer submitted a report and all modifications are covered by exemptions from the requirements of substantial equivalence granted by FDA. The FDA deems new tobacco products without required marketing authorization as adulterated and misbranded.

This bill would allow the AG to decline to include on the UTL any brand style that has not received a formal authorization, approval, or order under the FFDCA. Although the FDA has only authorized 23 tobacco-flavored e-cigarettes to date, there are thousands of flavored and arguably flavored tobacco products that remain available for retail sale in California despite lacking FDA authorization. Many of the unauthorized products are labeled "clear" or ambiguously branded with flavor concepts (i.e. "Blue" instead of "Blueberry") in order to avoid flavor bans.

This bill requires a manufacturer or reporter to submit to the AG a list of all brand styles of tobacco products that they manufacture or import for sale or distribution (to be included on the UTL), that lack a characterizing flavor. This bill also requires the manufacturer to certify under penalty of perjury that each brand style lacks a characterizing flavor.

**d)** **Benefits of an UTL.** According to an October 2019 DPH whitepaper, "Challenges in Enforcing Local Flavored Tobacco Restrictions," a non-flavored list, which includes all tobacco products that may be sold in a particular jurisdiction, has several substantial benefits. First, developing, maintaining and using a non-flavored list is significantly easier than a banned product list. Whereas a banned products list may contain thousands of products, a non-flavored list might only contain several hundred unflavored products. As a result, a non-flavored list will be easier to maintain and use for both enforcement officers and retailers looking to comply with flavored tobacco restrictions. Additionally, a non-flavored list will make enforcement easier; unflavored tobacco products are less likely to be regional in nature, as regional variations are found in flavors. Further, California's non-flavored list could be incorporated by reference in other states reducing the duplicative work required in building regional lists. Given the relatively static roster of unflavored tobacco products, a non-flavored list will require less training for enforcement personnel and be less vulnerable to enforcement difficulties at the retail level.

3) **SUPPORT.** AG Rob Bonta is the sponsor of this bill and states that under current law, the flavored tobacco ban prohibits the retail sale of flavored tobacco products. Despite the ban, these products are still being sold in California and are ending up in the hands of young people. Tobacco companies make and market flavored tobacco products, which come with high nicotine content in a myriad of kid-friendly flavors. Young people are predominately the consumers of these products, and the usage among youth has increased rapidly in recent years, specifically among middle school students. A 2023 study by the Centers for Disease Control and Prevention found that among middle school and high school students who currently use e-cigarettes, nearly nine in 10 use flavored e-cigarettes. The AG notes that without strict enforcement in this market, noncompliant sellers provide easy access to flavored tobacco products, and this bill would hold noncompliant sellers accountable and reduce the availability of flavored tobacco products in the following ways: i) establish a publicly available list of all tobacco products that are permissibly unflavored and allowed to be sold in California (UTL) so that industry participants and law enforcement entities can easily ascertain which products can and cannot be sold; ii) authorize the AG to seek civil penalties against distributors for selling products not appearing on the UTL to hold the distribution chain accountable at a higher level than the retail level; iii) render products not appearing on the UTL ineligible for tax stamps so that such products will be contraband and subject to seizure; iv) revise the definition of "characterizing flavor," which delineates which tobacco products are prohibited from being sold to specifically include products that impart menthol-like cooling sensations, as well as other flavors that are "distinguishable by an ordinary consumer" so that the ban will encompass "edge" products that have been subject to debate and litigation; and, v) authorize the AG to omit from the UTL any tobacco products lacking FDA authorization. The AG concludes this bill would provide the AG's Office, as well as other state and local enforcers, with the tools and support needed to keep flavored tobacco products out of the hands of young people; helping prevent young people from entering a lifetime of addiction and harm.

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)** SB 793 (Hill) 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.

   **c)** AB 598 (Rivas) of 2021, would have required the AG to establish and maintain a list of tobacco product brand styles that lack a characterizing flavor. AB 598 was not heard in the Assembly Health Committee.

5) **DOUBLE REFERRAL.** This bill has been double-referred; upon passage of this Committee, it will be referred to the Assembly Judiciary Committee.

**REGISTERED SUPPORT / OPPOSITION**:

**Support**

Attorney General Rob Bonta (sponsor)
American Cancer Society Cancer Action Network INC.
American Heart Association
American Lung Association of California
California Children's Hospital Association
California Dental Association
California Medical Association
Campaign for Tobacco Free Kids
County Health Executives Association of California (CHEAC)
County of Santa Clara
San Diego City Attorney's Office
The Greater Sacramento Smoke and Tobacco Free Coalition

**Opposition**

None on file.

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

Date of Hearing: April 9, 2024

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AJR 10 (Irwin) – As Introduced August 24, 2023

**SUBJECT**: Food date labeling.

**SUMMARY**: Urges the President and Congress of the United States to enact the federal Food Date Labeling Act of 2023. Specifically, **this resolution**:

1) Finds and declares the following:
   a) Over one-third of food in the United States is never eaten; and,
   b) Uneaten food wastes agricultural land, water, chemicals, and energy; and,
   c) Food and organic material is the most common material that ends up in landfills and incinerated in the United States; and,
   d) Managing wasted food costs the United States $444 billion each year; and,
   e) WHEREAS, Food loss and food waste represent 8 % of global anthropogenic greenhouse gas emissions; and,
   f) WHEREAS, California's short-lived climate pollutant strategy targets reductions in organic waste disposal and increased rescue of surplus food for people to eat in order to cut the state's methane production; and,
   g) WHEREAS, The United States has a goal to halve the amount of food loss and food waste in the country by 2030; and,
   h) WHEREAS, Consumer confusion about the meaning of date labels on food is a leading cause of wasted food; and,
   i) WHEREAS, Standardizing date labels on food has the potential to divert 800,000 tons of food waste from landfills and incineration each year; and,
   j) WHEREAS, Standardizing date labels on food would have a net financial benefit of $3.55 billion in the United States; and,
   k) WHEREAS, Key food brands and industry associations have voluntarily adopted streamlined date labeling phrases on food; and,
   l) WHEREAS, California enacted the voluntary date labeling on food standard in 2017 with Assembly Bill 954; and,
   m) WHEREAS, The federal Food Date Labeling Act of 2023 is a bill designed to end consumer confusion around food date labeling by standardizing date labels on food products to ensure usable food is not thrown away.
2) Resolves:
   a) That the Legislature urges the President and Congress of the United States to enact the federal Food Date Labeling Act of 2023; and be it further,
   b) That the Legislature commends all public and private efforts to address consumer confusion over date labels on food, but recognizes that efforts must be accelerated to ensure that food in this country is not wasted; and be it further,
   c) That the Chief Clerk of the Assembly transmits copies of this resolution to the President and Vice President of the United States, to the Speaker of the House of Representatives, to the Majority Leader of the Senate, and to each Senator and Representative from California in the Congress of the United States.

**EXISTING LAW**:

1) Requires the California Department of Food and Agriculture (CDFA), in consultation with the Department of Public Health (DPH) to publish information that encourages food manufacturers, processors, and retailers responsible for the labeling of food products to voluntarily use the following uniform terms on food product labels to communicate quality dates and safety dates:
   a) "BEST if Used by" or "BEST if Used or Frozen by" to indicate the quality date of a product; and,
   b) "USE by" or "USE by or Freeze by" to indicate the safety date of a product. [Food and Agriculture Code (FAC) § 82001]

2) Requires CDFA to promote the consistent use of the terms specified in 1) above in the course of its interactions with food manufacturers, processors, and retailers. Requires CDFA to encourage food distributors and retailers to develop alternatives to consumer-facing "sell by" dates, defined to mean a date on a label affixed to the packaging or container of food that is intended to communicate primarily to a distributor or retailer for purposes of stock rotation and that is not a quality date or a safety date. [*Id*.]

3) Defines the following terms for purposes of 1) above:
   a) "Quality date" means a date on a label affixed to the packaging or a container of food that communicates to consumers the date after which the food quality may begin to deteriorate but the food may still be acceptable for consumption.
   b) "Safety date" means a date on a label affixed to the packaging or container of food that communicates to consumers that the food should be consumed or frozen, if appropriate, by the date listed on the package that applies to perishable products with potential safety implications over time.
   c) "Sell by date" means a date on a label affixed to the packaging or container of food that is intended to communicate primarily to a distributor or retailer for purposes of stock rotation and that is not a quality date or a safety date. [*Id*.]

4) Provides that it is unlawful for an egg handler to sell, offer for sale, or expose for sale certain eggs that are packed for human consumption unless each container intended for sale to the ultimate consumer is labeled with certain information, including, among other information, the words "sell-by" immediately followed by the month and day in bold type, as specified. [FAC §27644, § 24644.5]
5) Requires repackaged eggs to be labeled with the original sell by date. [FAC § 27687]

6) Authorizes the Director of CDFA to enforce requirements relating to egg products [FAC § 27501-27690]

7) Establishes the Sherman Food, Drug and Cosmetics Law (Sherman Law), administered by DPH, which regulates the packaging, labeling, and advertising of food, drugs and devices, including dietary supplements. [Health & Safety Code (HSC) § 109875-111929.4]

**FISCAL EFFECT**: None.

**COMMENTS**:

1) **PURPOSE OF THIS RESOLUTION.** According to the author**,** food products often feature phrases next to dates such as "Best By," "Expires On," "Use By," "Enjoy By," "Best Before," and "Sell By," among countless other variations. The author states that the meaning of these phrases can be unclear to average consumers as they can indicate a product's peak freshness, when a product is no longer safe for consumption, or, in the case of "Sell By" dates, act as a guide for when retailers should pull products from the shelf. The author continues that these phrases are often all referred to as "expiration dates", which can lead to consumer confusion. With the exception of baby formula, date labels on packaged food are not federally regulated. The author continues that state rules can be widely inconsistent and only apply to certain product groups. This confusion ultimately leads to food being unnecessarily wasted, grocery budgets strained, and increased methane emissions from rotting food contributing to climate change. The author concludes that this resolution addresses this problem by urging the President and Congress of the United States to enact the federal Food Date Labeling Act of 2023, a bipartisan piece of federal legislation which would enact uniform food date labeling standards to eliminate consumer confusion and reduce food waste.

2) **BACKGROUND.**

   a) **Food Waste.** According to the United Nations Food and Agriculture Organization, food waste refers to the decrease in the quantity or quality of food resulting from decisions and actions by retailers, food service providers and consumers. Food waste burdens waste management systems, exacerbates food insecurity and is a major contributor of climate change and pollution. Globally, the United Nations Environment Programme 2021 Food Waste Index Report estimates that 931 million tons of food waste was generated in 2019, 61% of which came from households, 26% from food service and 13% from retail. This suggests that 17% of total global food production may be wasted. The Food Waste Index Report also found that household per capita food waste generation is found to be broadly similar across country income groups, suggesting that action on food waste is equally relevant in high, upper-middle and lower-middle income countries. This diverges from earlier narratives concentrating consumer food waste in developed countries, and food production, storage and transportation losses in developing countries.

   In the United States, the Department of Agriculture (USDA) estimates that 30 to 40% of food is lost or wasted at the retail and consumer level. Each year, Americans are discarding approximately 133 billion pounds of food worth $161 billion. In California, CDFA estimates that Californians throw away approximately 6 million tons of food waste annually. CalRecycle points out on its internet website that Californians send 11.2 billion pounds of food to landfills each year, some of which was still fresh enough to have been recovered to feed people in need.

   According to a 2022 study published on the *Journal of Agriculture and Research* entitled "Understanding and Addressing Food Waste From Confusion in Date Labeling Using a Stakeholder's Survey", the lack of uniformity of food date labels and lack of regulation by the U.S. Food and Drug Administration has widely lead to confusion among consumer, which is a significant contributor of food waste amounting to 20% total consumer food waste. Date labels such as "Best Before," "Best By," "Use By," are highly inconsistent, are not science-based and vary widely across jurisdictions, brands, and food

products. The article claims that more than 90% of Americans may be prematurely throwing food because of label misinterpretation.

**b) USDA Voluntary Quality and Safety Date Labels**. With the exception of infant formula, product dating is completely voluntary. In 2016, the USDA Food Safety and Inspection Services (FSIS) updated its guidance on food product labeling, including guidance aimed at reducing food waste. FSIS at that time recommended the use of Best If Used By because research shows that this phrase is easily understood by consumers as an indicator of quality, rather than safety. Examples of commonly used date labeling are:

**i)** A **"Best if Used By/Before"** date indicates when a product will be of best flavor or quality. It is not a purchase or safety date;

**ii)** A **"Sell-By"** date tells the store how long to display the product for sale for inventory management. It is not a safety date;

**iii)** A **"Use-By"** date is the last date recommended for the use of the product while at peak quality. It is not a safety date except for when used on infant formula as described below; and,

**iv)** A **"Freeze-By"** date indicates when a product should be frozen to maintain peak quality. It is not a purchase or safety date.

**c) Other States.** Massachusetts has one of the strictest date labeling requirements. All packaged foods must be labeled in accordance with Massachusetts and federal labeling regulations, including all foods intended for retail sale that are manufactured in licensed residential kitchens. To comply with the Massachusetts open-dating labeling regulation, a "sell-by" or "best-if-used-by" date is required if the product has a recommended shelf life of fewer than 90 days. Foods exempt from this requirement include: fresh meat, poultry, fish, fruits, and vegetables offered for sale unpackaged or in containers permitting sensory examination, and food products pre-packaged for retail sale with a net weight of less than 1½ ounces. Foods may be sold after the open-date if the following conditions are met: It is wholesome and good quality; the product is segregated from food products that are not "past date," and the product is clearly marked as being "past date**."**

**d) Mandatory Organic Waste Collection**. SB 1383 (Lara), Chapter 395, Statutes of 2016, among various provisions, establishes a target of 50% reduction in the statewide disposal of organic waste from the 2014 level by 2020 and a 75% reduction by 2025, and requires CalRecycle and the Air Resources Board to adopt regulations to achieve the organic waste reduction targets. SB 1383 also requires jurisdictions to provide organic waste collection services to all single-family and multifamily residences of all sizes and businesses that generate organic waste beginning January 1, 2022. Organic waste includes food, green material, landscape and pruning waste, organic textiles and carpets, lumber, wood, paper products, printing and writing paper, manure, biosolids, digestate, and sludges. Lastly, another provision of SB 1383 is the requirement for jurisdictions to establish food recovery programs aimed at reducing food waste and help address food insecurity.

**e) California's Voluntary Date Labelling Efforts.** In 2017, in an effort to lessen the confusion on food labelling and reduce food waste, AB 954 (Chiu), Chapter 787, Statutes of 2017, was signed into law. AB 954 required CDFA, in consultation with DPH, to publish information by July 1, 2018 that encourages food manufacturers, processors, and retailers to voluntarily use specified "best by" and "use by" labels that communicate

quality and safety dates, respectively. However, this voluntary system has not mitigated the amount of food waste.

**f) The Federal Food Date Labeling Act of 2023**. The Federal Food Date Labeling Act of 2023 would establish requirements for the format of quality date and discard date labels on food packaging. Specifically, the Act would require the quality date on a food label (i.e., the date after which the quality of the item may deteriorate) to include the phrase BEST If Used By or the abbreviation BB. Similarly, the Act would require the discard date on a food label (i.e., the date after which the item should not be consumed) to include the phrase USE By or the abbreviation UB. The Act would only permit abbreviations if the full phrase does not fit on the label. The Food Date Labeling Act also authorizes the Department of Health and Human Services and Department of Agriculture to specify alternative phrases through regulations.

**3) RELATED LEGISLATION.**

**a)** AB 660 (Irwin) of 2023 requires, on and after January 1, 2025, food manufacturers, processors, and retailers to label food products with the following quality and safety dates: "BEST if Used by" or "Best if Used or Frozen By" to indicate the quality date of a product; and/or "Use by" or "Use by or Freeze" to indicate the safety date of a product. AB 660 is pending a hearing in Senate Agriculture Committee.

**b)** AB 2577 (Irwin) of 2024 requires the regulations adopted by the Department of Resources Recycling and Recovery to meet the state's edible food recovery goal to include product labeling requirements that reduce food waste. AB 2577 is pending a hearing in Assembly Appropriations Committee.

**4) PREVIOUS LEGISLATION.** AB 954 (Chiu), Chapter 787, Statutes of 2017, requires CDFA, in consultation with DPH, to publish information by July 1, 2018 that encourages food manufacturers, processors, and retailers to voluntarily use specified "best by" and "use by" labels that communicate quality and safety dates.

**REGISTERED SUPPORT / OPPOSITION**:

**Support**

350 Humboldt
350 Sacramento
Californians Against Waste
Climate Action California
Climate Reality Project, Los Angeles Chapter
Climate Reality San Fernando Valley, CA Chapter
Elders Climate Action, Norcal and Socal Chapters
Natural Resources Defense Council
Santa Cruz Climate Action Network

**Opposition**

None on file.

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